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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	13 January 2023
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2023) 212 final ANNEX
Subject:	ANNEX to the COMMISSION DELEGATED REGULATION (EU) …/... amending Delegated Regulation (EU) 2020/686 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the 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

Delegations will find attached document C(2023) 212 final ANNEX.

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ANNEX

PART A

Annexes I to IV to Delegated Regulation (EU) 2020/686 are amended as follows:

(1) Annex I is amended as follows:

(a) Part 2 is amended as follows:

(i) point 1(a)(v) is replaced by the following:

‘(v) the marking of straws and other packages where oocytes or *in vivo* derived embryos are placed in accordance with the requirements set out in Article 10(1) and (5);’;

(ii) point 2 is replaced by the following:

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

(a) the embryo collection team must have at its disposal a laboratory where oocytes or *in vivo* derived 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 oocytes or *in vivo* derived 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 oocytes or *in vivo* derived embryo collection and processing, except when using only new single-use equipment,

– a room for the storing of oocytes or *in vivo* derived 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 oocytes or *in vivo* derived 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 oocytes or *in vivo* derived 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 oocytes or *in vivo* derived 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 oocytes or *in vivo* derived embryos;

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

(iii) they must have permanent records of all incoming and outgoing oocytes or *in vivo* derived embryos;

(iv) they must have storage containers for oocytes or *in vivo* derived embryos.';

(b) in Part 5, point 2(d) is deleted;

(2) Annex II is amended as follows:

(a) in Part 2, Chapter I, point 1(c)(iii) is deleted;

(b) in Part 2, Chapter I, point 1(c)(iv) is replaced by the following:

'(iv) as regards infection with porcine reproductive and respiratory syndrome virus, a serological test (IPMA, IFA, or ELISA) or 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 serological tests for infection with porcine reproductive and respiratory syndrome virus, the competent authority shall classify all animals in the quarantine accommodation as a suspected case in accordance with Article 9(1), point (b), of Delegated Regulation (EU) 2020/689. The operator shall isolate the positive animals immediately from other animals within the quarantine accommodation. The competent authority shall conduct an investigation to confirm or to rule out infection with porcine reproductive and respiratory syndrome virus in accordance with Article 8 of Delegated Regulation (EU) 2020/689.

If any of the animals prove positive in the tests for virus genome for porcine reproductive and respiratory syndrome virus, the competent authority shall classify all animals in the quarantine accommodation as a confirmed case in accordance with Article 9(2), point (b), of Delegated Regulation (EU) 2020/689. The operator shall remove those animals immediately from the quarantine accommodation and follow the instructions of the competent authority.';

(c) in Part 2, Chapter I, point 2(a)(iii) is replaced by the following:

‘(iii) as regards classical swine fever, an antibody ELISA or serum neutralisation test, in case of animals in 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;’;

(d) in Part 5, Chapter III is replaced by the following:

‘Chapter III

Requirements for bovine, ovine and caprine animals as regards infection with the epizootic haemorrhagic disease virus

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 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 for a period of at least 60 days prior to and during collection of the semen in a Member State or zone thereof seasonally free from infection with epizootic haemorrhagic disease virus;

   (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 infection with epizootic haemorrhagic disease virus, 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;

   (e) they have been subjected to an agent identification test for infection with epizootic haemorrhagic disease virus, 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 virus isolation test; or

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

2. The bovine, ovine and caprine animals which are oocyte donors for the *in vitro* production of embryos and *in vivo* derived embryo 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 oocytes or embryos in a Member State or zone thereof where infection with epizootic haemorrhagic disease virus 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 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 seasonally free from infection with epizootic haemorrhagic disease virus;

(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 infection with epizootic haemorrhagic disease virus, 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 infection with epizootic haemorrhagic disease virus, 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.';

(3) Annex III is amended as follows:

(a) in Part 1, point 3 is replaced by the following:

'3. Where necessary, antibiotics or mixtures of antibiotics may be added to semen or contained in semen diluents.';

(b) in Part 1, points 4 and 5 are deleted;

(4) in Annex IV, in point 2, the introductory wording is replaced by the following:

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

PART B

Annex I to Delegated Regulation (EU) 2020/686 is corrected as follows:

(1) in Part 1, point 1(a)(iii) is replaced by the following:

'(iii) the entry of unauthorised persons is effectively prevented;';

(2) in Part 1, point 1(e) is replaced by the following:

'(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), point (a), 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).';

(3) in Part 4, point 1(a)(ii) is replaced by the following:

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