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Delegations will find attached document C(2019) 4055 final ANNEXES 1 to 4.

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ANNEXES 1 to 4

ANNEXES

to the

COMMISSION DELEGATED REGULATION (EU) .../...

supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards approval of germinal product establishments and the traceability and animal health requirements for movements within the Union of germinal products of certain kept terrestrial animals

ANNEX I

RULES FOR THE COLLECTION, PRODUCTION, PROCESSING AND STORAGE OF GERMINAL PRODUCTS OF BOVINE, PORCINE, OVINE, CAPRINE AND EQUINE ANIMALS AS REFERRED TO IN CHAPTER 1 OF PART II

Part 1
Requirements for semen collection centres referred to in Article 4

1. The responsibilities of the centre veterinarian, as referred to in Article 4(1)(a)(i), shall be the following:

   (a) the centre veterinarian shall ensure that:

      (i) at the semen collection centre, only animals which have not been used for natural breeding for a period of at least 30 days prior to the date of the first semen collection and during the collection period are kept;

      (ii) at the semen collection centre, records are kept in accordance with the requirements laid down in Article 8(1)(a);

      (iii) the entry of unauthorised persons is prevented;

      (iv) authorised visitors comply with the animal health and biosecurity requirements referred to in point (c)(i);

      (v) each individual dose of semen is clearly marked in accordance with the requirements laid down in Article 10;

      (vi) the collection, processing and storage of semen takes place only on the premises set aside for that purpose and under strict hygiene conditions;

      (vii) only semen collected at a semen collection centre is processed and stored at that semen collection centre, and it must not come into contact with any other consignment of germinal products of lesser health status;

      (viii) all instruments which come into contact with the semen or the donor animal during the collection and processing of semen are cleaned and either disinfected or sterilised prior to use, except for new single-use instruments;

      (ix) where, in the case of equine animals, the semen collection centre is located within the perimeters of a registered establishment which also hosts an artificial insemination or service centre, there is a strict separation between the instruments and equipment coming into contact with donor animals, their semen and other animals kept in the semen collection centre and the semen, instruments and equipment used for artificial insemination or natural service;

      (x) any biological product originating from animals used in the processing of semen, including diluents, additives or extenders, is obtained from sources which present no animal health risk or which are treated prior to use so that such risk is prevented;

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

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

(xiii) the staff employed at the semen collection centre have received adequate training on disinfection and hygiene techniques to prevent the spread of diseases;

(b) by way of derogation from point (a)(vii), the centre veterinarian may authorise semen that was not collected at a semen collection centre to be processed at the semen collection centre provided that the following conditions are met:

(i) such semen is collected from animals which fulfil the following requirements set out in Annex II

– in respect of bovine animals, the requirements set out in point 1(b) of Chapter I of Part 1, and as applicable in Chapters I, II and III of Part 5 thereof;

– in respect of porcine animals, the requirements set out in point 1(b) of Chapter I of Part 2, and as applicable in Chapters I and IV of Part 5 thereof;

– in respect of ovine and caprine animals, the requirements set out in point 1(c) of Chapter I of Part 3, and as applicable in Chapters I, II and III of Part 5 thereof;

– in respect of equine animals, in point 1(a) of Chapter I of Part 4 thereof;

(ii) processing is carried out with separate equipment or at a different time from semen intended to be moved to another Member State, and the equipment in the latter case must be cleaned and sterilised after use;

(iii) such semen is not moved to another Member State and does not at any time come into contact with, or is stored with, semen intended to be moved to another Member State;

(iv) such semen is identifiable by a marking which must be different from that referred to in point (a)(v);

(c) the centre veterinarian shall:

(i) lay down the animal health and biosecurity requirements for the operation of the semen collection centre and the measures to ensure compliance with those requirements;

(ii) only accept into the semen collection centre animals of species whose semen is to be collected;

(d) by way of derogation from point (c)(ii), the centre veterinarian may authorise kept animals other than bovine, porcine, ovine, caprine or equine animals to be admitted to the semen collection centre, provided that they present no risk of infection to those species whose semen is to be collected, and they comply with the animal health and biosecurity requirements referred to in point (c)(i);

(e) the centre veterinarian of a semen collection centre for equine animals, located within the perimeters of a registered establishment which also hosts an artificial insemination or service centre, shall ensure that equine animals entering the establishment meet the requirements of Article 23(1)(a) to (c) and may decide that where direct contact of donor male equine animals with female equine animals or castrated male equine animals for teasing or with uncastrated

male equine animals used on the establishment outside the semen collection centre for natural service cannot be excluded, those female and male equine animals must meet all the requirements of Article 23(1).

2. The requirements for the facilities, equipment and operational procedures of the semen collection centre, as referred to in Article 4(1)(b)(i), shall be the following:

(a) the semen collection centre must have at least:

(i) lockable animal accommodation and, if required, an exercise area for equine animals which is physically separated from the semen collection facilities, the semen processing room and the storage room;

(ii) isolation facilities for animals which have failed tests referred to in Annex II of this Regulation or which show symptoms or signs of any of the category D diseases relevant for the bovine, porcine, ovine, caprine or equine animals, and which have no direct connection with the regular animal accommodation referred to in point (i);

(iii) semen collection facilities that may be open air provided that they are protected from adverse weather effects and are equipped with slip-proof flooring at and around the place of semen collection;

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

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

(vi) a semen storage room, which need not necessarily be on the same site; the semen storage room must be furnished with the necessary installation to store germinal products, which must be so constructed that it protects those germinal products and the installation from adverse weather and environment effects;

(b) the semen collection centre must be so constructed or isolated that contact with outside livestock is prevented;

(c) the semen collection centre must be so constructed that, except for the office rooms and, in the case of equine animals, the exercise area, it can be readily cleansed and disinfected;

(d) the semen collection centre must be so constructed that unauthorised access of people is effectively prevented.

Part 2

Requirements for the approval of an embryo collection team referred to in Article 4

1. The responsibilities of the team veterinarian of an embryo collection team, as referred to in Article 4(1)(a)(ii), shall be the following:

(a) the team veterinarian shall be responsible for all embryo collection team operations, including, amongst others, the following:

(i) the verification of the identity and health status of donor animals;

(ii) the clinical examination and surgery of donor animals;

(iii) the disinfection and hygiene procedures, including procedures ensuring the transport of embryos to the laboratory in a hygienic and safe manner;

(iv) record-keeping in accordance with the requirements laid down in Article 8(1)(b));

(v) the marking of straws and other packages where embryos are placed in accordance with the requirements set out in Article 10(1) and (5);

(vi) the training of members of the embryo collection team on disinfection and hygiene techniques to prevent the spread of diseases;

(b) the team veterinarian shall lay down the animal health and biosecurity requirements for the operation of the embryo collection team and the measures to ensure compliance with those requirements, including the testing of samples within a quality control scheme.

2. The facilities, equipment and operational procedures of the embryo collection team, as referred to in Article 4(1)(b)(ii), shall comply with the following points (a) and (b):

(a) the embryo collection team must have at its disposal a laboratory where embryos can be examined, processed and packaged with adequate equipment, and that laboratory must be either:

(i) a permanently located laboratory, which must have the following:

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

– a room or area for cleansing and sterilising instruments used for embryo collection and processing, except when using only new single-use equipment;

– a room for the storing of embryos;

or

(ii) a mobile laboratory, which must:

– have a specially equipped part of the vehicle consisting of two separate sections: one section for the examination and processing of embryos, which must be the clean section; and another section for accommodating equipment and materials used in contact with the donor animals;

– use only new 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 is carried out at a permanently located laboratory.

The laboratories referred to in points (i) and (ii) must be designed and have a layout so as to prevent the cross-contamination of embryos, and team operations shall be carried out in a manner that prevents such cross-contamination;

(b) the embryo collection team must have at its disposal storage premises which comply with the following conditions:

(i) they comprise at least one lockable room for the storage of embryos;

(ii) they must be easy to cleanse and disinfect;

(iii) they must have permanent records of all incoming and outgoing embryos;

(iv) they must have storage containers for embryos.

Part 3

Requirements for the approval of an embryo production team referred to in Article 4

1. In addition to the responsibilities listed in point 1 of Part 2 of this Annex, the team veterinarian of an embryo production team, referred to in Article 4(1)(a)(ii), shall ensure that the embryo production team members have received adequate training on disease control and laboratory techniques, particularly on procedures for working in sterile conditions.

2. In addition to the requirements listed in point 2 of Part 2 of this Annex, the facilities, equipment and operational procedures of an embryo production team, referred to in Article 4(1)(b)(iii), shall comply with the following requirements:

(a) the embryo production team must have at its disposal a permanently located laboratory which must have:

(i) adequate equipment and facilities, including separate rooms or areas for:

– the recovery of oocytes from ovaries;

– the processing of oocytes and embryos; and

– the storing of embryos and semen;

(ii) a laminar flow facility or other suitable facilities where all technical operations associated with specific sterile conditions (namely, the processing of oocytes, 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 hygiene precautions are taken;

(b) where oocytes and other tissues are to be collected in a slaughterhouse, the embryo production team must 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;

(c) the embryo production team may outsource the collection of oocytes to a group of specialised professionals provided that their activity is included in the approval by the competent authority of the embryo production team and the responsibilities of the team veterinarian referred to in point 1 are extended to their activities;

(d) the embryo production team shall use semen which:

(i) meets the requirements of this Regulation;

(ii) is stored for the operation of the embryo production team in separate storage containers in the premises referred to in point 2(b) of Part 2 for the storing of produced embryos.

Part 4

Requirements for the approval of a germinal product processing establishment referred to in Article 4

1. The responsibilities of the centre veterinarian, referred to in Article 4(1)(a)(i), shall be the following:

(a) the centre veterinarian shall ensure that:

(i) at the germinal product processing establishment records are kept in accordance with the requirements laid down in Article 8(1)(c);

(ii) the entry of unauthorised persons is prevented;

(iii) authorised visitors comply with the animal health and biosecurity requirements referred to in point (b)(i);

(iv) each individual dose of semen, oocytes or embryos is clearly marked in accordance with the traceability requirements set out in Article 10;

(v) the processing and storage of germinal products takes place only on the premises set aside for that purpose and under strict hygiene conditions;

(vi) all instruments which come into contact with the germinal products are cleansed and either disinfected or sterilised prior to use, except for new single-use instruments;

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

(viii) cryogenic agents used for the preservation or storage of germinal products have not previously been used for other products;

(ix) the staff of the germinal product processing establishment have received adequate training:

– on disinfection and hygiene techniques to prevent the spread of diseases;

– for the purpose of processing germinal products, on laboratory techniques and particularly on procedures for working in sterile conditions;

(b) the centre veterinarian shall:

(i) lay down the animal health and biosecurity requirements for the operation of the germinal product processing establishment and the measures to ensure compliance with those requirements;

(ii) only accept into a germinal product processing establishment semen, oocytes or embryos collected, produced, processed and stored in an approved germinal product establishment, and transported under conditions that ensure that cross-contamination of semen, oocytes or embryos is prevented, as they have had no contact with germinal products which do not comply with the rules laid down in this Regulation.

2. The requirements for the facilities, equipment and operational procedures of a germinal product processing establishment, referred to in Article 4(1)(b)(iv), shall be the following:

(a) the germinal product processing establishment must have at least:

(i) a germinal products processing room, separated from the germinal products storage room referred to in point (ii) and the room used for cleansing equipment referred to in point (iii);

(ii) a germinal products storage room, which need not necessarily be on the same site, furnished with the necessary installation to store germinal products, and which is so constructed that it protects those germinal products and the installation from adverse weather and environment effects;

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

(b) where processing is not limited to germinal products delivered from one approved germinal product establishment or is not limited to a germinal product of one type or of a single species, the germinal product processing establishment must have procedures in place to ensure that:

(i) the processing of each consignment of germinal products is separated in time; and

(ii) the equipment is cleansed and disinfected between the processing of different consignments;

(c) where storage is not limited to a germinal product of one type or of a single species,

(i) the germinal product processing establishment must have distinct storage containers assigned for each type and species of germinal product that is stored in the germinal products storage room referred to in point (a)(ii), and

(ii) the handling of stored germinal products of different types and species must be carried out by separate staff or at a different time;

(d) the germinal product processing establishment must be so constructed that, except the office rooms, it can be readily cleansed and disinfected;

(e) the germinal product processing establishment must be so constructed that unauthorised access of people is effectively prevented.

Part 5

Requirements for the approval of a germinal product storage centre referred to in Article 4

1. The responsibilities of the centre veterinarian, referred to in Article 4(1)(a)(i), shall be the following:

(a) the centre veterinarian shall ensure that:

(i) at the germinal product storage centre records are kept in accordance with the requirements laid down in Article 8(1)(c);

(ii) the entry of unauthorised persons is effectively prevented;

(iii) authorised visitors comply with the animal health and biosecurity requirements referred to in point (b)(i);

(iv) each individual dose of semen, oocytes or embryos is clearly marked in accordance with the requirements set out in Article 10;

(v) storage of germinal products takes place only on the premises set aside for that purpose and under strict hygiene conditions;

(vi) all instruments which come into contact with the germinal products are cleansed and either disinfected or sterilised prior to use, except for new single-use instruments;

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

(viii) cryogenic agents used for preservation or storage of germinal products have not previously been used for other products;

(ix) the staff employed at the germinal product storage centre have received adequate training on disinfection and hygiene techniques to prevent the spread of diseases;

(b) the centre veterinarian shall:

(i) lay down the animal health and biosecurity requirements for the operation of the germinal product storage centre and the measures to ensure compliance with those requirements;

(ii) only accept into a germinal product storage centre semen, oocytes or embryos collected, produced, processed and stored in an approved germinal product establishment, and transported in conditions which ensure that cross-contamination of semen, oocytes or embryos is prevented, as they have had no contact with germinal products which do not comply with the rules laid down in this Regulation.

2. The requirements for the facilities, equipment and operational procedures of a germinal product storage centre, referred to in Article 4(1)(b)(v), shall be the following:

(a) the germinal product storage centre must have a storage room furnished with necessary installation to store germinal products, which is so constructed that it protects those germinal products and the installation from adverse weather and environment effects;

(b) where storage is not limited to a germinal product of one type or of a single species,

(i) the germinal product storage centre must have distinct storage containers assigned for each type and species of germinal product that is stored at the centre, and

(ii) the handling of stored germinal products of different types and species must be carried out by separate staff or at a different time;

(c) the germinal product storage centre must be so constructed that, except the office rooms, it can be readily cleansed and disinfected;

(d) the germinal product storage centre must be so constructed or isolated that contact with outside livestock is prevented;

(e) the germinal product storage centre must be so constructed that unauthorised access of people is effectively prevented.

ANNEX II

ADDITIONAL ANIMAL HEALTH REQUIREMENTS FOR BOVINE, OVINE, CAPRINE, PORCINE AND EQUINE ANIMALS FROM WHICH GERMINAL PRODUCTS ARE COLLECTED, AND CONCERNING QUARANTINE AND LABORATORY OR OTHER TESTS OF THOSE ANIMALS AS REFERRED TO IN SECTION 2 OF CHAPTER 1 OF PART III

Part 1

Additional animal health requirements for bovine animals from which germinal products are collected, and concerning quarantine and laboratory or other tests of those animals, as referred to in Article 20

Chapter I

Additional animal health requirements for bovine animals from which semen is collected, and concerning quarantine and laboratory or other tests for those animals

1. For all bovine animals admitted to a semen collection centre, the following requirements shall apply:

   (a) the animals must have been subjected to quarantine in quarantine accommodation where only other cloven-hoofed animals with at least the same health status were present;

   (b) within the period of 30 days prior to the commencement of the quarantine referred to in point (a), the animals must have been subjected to the following tests with a negative result in each case, except for the bovine viral diarrhoea antibody test referred to in point (v):

      (i) for infection with *Mycobacterium tuberculosis* complex (*M. bovis, M. caprae* and *M. tuberculosis*), an intradermal tuberculin test referred to in point 1 of Part 2 of Annex I to Regulation (EU) 2019/… [document SANTE/7072/2019, C(2019)4058];

      (ii) for infection with *Brucella abortus, Brucella melitensis* and *Brucella suis*, a serological test referred to in point 1 of Part 1 of Annex I to Regulation (EU) 2019/… [document SANTE/7072/2019, C(2019)4058];

      (iii) for enzootic bovine leukosis, a serological test referred to in point (a) of Part 4 of Annex I to Regulation (EU) 2019/… [document SANTE/7072/2019, C(2019)4058], using the derogation provided for in Article 20(2)(a);

      (iv) for infectious bovine rhinotracheitis/infectious pustular vulvovaginitis, a serological test (whole virus) on a blood sample if the animals do not come from an establishment free from infectious bovine rhinotracheitis/infectious pustular vulvovaginitis;

      (v) for bovine viral diarrhoea:

         – a virus isolation test, a test for virus genome or a test for virus antigen, and

         – a serological test to determine the presence or absence of antibodies;

   (c) during the quarantine referred to in point (a), and for a period of at least 21 days, or 7 days in the case of the tests required in accordance with points (iv)

and (v), after being admitted to the quarantine accommodation, the animals must have been subjected to the following tests with a negative result in each case, except for the bovine viral diarrhoea antibody test referred to in point (iii):

(i) for infection with *Brucella abortus, Brucella melitensis* and *Brucella suis*, a serological test referred to in point 1 of Part 1 of Annex I to Regulation (EU) 2019/… [document SANTE/7072/2019, C(2019)4058];

(ii) for infectious bovine rhinotracheitis/infectious pustular vulvovaginitis, a serological test (whole virus) on a blood sample.

If any animals prove positive, these animals shall be removed immediately from the quarantine accommodation and the other animals of the same group shall remain in quarantine and be retested, with negative results, not earlier than on the 21st day from the date of the removal of the positive animal(s);

(iii) for bovine viral diarrhoea:

– a virus isolation test, a test for virus genome or a test for virus antigen, and

– a serological test to determine the presence or absence of antibodies.

Any seronegative or seropositive animal shall only be allowed to enter the semen collection centre if no seroconversion occurs in animals which tested seronegative before entry into the quarantine accommodation.

If seroconversion occurs, all animals that remain seronegative shall be kept in quarantine accommodation over a prolonged period until there is no longer seroconversion in the group of animals for a period of 3 weeks. Serologically positive animals may be allowed to enter the semen collection centre;

(iv) for bovine genital campylobacteriosis (*Campylobacter fetus ssp. venerealis*):

– in the case of animals less than 6 months old or kept since that age in a single sex group without contact with females prior to the quarantine referred to in point (a), a single test carried out on a sample of artificial vagina washings or preputial specimen; or

– tests carried out on samples of artificial vagina washings or preputial specimens taken on three occasions at intervals of at least 7 days;

(v) for trichomonosis (*Trichomonas foetus*):

– in the case of animals less than 6 months old or kept since that age in a single sex group without contact with females prior to the quarantine referred to in point (a), a single test carried out on a sample of preputial specimen; or

– tests carried out on preputial specimens taken on three occasions at intervals of at least 7 days;

If any of the tests referred to in point (c) prove positive, the animal concerned shall be removed immediately from the quarantine accommodation. In the event of the quarantine of a group of animals, the competent authority shall take all necessary measures to re-establish the eligibility of the remaining animals for entry into the semen collection centre in accordance with Chapter I of Part 1 of this Annex;

(d) prior to the initial dispatch of semen from bovine viral diarrhoea serologically positive bulls, a semen sample from each animal shall be subjected to a virus isolation or virus antigen enzyme-linked immunosorbent assay (ELISA) for bovine viral diarrhoea. In the event of a positive result, the bull shall be removed from the semen collection centre and all of its semen shall be destroyed.

2. All bovine animals kept at a semen collection centre shall be subjected at least once a year to the following tests (compulsory routine tests), with negative results:

(a) for infection with *Mycobacterium tuberculosis* complex (*M. bovis, M. caprae* and *M. tuberculosis*), an intradermal tuberculin test referred to in point 1 of Part 2 of Annex I to Regulation (EU) 2019/… [document SANTE/7072/2019, C(2019)4058];

(b) for infection with *Brucella abortus, Brucella melitensis* and *Brucella suis*, a serological test referred to in point 1 of Part 1 of Annex I to Regulation (EU) 2019/… [document SANTE/7072/2019, C(2019)4058];

(c) for enzootic bovine leukosis, a serological test referred to in point (a) of Part 4 of Annex I to Regulation (EU) 2019/… [document SANTE/7072/2019, C(2019)4058];

(d) for infectious bovine rhinotracheitis/infectious pustular vulvovaginitis, a serological test (whole virus) on a blood sample;

(e) for bovine viral diarrhoea, a serological test for the detection of an antibody which is applied only to seronegative animals.

In the event that an animal becomes serologically positive, every ejaculate of that animal collected since the last negative test shall be either discarded or tested for virus or virus genome with negative results;

(f) for bovine genital campylobacteriosis, a test on a sample of preputial specimen. Only bulls in semen production or having contact with bulls in semen production shall be required to be tested. Bulls returning to collection after a lay-off period of more than 6 months shall be tested during a period of 30 days prior to resuming production;

(g) for trichomonosis, a test on a sample of preputial specimen. Only bulls in semen production or having contact with bulls in semen production shall be required to be tested. Bulls returning to collection after a lay-off period of more than 6 months shall be tested during a period of 30 days prior to resuming production.

3. If any of the tests referred to in point 2 prove positive, the animal shall be isolated and the semen collected from it since the last negative test shall not be moved to another Member State, with the exception, for bovine viral diarrhoea, of semen from every ejaculate which has been tested negative for either bovine viral diarrhoea virus or virus genome.

The animal referred to in the first subparagraph shall be removed from the semen collection centre.

Semen collected from all other animals at the semen collection centre since the date when the last sample was taken that gave a negative result in one of the tests described in point 2 shall be kept in separate storage and shall not be subject to movement between Member States 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 that cause diseases referred to in point 2.

Chapter II

Additional animal health requirements for bovine animals which are *in vivo* derived embryos donors, and concerning the quarantine of those animals

1. Donor bovine animals must have been clinically examined by the team veterinarian or a team member and certified to be free of symptoms or signs of any of the category D diseases relevant for the animals of the bovine species on the day of embryo collection.

2. Semen used to inseminate donor bovine animals artificially must have been collected, processed and stored in accordance with the requirements of Chapter I of Part 1 of Annex II, and of Part 1 of Annex III.

Chapter III

Additional animal health requirements for bovine animals from which oocytes for *in vitro* production of embryos are collected, and concerning quarantine of those animals

1. When oocytes are recovered from individual live bovine animals (either by aspiration from surgically excised ovaries (‘ovariectomy’) or by ultrasonographically guided transvaginal aspiration (‘ovum pick-up’)), the requirements laid down in Chapter II shall apply to the donor animals of such oocytes.

2. In the case of donor bovine animals of ovaries and other tissues to be collected after slaughter in a slaughterhouse, those animals must not have been designated for slaughter as part of an approved eradication programme, nor have come from an establishment situated in a restricted zone established due to an outbreak of a category A disease or of an emerging disease in accordance with Article 6 of Regulation (EU) 2016/429 in donor bovine animals.

3. The slaughterhouse where the ovaries and other tissues are collected must not be situated in a restricted zone established due to an outbreak of a category A disease or of an emerging disease in accordance with Article 6 of Regulation (EU) 2016/429 in donor bovine animals.

4. Semen used to fertilise oocytes of bovine animals for *in vitro* production of embryos must have been collected, processed and stored in accordance with the requirements of Chapter I of Part 1 of Annex II, and of Part 1 of Annex III.

Part 2

Additional animal health requirements for porcine animals from which germinal products are collected, and concerning quarantine and laboratory or other tests of those animals, as referred to in Article 21

Chapter I

Additional animal health requirements for porcine animals from which semen is collected, and concerning quarantine and laboratory or other tests of those animals

1. For all porcine animals admitted to a semen collection centre, the following requirements shall apply:

   (a) the animals must have been subjected to quarantine in quarantine accommodation where only other cloven-hoofed animals with at least the same health status were present;

   (b) within a period of 30 days prior to entering the quarantine accommodation referred to in point (a), the animals must have been subjected to the following tests, with negative results:

      (i) as regards infection with *Brucella abortus, Brucella melitensis* and *Brucella suis*, a buffered Brucella antigen test (rose Bengal test), a competitive ELISA or an indirect ELISA for the detection of antibodies to smooth *Brucella* species.

      If any of the animals prove positive in the serological tests detecting antibodies to smooth *Brucella* species (including *Brucella abortus, Brucella melitensis* and *Brucella suis)*, animals with negative results in the same establishment shall not be admitted into the quarantine accommodation until a disease-free status of the infection with *Brucella abortus, Brucella melitensis* and *Brucella suis* of the establishments of origin of the animals that proved positive has been confirmed.

      (ii) as regards infection with Aujeszky's disease virus:

      – in the case of non-vaccinated animals, an ELISA to detect antibodies to the whole Aujeszky's disease virus or to glycoprotein B (ADV-gB) or glycoprotein D (ADV-gD) of the virus or a serum neutralisation test;

      – in the case of animals vaccinated with a gE deleted vaccine, an ELISA to detect antibodies to glycoprotein E (ADV-gE) of Aujeszky's disease virus.

      The serological tests for infection with Aujeszky's disease virus must meet the standards set out in Part 7 of Annex I to Regulation (EU) 2019/… [document SANTE/7072/2019, C(2019)4058];

      (iii) as regards classical swine fever, an antibody ELISA or serum neutralisation test, in case of animals coming from a Member State or zone thereof where classical swine fever has been reported or vaccination against this disease has been practiced for the period of the preceding 12 months;

(iv) as regards infection with porcine reproductive and respiratory syndrome virus, a serological test (the immunoperoxidase monolayer assay (IPMA), immunofluorescence assay (IFA), or ELISA);

(c) the animals have been subjected to the following tests carried out on samples taken during a period of at least 21 days after being admitted to the quarantine accommodation referred to in point (a):

(i) as regards infection with *Brucella abortus, Brucella melitensis* and *Brucella suis*, a buffered Brucella antigen test (rose Bengal test), a competitive ELISA or an indirect ELISA for the detection of antibodies to smooth *Brucella* species.

Animals which proved positive in a test referred to in the first subparagraph are to be removed from the quarantine accommodation, unless the suspicion of infection with *Brucella abortus, Brucella melitensis* and *Brucella suis* has been ruled out in accordance with point (d).

(ii) as regards infection with Aujeszky's disease virus:

– in the case of non-vaccinated animals, an ELISA to detect antibodies to the whole Aujeszky's disease virus or to glycoprotein B (ADV-gB) or glycoprotein D (ADV-gD) of the virus or a serum neutralisation test;

– in the case of animals vaccinated with a gE deleted vaccine, an ELISA to detect antibodies to glycoprotein E (ADV-gE) of Aujeszky's disease virus.

If any of the animals prove positive in the tests for infection with Aujeszky's disease virus, those animals shall be removed immediately from the quarantine accommodation.

(iii) as regards classical swine fever, an antibody ELISA or serum neutralisation test, in case of animals coming from a Member State or zone thereof where classical swine fever has not been reported and vaccination against this disease has not been practiced for the period of the preceding 12 months;

(iv) as regards infection with porcine reproductive and respiratory syndrome virus, a serological test (IPMA, IFA, or ELISA) and a test for virus genome (reverse-transcription polymerase chain reaction (RT-PCR), nested set RT-PCR, real-time RT-PCR).

If any of the animals prove positive in the tests for infection with porcine reproductive and respiratory syndrome virus, those animals shall be removed immediately from the quarantine accommodation.

Where a group of animals is quarantined, the competent authority shall take all necessary measures to ensure that the remaining animals which have proved negative in the tests referred to in points (i), (ii), (iii) and (iv) have a satisfactory health status before they are admitted to the semen collection centre in accordance with this Chapter;

(d) the following measures shall be taken in the case of a suspicion of infection with *Brucella abortus, Brucella melitensis* and *Brucella suis*:

(i) the following protocol shall be implemented with regard to animals which have proved positive for infection with *Brucella abortus, Brucella melitensis* and *Brucella suis* in a test referred to in point (c)(i):

– the positive sera are subjected to at least one of the alternative tests set out in point (c)(i) which has not been carried out on the samples referred to in point (c);

– an epidemiological enquiry is carried out on the establishment(s) of origin of the animals which have proved positive in the test for infection with *Brucella abortus, Brucella melitensis* and *Brucella suis*;

– not earlier than 7 days following the date of the collection of the samples referred to in point (c), samples are taken from all the animals which have proved positive in the tests referred to in point (c)(i) and in the first indent of point (d)(i) and subjected to a serological test provided for in point (c)(i), or all animals referred to in point (c) are subjected to a brucelin skin test;

(ii) the suspicion of infection with *Brucella abortus, Brucella melitensis* and *Brucella suis* shall be ruled out provided that the epidemiological enquiry on the establishment(s) of origin did not reveal the presence of infection with *Brucella abortus, Brucella melitensis* and *Brucella suis* and either:

– the repeat testing referred to in the first indent of point (d)(i) or the test referred to in the third indent of point (d)(i) were carried out with a negative result;

or

– all animals which proved positive in the tests referred to in the first or third indent of point (d)(i) have been subjected to a *post-mortem* inspection and agent detection test (PCR or bacteriological culture) for smooth *Brucella* species (including *Brucella abortus, Brucella melitensis* and *Brucella suis)*, with a negative result in each case;

(iii) after the suspicion of infection with *Brucella abortus, Brucella melitensis* and *Brucella suis* is ruled out, all of the animals from the quarantine accommodation referred to in the second paragraph of point (c) may be admitted to the semen collection centre.

2. Compulsory routine testing of porcine animals kept at semen collection centres shall be carried out as follows:

(a) all porcine animals kept at the semen collection centre shall be subjected to the following tests with negative results:

(i) as regards infection with *Brucella abortus, Brucella melitensis* and *Brucella suis*, a buffered Brucella antigen test (rose Bengal test), or a competitive ELISA or an indirect ELISA;

(ii) as regards infection with Aujeszky's disease virus:

– in the case of non-vaccinated animals, an ELISA to detect antibodies to the whole Aujeszky's disease virus or to glycoprotein B (ADV-gB) or glycoprotein D (ADV-gD) of the virus or a serum neutralisation test;

– in the case of animals vaccinated with a gE deleted vaccine, an ELISA to detect antibodies to glycoprotein E (ADV-gE) of Aujeszky's disease virus;

(iii) as regards classical swine fever, an antibody ELISA or serum neutralisation test;

(iv) as regards infection with porcine reproductive and respiratory syndrome virus, a serological test (IPMA, IFA, or ELISA);

(b) the tests set out in point (a) shall be carried out on samples taken from:

(i) all animals immediately prior to leaving the semen collection centre, or upon arrival at the slaughterhouse, and in no case later than 12 months from the date of admission to the semen collection centre; or

(ii) at least:

– 25 % of the animals in the semen collection centre every 3 months to test for infection with *Brucella abortus, Brucella melitensis* and *Brucella suis*, infection with Aujeszky's disease virus and classical swine fever and from at least 10 % of the animals in the semen collection centre every month to test for infection with porcine reproductive and respiratory syndrome virus, or

– 10 % of the animals in the semen collection centre every month to test for infection with *Brucella abortus, Brucella melitensis* and *Brucella suis*, infection with Aujeszky's disease virus, classical swine fever and infection with porcine reproductive and respiratory syndrome virus.

In the case of sampling carried out in accordance with the two options listed in point (ii), the centre veterinarian shall ensure that the sampled animals are representative of the total population of that centre, in particular with respect to age groups and housing;

(c) where the testing is carried out in accordance with point 2(b)(ii), the centre veterinarian shall ensure that all animals are tested for the diseases referred to in point 2(a) at least every 12 months from the date of admission to the semen collection centre.

3. If any of the tests set out in point 2(a) prove positive, the animal shall be isolated and the semen collected from them since the last negative test shall not be the subject of movement between Member States.

The animal referred to in the first subparagraph shall be removed immediately from the semen collection centre.

Semen collected from all other animals present at the semen collection centre since the date when the last sample was taken that gave a negative result in one of the tests described in point 2(a) shall be kept in separate storage and shall not be the subject of movement between Member States 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 that cause diseases referred to in point 2(a).

Chapter II

Additional animal health requirements for porcine animals from which oocytes and embryos are collected, and concerning the quarantine of those animals

1. Donor porcine animals must have been clinically examined by the team veterinarian or a team member and certified to be free of symptoms or signs of any of the category D diseases relevant for the porcine animals on the day of oocyte or embryo collection.

2. In addition to the requirements referred to in point 1, donor porcine females shall, except donors of *in vivo* derived embryos subject to trypsin treatment, come from a Member State or zone thereof which is free from infection with Aujeszky's disease virus or where an approved eradication programme for infection with Aujeszky's disease virus is carried out.

3. As regards infection with porcine reproductive and respiratory syndrome virus, the donor porcine females of *in vivo* derived embryos shall be subjected to a serological test for infection with porcine reproductive and respiratory syndrome virus, with negative results, on two occasions, at an interval of not less than 21 days, the second test being performed within a period of 15 days prior to embryo collection.

4. Semen used to inseminate donor porcine animals artificially must have been collected, processed and stored in accordance with the requirements of Chapter I of Part 2 of Annex II, and of Part 1 of Annex III.

Part 3

Additional animal health requirements for ovine and caprine animals from which germinal products are collected, and concerning the quarantine and laboratory or other tests of those animals, as referred to in Article 22

Chapter I

Additional animal health requirements for ovine and caprine animals from which semen is collected, and concerning the quarantine and laboratory or other tests of those animals

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

   (a) the animals must have been subjected to quarantine in quarantine accommodation where only other cloven-hoofed animals with at least the same health status were present;

   (b) in the case of ovine animals, they must come from an establishment where, during the period of 60 days prior to their stay in the quarantine accommodation referred to in point (a), they have been subjected to a serological test for ovine epidydimitis (*Brucella ovis*) or any other test with an equivalent documented sensitivity and specificity.

   In the case where ovine animals are kept together with caprine animals, those caprine animals shall also be subjected to a serological test for ovine epididymitis (*Brucella ovis*) with negative results;

   (c) the animals have been subjected to the following tests carried out on a blood sample taken within a period of 30 days preceding the commencement of the period of quarantine referred to in point (a), with a negative result in each case:

(i) for infection with *Brucella abortus, Brucella melitensis* and *Brucella suis*, a serological test referred to in point 1 of Part 1 of Annex I to Regulation (EU) 2019/… [document SANTE/7072/2019, C(2019)4058];

(ii) in the case of ovine animals, for ovine epidydimitis (*Brucella ovis*), a serological test or any other test with an equivalent documented sensitivity and specificity.

In the case where ovine animals are kept together with caprine animals, those caprine animals shall also be subjected to a serological test for ovine epididymitis (*Brucella ovis*) with negative results;

(d) the animals have been subjected to the following tests carried out on samples taken during the period of quarantine referred to in point (a), and within a period of at least 21 days from the date of being admitted to the quarantine accommodation, with negative results:

(i) for infection with *Brucella abortus, Brucella melitensis* and *Brucella suis*, a serological test referred to in point 1 of Part 1 of Annex I to Regulation (EU) 2019/… [document SANTE/7072/2019, C(2019)4058];

(ii) in the case of ovine animals, for ovine epidydimitis (*Brucella ovis*), a serological test or any other test with an equivalent documented sensitivity and specificity.

In the case where ovine animals are kept together with caprine animals, those caprine animals shall also be subjected to a serological test for ovine epididymitis (*Brucella ovis*) with negative results.

2. All ovine and caprine animals kept at an approved semen collection centre shall be subjected at least once a year to the following tests (compulsory routine tests), with negative results:

(a) for infection with *Brucella abortus, Brucella melitensis* and *Brucella suis*, a serological test referred to in point 1 of Part 1 of Annex I to Regulation (EU) 2019/… [document SANTE/7072/2019, C(2019)4058];

(b) in the case of ovine animals, for ovine epidydimitis (*Brucella ovis*) a serological test or any other test with an equivalent documented sensitivity and specificity.

In the case where ovine animals are kept together with caprine animals, those caprine animals shall also be subjected to a serological test for ovine epididymitis (*Brucella ovis*) with negative results.

3. If any of the tests described in point 2 prove positive, the animal shall be isolated and the semen collected from it since the date of the last negative test shall not be moved between Member States.

The animal referred to in the first subparagraph shall be removed from the semen collection centre.

Semen collected from all other animals present at the semen collection centre since the date when the last sample was taken that gave a negative result in one of the tests described in point 2 shall be kept in separate storage and shall not be moved between Member States 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 that cause diseases referred to in point 2.

Chapter II

Additional animal health requirements for ovine and caprine animals from which oocytes and embryos are collected, and concerning the quarantine of those animals

1. Donor ovine and caprine animals must have been clinically examined by the team veterinarian or a team member and certified to be free of symptoms or signs of any of the category D diseases relevant for the animals of the ovine and caprine species on the day of collection of the oocytes or embryos.

2. Semen used to inseminate donor ovine and caprine animals artificially must have been collected, processed and stored in accordance with the requirements of Chapter I of Part 3 of Annex II, and of Part 1 of Annex III.

Part 4

Additional animal health requirements for equine animals from which germinal products are collected, and concerning the quarantine and laboratory or other tests of those animals, as referred to in Article 23

Chapter I

Additional animal health requirements for equine animals from which semen is collected, and concerning the quarantine and laboratory or other tests of those animals

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

   (a) the animal shall be subjected to the following tests, in accordance with one of the testing programmes provided for in point (b):

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

      (ii) 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 a negative result on an aliquot of the entire semen of the donor stallion, unless the donor stallion has been subjected to a serum neutralisation test for equine viral arteritis where a negative result was obtained at a serum dilution of one in four;

      (iii) an agent identification test for contagious equine metritis *(Taylorella equigenitalis)*, carried out with a negative result in each case on three specimens (swabs) taken from the donor stallion on two occasions with an interval of not less than 7 days, and in any case no earlier than 7 days (systemic treatment) or 21 days (local treatment) after the 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 a transport medium with activated charcoal, such as Amies medium, before being dispatched to the laboratory.

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

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

or

– PCR or real-time PCR for the detection of genome of *Taylorella equigenitalis*, carried out within 48 hours from the time of taking the specimens from the donor animal;

(b) the animal shall be subjected to one of the following testing programmes:

(i) if the donor stallion is continuously resident at the semen collection centre for a period of at least 30 days prior to the date of the first semen collection and during the collection period, and no equine animals in the semen collection centre come into direct contact with equine animals of a lower health status than the donor stallion, the tests required in accordance with point (a) shall be carried out on samples taken from the donor stallion at least once a year (compulsory routine tests) at the beginning of the breeding season or prior to the first collection of semen intended for movement to another Member State as 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;

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

– 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 movement to another Member State as 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

– during the period of collection of semen intended for movement to another Member State as fresh, chilled or frozen semen as follows:

- the test required in point (a)(i) on samples taken not more than 90 days prior to the date of the collection of semen intended for movement to another Member State,
- the test required in point (a)(ii) on samples taken not more than 30 days prior to the date of the collection of semen intended for movement to another Member State, unless the non-shedder state of the donor stallion is confirmed by a 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 date of the collection of semen intended for movement to another Member State and the donor stallion has been subjected to a serum neutralisation test for equine viral arteritis with a positive result at a serum dilution of at least one in four,

- the test required in point (a)(iii) on samples taken not more than 60 days prior to the date of the collection of semen intended for movement to another Member State, which in the case of PCR or real-time PCR may be carried out on three specimens (swabs) taken on a single occasion;

(iii) if the donor stallion does not meet the conditions set out in points (i) and (ii) and the semen is collected for movement to another Member State as frozen semen, the tests required in accordance with point (a) shall be carried out on samples taken from the donor stallion as follows:

– at least once a year at the beginning of the breeding season;

– during the storage period provided for in point 2(b) of Part 1 of Annex III and before the semen is removed from the semen collection 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 the second indent of point (iii), post-collection sampling and testing for equine viral arteritis as described in point (a)(ii) shall not be required where the non-shedder state of a seropositive donor stallion is confirmed by a virus isolation test, PCR or real-time PCR carried out with a 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 4 months and the donor stallion has been subjected to a serum neutralisation test for equine viral arteritis with a positive result at a serum dilution of at least one in four;

(c) if any of the tests provided for in point (b) prove positive, the donor stallion shall be isolated and the semen collected from it since the date of the last negative test shall not be moved between Member States with the exception, for equine viral arteritis, of semen from every ejaculate which has undergone the equine arteritis virus isolation test with a negative result.

Semen collected from all other stallions at the semen collection centre since the date when the last sample was taken that gave a negative result in one of the tests provided for in point (b) shall be kept in separate storage and shall not be moved between Member States 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 that cause diseases referred to in point (b).

Chapter II

Additional animal health requirements for equine animals from which oocytes and embryos are collected, and concerning the quarantine and laboratory or other tests of those animals

1. Donor equine animals must have been clinically examined by the team veterinarian or a team member and certified to be free of symptoms or signs of any of the category D diseases relevant for the animals of the equine species on the day of oocyte or embryo collection.

2. In addition to the requirements referred to in point 1, donor equine animals shall:

   (a) not be used for natural breeding during a period of at least 30 days prior to the date of collection of oocytes or embryos and between the date of the first sample referred to in points (b) and (c) and the date of the collection of oocytes and embryos;

   (b) be subjected with a 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 (a) and not more than 90 days prior to the date of the collection of oocytes or embryos for movement between Member States;

   (c) be subjected to an agent identification test for contagious equine metritis *(Taylorella equigenitalis)*, carried out with a negative result in each case on at least two specimens (swabs) taken from the donor animal, which must in any case not be earlier than 7 days (systemic treatment) or 21 days (local treatment) after the possible antimicrobial treatment of the donor animal, from at least the following sites:

      – the mucosal surfaces of the clitoral fossa,

      – the clitoral sinuses.

   The specimens shall be taken during the period of at least 30 days referred to in point (a) on two occasions with an interval of not less than 7 days in the case of the test referred to in point (i) below, or on one occasion in the case of the test referred to in point (ii) below.

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

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

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

   or

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

3. Semen used to inseminate donor animals artificially must have been collected, processed and stored in accordance with the requirements of Chapter I of Part 4 of Annex II, and of Part 1 of Annex III.

Part 5

Other animal health requirements for bovine, porcine, ovine and caprine animals and animals of the families *Camelidae* and *Cervidae* from which germinal products are collected, and concerning the quarantine and laboratory or other tests of those animals, as referred to in Articles 20, 21, 22 and 38

Chapter I

Requirements for bovine, porcine, ovine and caprine animals as regards foot-and-mouth disease

1. The bovine, porcine, ovine and caprine animals which are semen, oocyte or embryo donors must:

   (a) come from establishments:

      (i) situated in an area where foot-and-mouth disease has not been reported within a 10-km radius centred on the establishment for a period of at least 30 days immediately prior to the date of collection;

      (ii) in which foot-and-mouth disease has not been reported during a period of at least 3 months immediately prior to the date of collection;

   (b) have not been vaccinated against foot-and-mouth disease during the period of 12 months immediately prior to the date of collection.

2. The centre veterinarian shall ensure that:

   (a) the bovine, porcine, ovine and caprine animals which are semen donors are only admitted to the semen collection centre after they have undergone isolation in the quarantine accommodation, which on the day of admission of the animals to the semen collection centre must:

      (i) be situated in an area where foot-and-mouth disease has not been reported within a 10-km radius centred on the quarantine accommodation for a period of at least 30 days;

      (ii) have had no outbreak of foot-and-mouth disease reported during the period of 3 months preceding the date of admission of the animals into the semen collection centre;

   (b) semen is only moved to another Member State subject to compliance with the following conditions:

      (i) the semen collection centre is situated in an area where foot-and-mouth disease has not been reported within a 10-km radius centred on the semen collection centre for a period of at least 30 days;

      (ii) the semen collection centre has been free from foot-and-mouth disease for a period of at least 3 months prior to the date of collection of the semen and 30 days from the date of collection or, in the case of fresh semen, until the date of dispatch of the consignment of semen to another Member State;

(iii) in the case of fresh semen, the donor animal has been kept at the semen collection centre referred to in point (i) for a continuous period of at least 30 days immediately prior to the date of collection of the semen.

3. By way of derogation from point 1(b), the centre veterinarian may authorise the dispatch of semen collected from a kept donor animal which has been vaccinated against foot-and-mouth disease during the period of 12 months immediately prior to the date of collection, provided that:

(a) the donor animal has not been vaccinated against foot-and-mouth disease within the period of at least 30 days immediately prior to the date of collection;

(b) 5 % (with a minimum of five straws) of each quantity of semen taken from a donor animal at any time is submitted to a virus isolation test for foot and mouth disease with negative results.

4. By way of derogation from point 1(b), the team veterinarian may authorise the dispatch, to another Member State, of *in vivo* derived embryos collected from a donor animal which has been vaccinated against foot-and-mouth disease during the 12 months period immediately prior to the date of collection, provided that:

(a) the female donor animal has not been vaccinated against foot-and-mouth disease within the period of at least 30 days immediately prior to the date of collection;

(b) the semen used for fertilisation was collected from a male donor that complies with the conditions set out in point 1(b) or the semen complies with the conditions set out in point 2;

(c) prior to freezing, the embryos have been subjected to trypsin washing carried out in accordance with the recommendations of the IETS Manual[1];

(d) the embryos are stored deep frozen for a period of at least 30 days from the date of collection, and during this period the donor animal has not shown clinical signs of foot-and-mouth disease.

Chapter II

Requirements for bovine, ovine and caprine animals and for animals of the families *Camelidae* and *Cervidae* as regards infection with bluetongue virus (serotypes 1-24)

1. The bovine, ovine and caprine animals and animals of the families *Camelidae* and *Cervidae* which are semen donors must fulfil at least one of the following conditions:

(a) they have been kept in a Member State or zone thereof free from infection with bluetongue virus (serotypes 1-24) for a period of at least 60 days prior to and during collection of the semen;

(b) they have been kept in a seasonally disease-free zone, during the seasonally disease-free period, for a period of at least 60 days prior to and during collection of the semen, in a Member State or zone thereof:

(i) with an approved eradication programme against infection with bluetongue virus (serotype 1-24), or

[1] 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 1 111 North Dunlap Avenue, Savoy, Illinois 61 874 USA (http://www.iets.org/).

(ii) where the competent authority of the place of origin of the consignment of semen has obtained the prior written consent of the competent authority of the Member State of destination to the conditions for establishment of that seasonally disease-free zone and to accept the consignment of semen;

(c) they have been kept in a vector-protected establishment for a period of at least 60 days prior to and during collection of the semen;

(d) they have been subjected to a serological test to detect antibodies to the bluetongue virus serogroup 1-24, with negative results, between 28 and 60 days from the date of each collection of the semen;

(e) they have been subjected to an agent identification test for bluetongue virus (serotypes 1-24), with negative results, on blood samples taken at commencement and final collection of the semen and during collection of the semen at intervals of:

(i) at least every 7 days, in the case of the virus isolation test;
or

(ii) at least every 28 days, in the case of PCR.

2. The ovine and caprine animals and animals of the families *Camelidae* and *Cervidae* which are *in vivo* derived embryo donors and bovine, ovine and caprine animals and animals of the families *Camelidae* and *Cervidae* which are oocyte donors for the *in vitro* production of embryos must fulfil at least one of the following conditions:

(a) they have been kept in a Member State or zone thereof free from infection with bluetongue virus (serotypes 1-24) for a period of at least 60 days prior to and during collection of the oocytes or embryos;

(b) they have been kept in a seasonally disease-free zone, during the seasonally disease-free period, for a period of at least 60 days prior to and during collection of the oocytes or embryos, in a Member State or zone thereof:

(i) with an approved eradication programme against infection with bluetongue virus (serotype 1-24), or

(ii) where the competent authority of the place of origin of the consignment of oocytes or embryos has obtained the prior written consent of the competent authority of the Member State of destination to the conditions for establishment of that seasonally disease-free zone and to accept the consignment of oocytes or embryos;

(c) they have been kept in a vector-protected establishment for a period of at least 60 days prior to and during collection of the oocytes or embryos;

(d) they have been subjected to a serological test to detect antibodies to the bluetongue virus serogroup 1-24, with negative results, on a blood sample taken between 28 and 60 days from the date of collection of the oocytes or embryos;

(e) they have been subjected to an agent identification test for bluetongue virus (serotypes 1-24), with negative results, on a blood sample taken on the date of collection of the oocytes or embryos.

3. The semen used to fertilise the oocytes must be collected from animals which comply with the requirements set out in point 1.

Chapter III

Requirements for bovine, ovine and caprine animals as regards infection with the epizootic haemorrhagic disease virus (serotypes 1-7)

1. The bovine, ovine and caprine animals which are semen donors must fulfil at least one of the following conditions:

   (a) they have been kept for a period of at least 60 days prior to and during collection of the semen in a Member State or zone thereof where infection with epizootic haemorrhagic disease virus (serotypes 1-7) (EHDV 1-7) has not been reported for a period of at least the preceding 2 years within a radius of 150 km of the establishment;

   (b) they have been kept in a vector-protected establishment for a period of at least 60 days prior to and during collection of the semen;

   (c) they have been subjected to a serological test to detect antibodies to EHDV 1-7, with negative results, at least every 60 days throughout the collection period and between 28 and 60 days from the date of the final collection of the semen;

   (d) they have been subjected to an agent identification test for EHDV 1-7, with negative results, on blood samples taken at the commencement and final collection of the semen and during the collection of the semen at intervals of:

      (i) at least every 7 days, in the case of virus isolation test; or

      (ii) at least every 28 days, in the case of PCR.

2. The ovine and caprine animals which are *in vivo* derived embryo donors and bovine, ovine and caprine animals which are oocyte donors for the *in vitro* production of embryos must fulfil at least one of the following conditions:

   (a) they have been kept for a period of at least 60 days prior to and during collection of the oocytes or embryos in a Member State or zone where EHDV 1-7 has not been reported for a period of at least the preceding 2 years within a radius of 150 km of the establishment;

   (b) they have been kept in a vector-protected establishment for a period of at least 60 days prior to and during collection of the oocytes or embryos;

   (c) they have been subjected to a serological test to detect antibodies to EHDV 1-7, with negative results, on a blood sample taken between 28 and 60 days from the date of collection of the oocytes or embryos;

   (d) they have been subjected to an agent identification test for EHDV 1-7, with negative results, on a blood sample taken on the date of collection of the oocytes or embryos.

3. The semen used to fertilise the oocytes must be collected from animals which comply with the requirements set out in point 1.

Chapter IV

Requirements for an establishment to be considered free from infection with *Brucella abortus, Brucella melitensis* and *Brucella suis* in porcine animals

To qualify as free from infection with *Brucella abortus, Brucella melitensis* and *Brucella suis*, an establishment of porcine animals must satisfy the following requirements:

(a) infection with *Brucella abortus, Brucella melitensis* and *Brucella suis* must be a notifiable disease in porcine animals in the Member State;

(b) infection with *Brucella abortus, Brucella melitensis* and *Brucella suis* has not been confirmed in the establishment for a period of at least the preceding 3 years;

(c) animals showing clinical signs consistent with infection with *Brucella abortus, Brucella melitensis* and *Brucella suis* such as abortions or orchitis are subjected to the necessary diagnostic tests with negative results;

(d) no porcine animals belonging to the establishment have been vaccinated against infection with *Brucella abortus, Brucella melitensis* and *Brucella suis* for at least the preceding 3 years;

(e) porcine animals which have been introduced to the establishment:

(i) either come from establishments free from infection with *Brucella abortus, Brucella melitensis* and *Brucella suis* for a period of at least the preceding 3 years, or were tested on a sample taken within a period of 30 days prior to the date of dispatch with negative results;

and

(ii) have not been vaccinated against infection with *Brucella abortus, Brucella melitensis* and *Brucella suis* for a period of at least the preceding 3 years;

(f) for a period of at least the preceding 3 years, there has been no evidence of infection with *Brucella abortus, Brucella melitensis* and *Brucella suis* in other epidemiological units of the same establishment, or measures have been implemented to prevent any transmission of infection with *Brucella abortus, Brucella melitensis* and *Brucella suis* from those other epidemiological units.

ANNEX III

ANIMAL HEALTH REQUIREMENTS FOR THE COLLECTION, PRODUCTION, PROCESSING AND STORAGE OF GERMINAL PRODUCTS OF BOVINE, PORCINE, OVINE, CAPRINE AND EQUINE ANIMALS AS REFERRED TO IN ARTICLE 26

Part 1

Animal health requirements for the collection, processing and storage of fresh, chilled or frozen semen of bovine, porcine, ovine, caprine and equine animals, and for the transport of that semen

1. All instruments used for the collection, processing, preservation or freezing of semen shall be cleansed and either disinfected or sterilised before use, except for new single-use instruments.

2. Frozen semen shall:

   (a) be placed and stored in storage containers:

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

      (ii) with a cryogenic agent, which must not have previously been used for other biological products originating from animals;

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

3. Where necessary, the antibiotics or mixtures of antibiotics with a bactericidal activity at least equivalent to that of the following antibiotics or their mixtures in each ml of semen, may be added to semen or contained in semen diluents:

   (a) in the case of semen of bovine and porcine animals, a mixture of lincomycin-spectinomycin (150/300 μg), penicillin (500 IU) and streptomycin (500 μg); or

   (b) in the case of semen of ovine and caprine animals, gentamicin (250 μg) or a mixture of penicillin (500 IU) and streptomycin (500 μg); or

   (c) a mixture of gentamicin (250 μg), tylosin (50 μg), lincomycin-spectinomycin (150/300 μg), penicillin (500 IU) and streptomycin (500 μg); or

   (d) a mixture of amikacin (75 μg) and divekacin (25 μg).

4. In respect of semen of bovine animals, antibiotics referred to in point 3(a), (c) and (d), or semen diluents containing such antibiotics or mixtures of antibiotics, shall be added and be effective in particular against campylobacters, leptospires and mycoplasmas.

5. In respect of semen of porcine animals, antibiotics or mixtures of antibiotics referred to in point 3(a), (c) and (d), or semen diluents containing such antibiotics or mixtures of antibiotics, shall be added and be effective in particular against leptospires.

6. Where an antibiotic or a mixture of antibiotics is(are) added to semen:

   (a) the name(s) of the antibiotic(s) added and its(their) concentration or the commercial name of the semen diluent containing antibiotics shall be stated in the animal health certificate accompanying the consignment;

   (b) it(they) shall be added to the semen after final dilution or to the diluent;

(c) in the case of frozen semen, it(they) shall be added before the semen is frozen.

7. For frozen or chilled semen, immediately after the addition of the antibiotics, the diluted semen shall be kept at:

(a) a temperature of at least 5 °C, except in the case of semen of porcine animals, which may be kept at a temperature of at least 15 °C for a period of not less than 45 minutes, or

(b) a time-temperature regime with a documented equivalent bactericidal activity.

Part 2

Animal health requirements for the collection and processing of *in vivo* derived embryos of bovine, porcine, ovine, caprine and equine animals

In vivo derived embryos shall be collected, processed and preserved in accordance with the following requirements:

1. Embryos shall be collected and processed by an embryo collection team, without coming into contact with any other consignment of embryos not complying with the requirements of this Regulation.

2. Embryos shall be collected in a place which is separated from other parts of the premises or establishment and which shall be kept in good repair and constructed with materials which permit its effective and easy cleansing and disinfection.

3. Embryos shall be processed (examined, washed, treated and placed in straws or other packages) in either a permanently located laboratory or a mobile laboratory.

4. All equipment used to collect, handle, wash, freeze and store embryos shall be cleansed and either disinfected or sterilised before use, according to the IETS Manual, or be a new single-use equipment.

5. Any biological product originating from animals used in the media and solutions for the collection, processing, washing or storage of embryos shall be free from pathogenic microorganisms. Media and solutions used in the collection, freezing and storage of embryos shall be sterilised by methods approved in accordance with the IETS Manual and handled in such a manner as to ensure sterility.

6. Where, according to the IETS Manual, antibiotics or a mixture of antibiotics are added to the collection, processing, washing and storage media, the names of the antibiotics added and their concentration shall be stated in the animal health certificate accompanying the consignment.

7. The cryogenic agents used for the preservation or storage of embryos shall not have previously been used for other biological products originating from animals.

8. The embryos shall be washed according to the IETS Manual and have an intact *zona pellucida* or, in the case of equine embryos, the embryonic capsule, before and immediately after washing. Each embryo shall be washed at least 10 times in a special fluid for embryos, which shall be changed each time. Each wash shall be a 100-fold dilution of the previous wash and a sterile micropipette shall be used to transfer the embryo on each occasion.

   The standard washing procedure shall be modified to include additional washes with the enzyme trypsin, according to the IETS Manual, when inactivation or removal of certain pathogens is required.

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

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

11. Embryos that have successfully undergone the examination set out in point 10 shall be placed in a cleansed and either disinfected or sterile, except for a new single-use, straw or another package which is marked in accordance with Article 10(1) and (5) and which shall be sealed immediately.

12. Each embryo shall, where appropriate, be frozen as soon as possible and stored in a storage premises, referred to in point 2(b) of Part 2 of Annex I, which is under the responsibility of the team veterinarian.

13. Where there is no other procedure to verify the health status of the donor animals, or in order to verify compliance with the animal health and biosecurity requirements laid down by the team veterinarian, including in the framework of the quality control scheme referred to in point 1(b) of Part 2 of Annex I, the embryo collection team shall, in accordance with the IETS Manual, submit to an official or authorised by the competent authority laboratory routine samples of non-viable embryos or oocytes, flushing fluids or washing fluids resulting from its activities for the detection of bacterial and viral contamination at a frequency to be established by the team veterinarian.

Part 3

Animal health requirements for the collection and processing of oocytes, ovaries and other tissues for *in vitro* production of embryos of bovine, porcine, ovine, caprine and equine animals

In addition to the requirements set out in Part 2, the following additional requirements shall apply to the collection, processing and transport of oocytes, ovaries and other tissues for use in *in vitro* fertilisation and *in vitro* culture:

1. The ovaries and other tissues collected at a slaughterhouse, either from an individual donor animal or from a batch of donor animals, shall be collected in a slaughterhouse approved in accordance with Article 148 of Regulation (EU) 2017/625.

   Those potential donor animals must have undergone *ante-mortem* and *post-mortem* inspections carried out by a veterinarian at the slaughterhouse who must have certified them to be free of symptoms and signs of any of the category A, B, C and D diseases relevant for the bovine, porcine, ovine, caprine or equine animals.

   The slaughterhouse must be situated in an area where foot-and-mouth disease has not been reported within a 10-km radius for a period of at least the preceding 30 days before the date of collection of the ovaries and other tissues.

2. Ovaries shall not be brought into the laboratory of an embryo production team for processing until a *post-mortem* inspection of donor animals is completed with satisfactory results.

   If a disease referred to in point 1 is found in the individual donor animal, the batch of donor animals or in any animals slaughtered in that slaughterhouse on that day, all ovaries and other tissues from those donor animals shall be traced and discarded.

3. Equipment for the removal and transport of ovaries and other tissues shall be cleansed and either disinfected or sterilised before use, except for new single-use equipment, and exclusively used for those purposes.

Separate equipment shall be used to handle oocytes and embryos from different individual donor animals and from different batches of donor animals.

Part 4

Animal health requirements for the processing of *in vitro* produced embryos of bovine, porcine, ovine, caprine and equine animals

In addition to the requirements set out in Part 2, the following additional requirements shall apply to the processing of *in vitro* produced embryos:

1. After the *in vitro* culture period is completed, but prior to the freezing, storage and transport of the embryos, they shall be washed and undergo the treatments referred to in points 7, 10 and 11 of Part 2.

2. Embryos from different individual donor animals or from different batches of donor animals, referred to in point 1 of Part 3, shall not be washed together.

3. Embryos from different individual donor animals or from different batches of donor animals shall not be placed in the same straw or other package.

Part 5

Animal health requirements for the processing of micromanipulated embryos of bovine, porcine, ovine, caprine and equine animals

Prior to any micromanipulation which compromises the integrity of the *zona pellucida* or, in the case of equine embryos, the embryonic capsule, all embryos or oocytes shall be collected and processed in accordance with the animal health requirements set out in Parts 2, 3 and 4.

In addition, the following requirements shall apply:

1. Where micromanipulation of the embryo which involves penetration of the *zona pellucida* or*,* in the case of equine embryos, the embryonic capsule, this shall be carried out in a laboratory referred to in point 2(a) of Part 3 of Annex I, which is under the responsibility of the team veterinarian.

2. Each embryo production team shall keep records of its activities in accordance with Article 8(1)(b).

   In the case of embryos produced by *in vitro* fertilisation, the identification of the embryos may be done on the basis of a batch of donor animals, but shall contain details of the date and place of collection of ovaries and oocytes. It shall also allow the establishment of origin of the donor animals to be traced.

3. Any micromanipulation which involves penetration of the *zona pellucida* or, in the case of equine embryos, the embryonic capsule, shall be carried out in the facilities approved for that purpose, and after the last wash and examination.

   Such micromanipulation may only be carried out on an embryo with an intact *zona pellucida* or, in the case of equine embryos, an intact embryonic capsule.

Part 6

Animal health requirements for the storage of *in vivo* derived and *in vitro* produced embryos, and of oocytes of bovine, porcine, ovine, caprine and equine animals

1. Each embryo collection team and embryo production team shall ensure that the embryos and oocytes are stored at suitable temperatures in storage premises referred to in point 2(b) of Part 2 of Annex I.

2. Only embryos collected by an embryo collection team, or oocytes collected by and embryos produced by an embryo production team, and transported in conditions ensuring that cross-contamination of embryos and oocytes is prevented, as they have had no contact with embryos and oocytes which do not comply with the requirements laid down in this Regulation, may be brought into the storage premises referred to in point 2(b) of Part 2 of Annex I.

In vivo derived embryos, *in vitro* produced embryos and oocytes shall be stored in distinct storage containers assigned for each type of germinal product and the handling of stored germinal products of different types and species must be carried out by separate staff or at a different time.

3. The team veterinarian may decide that embryos not collected by an embryo collection team, or oocytes not collected and embryos not produced by an embryo production team, may be processed by the embryo collection team or the embryo production team provided that:

(a) such oocytes and embryos are collected from animals which fulfil the conditions laid down:

(i) in respect of bovine animals, in point 1 of Chapter II of Part 1 of Annex II and as applicable in Chapters I, II and III of Part 5 of Annex II;

(ii) in respect of porcine animals, in points 1, 2 and 3 of Chapter II of Part 2 of Annex II and as applicable in Chapters I and IV of Part 5 of Annex II;

(iii) in respect of ovine and caprine animals, in point 1 of Chapter II of Part 3 of Annex II and as applicable in Chapters I to III of Part 5 of Annex II;

(iv) in respect of equine animals, in points 1 and 2 of Chapter II of Part 4 of Annex II;

(b) processing is carried out with separate equipment or at a different time from oocytes and embryos intended to be moved to another Member State, the equipment in the latter case being cleaned and sterilised after use;

(c) such oocytes and embryos shall not be moved to another Member State and shall not at any time come into contact with, or be stored with, oocytes and embryos intended to be moved to another Member State;

(d) such oocytes and embryos must be identifiable by a marking which is different from that referred to in point 1(a)(v) of Part 1 of Annex I.

4. Frozen embryos or oocytes shall, prior to dispatch to another Member State, be stored in storage premises referred to in point 2(b) of Part 2 of Annex I for a period of at least 30 days from the date of their collection or production.

5. Only embryos or oocytes from an individual donor animal or from one batch of donor animals, referred to in point 1 of Part 3, shall be placed in the same straw or another package.

ANNEX IV

INFORMATION TO BE CONTAINED IN THE ANIMAL HEALTH CERTIFICATE FOR GERMINAL PRODUCTS MOVED BETWEEN MEMBER STATES AS REFERRED TO IN ARTICLES 31 AND 40

1. The animal health certificate for germinal products of bovine, porcine, ovine, caprine and equine animals moved between Member States, referred to in Article 31, shall contain at least the following information:

   (a) the name and address of the consignor and the consignee;

   (b) the name and address of the establishment of dispatch, and

      (i) the unique approval number of that establishment, where the establishment of dispatch is an approved germinal product establishment or a confined establishment, referred to in Article 14;

      or

      (ii) the unique registration number of that establishment, where the establishment of dispatch is an establishment where ovine and caprine animals are kept, referred to in Article 13;

   (c) the name and address of the establishment of destination, and

      (i) the unique approval number of that establishment, where the establishment of destination is an approved germinal product establishment or a confined establishment;

      or

      (ii) the unique registration number of that establishment, where the establishment of destination is a registered germinal product establishment or any other registered establishment;

   (d) the type of germinal products and the species of donor animals;

   (e) the number of straws or other packages to be dispatched;

   (f) the information allowing identification of germinal products:

      (i) the species, breed and identification of the donor animals in accordance with the requirements laid down in Title I, II, III or IV of Part III of Regulation (EU) 2019/2035 from which germinal products were collected;

      (ii) the marking applied to the straws or other packages in accordance with the requirements provided for in Article 10;

      (iii) the place and date of their collection or production;

   (g) the number on the seal applied to the transport container;

   (h) the information on the animal health situation, additional guarantees and, where necessary, test results in relation to:

      (i) the Member State or zone thereof;

      (ii) the establishment of origin of the donor animals;

(iii) the germinal product establishment or, in the case provided for in Article 14, the confined establishment of germinal products collection or production, processing and storage;

(iv) the donor animals from which germinal products were collected;

(v) the germinal products to be dispatched;

(i) the date and place of issue of the animal health certificate, the name, capacity and signature of the official veterinarian, and the stamp of the competent authority of the place of origin of the consignment.

2. The animal health certificate for the germinal products of dogs and cats, and of terrestrial animals other than bovine, porcine, ovine, caprine and equine animals kept at confined establishments and of animals of the families *Camelidae* and *Cervidae* moved between Member States, referred to in Article 40, shall contain at least the following information:

(a) the name and address of the consignor and the consignee;

(b) the name and address of the establishment of dispatch, and

(i) the unique registration number, where the establishment of dispatch was assigned with such registration number;

or

(ii) the unique approval number of that confined establishment, where the establishment of dispatch is a confined establishment;

(c) the name and address of the establishment of destination and, where the establishment of destination is a confined establishment, the unique approval number of that confined establishment;

(d) the type of germinal products and the species of donor animals;

(e) the number of straws or other packages to be dispatched;

(f) the information allowing identification of germinal products:

(i) the species, where necessary the subspecies, and identification of the donor animals from which germinal products were collected,

– in the case of dogs and cats, in accordance with Article 17(1) of Regulation (EU) No 576/2013 or Article 70 of Regulation (EU) 2019/2035;

or

– in the case of terrestrial animals other than bovine, porcine, ovine, caprine and equine animals kept at confined establishments, in accordance with the rules of that confined establishment; or

– in the case of animals of the families *Camelidae* and *Cervidae,* in accordance with Article 73(1) or (2) or Article 74 of Regulation (EU) 2019/2035;

(ii) the marking applied to the straws or other packages in accordance with Article 11;

(iii) the place and date of their collection or production;

(g) the number on the seal applied to the transport container;

(h) the information on the animal health situation, additional guarantees and, where necessary, test results in relation to:

(i) the Member State or zone thereof;

(ii) the establishment of origin of the donor animals;

(iii) the donor animals from which germinal products were collected;

(iv) the germinal products to be dispatched;

(i) the date and place of issue of the animal health certificate, the name, capacity and signature of the official veterinarian, and the stamp of the competent authority of the place of origin of the consignment.