

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2023/647

of 13 January 2023

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') ⁽¹⁾, and in particular Article 160(1) and (2), and Articles 162(4) and 164(2) thereof,

Whereas:

- (1) Regulation (EU) 2016/429 lays down rules for the prevention and control of animal diseases which are transmissible to animals or humans, including rules for the registration and approval of germinal product establishments, and for the traceability and animal health requirements for movements of consignments of germinal products within the Union. Regulation (EU) 2016/429 also empowers the Commission to adopt rules to supplement certain non-essential elements of that Regulation by means of delegated acts.
- (2) Commission Delegated Regulation (EU) 2020/686 ⁽²⁾ lays down supplementing rules for the approval of germinal product establishments, record keeping and traceability of germinal products, as well as animal health and certification requirements for movements within the Union of germinal products of certain kept terrestrial animals.
- (3) The rules laid down in this Regulation are required to supplement those laid down in Part IV, Title I, Chapter 5, of Regulation (EU) 2016/429 as regards the traceability and animal health requirements and animal health certification requirements for movements within the Union of consignments of germinal products of certain kept terrestrial animals in order to prevent the spread of transmissible animal diseases within the Union by those products.
- (4) These rules are substantively linked and many are intended to be applied in tandem. In the interests of simplicity and transparency, as well as to facilitate their application and to avoid a multiplication of rules, they therefore should be laid down in a single act rather than in a number of separate acts with many cross-references and the risk of duplication.

⁽¹⁾ OJ L 84, 31.3.2016, p. 1.

⁽²⁾ Commission Delegated Regulation (EU) 2020/686 of 17 December 2019 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 (OJ L 174, 3.6.2020, p. 1).

- (5) During the implementation of Delegated Regulation (EU) 2020/686 several Member States and stakeholders indicated that following recent developments and specialisations in the germinal product sector, the definition of embryo collection team should also include a team which only collects and handles unfertilised oocytes. That definition and the related requirements should therefore be amended to cover such a team.
- (6) Germinal product establishments of processing may engage in other processes than sex-sorting of semen. In the interest of the traceability of the processed products, the supplementary traceability requirements previously applicable only to sex-sorted semen should be equally extended to all processed products.
- (7) Article 19 of Delegated Regulation (EU) 2020/686 lays down a derogation from the animal health requirements for donor bovine, porcine, ovine, caprine and equine animals moved between semen collection centres. Experience from Member States and stakeholders with the implementation of that Article have indicated legal uncertainty as regards the degree of involvement of official veterinarians. That Article should therefore be clarified.
- (8) Article 36 of Delegated Regulation (EU) 2020/686 lays down animal health requirements for movements within the Union of germinal products of dogs and cats, mainly to mitigate rabies and promote compliance with preventive animal health measures against *Echinococcus multilocularis*. Member States and stakeholders have questioned the relevance and proportionality of these requirements. As the relevant international standards of the World Organisation for Animal Health (WOAH) do not contain comparable requirements, Article 36 of Delegated Regulation (EU) 2020/686 and related wording in requirements concerning official certification and notification of movement of germinal products of dogs and cats between Member States should be deleted.
- (9) Part 2 of Annex II to Delegated Regulation (EU) 2020/686 lays down additional animal health requirements for porcine donor animals. In accordance with Part 2, Chapter I, point 1(c)(iv), of that Annex, animals positive for infection with porcine reproductive and respiratory syndrome virus are to be removed immediately from the quarantine accommodation. Member States and stakeholders have questioned the proportionality of this requirement in the light of practical and scientifically proven difficulties with current diagnostic methods. Therefore, Delegated Regulation (EU) 2020/686 should be amended in order to provide for different possibilities of follow-up when using different types of diagnostic methods to confirm or rule out suspected cases in accordance with Commission Delegated Regulation (EU) 2020/689 ⁽³⁾.
- (10) Part 2 of Annex II to Delegated Regulation (EU) 2020/686 lays down additional animal health requirements, including testing for classical swine fever of porcine animals kept at semen collection centres. However, the relevant international standards of the WOAH do not require testing of such animals in countries where outbreaks of classical swine fever have not been reported and vaccination against this disease has not been practised in the preceding 12 months. Therefore, testing for that disease of porcine animals kept at semen collection centres should be discontinued in those countries which neither have reported classical swine fever, nor have vaccinated against it in the preceding 12 months.
- (11) References to the epizootic haemorrhagic disease virus should be amended to align them with references to that virus in other Union acts and to clarify that all serotypes of that virus are covered by the rules. In addition, requirements related to infection with epizootic haemorrhagic disease virus should more closely follow international standards of the WOAH to provide for the possibility of a vector-free period as an optional and additional risk mitigating measure related to that infection, to ensure safe trade in germinal products of bovine, ovine and caprine animals.

⁽³⁾ Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases (OJ L 174, 3.6.2020, p. 211).

- (12) Annex III to Delegated Regulation (EU) 2020/686 lays down additional animal health requirements with respect to the addition of antibiotics to semen, including their compulsory addition to semen of bovine and porcine animals. While those requirements are in line with international standards of the WOAH, those international standards are in the process of being amended, towards the voluntary, more flexible and prudent use of antibiotics. In addition, information from scientific literature, Member States and stakeholders indicates similar needs. Therefore, the relevant requirements should be streamlined and made optional.
- (13) After the publication of Delegated Regulation (EU) 2020/686 in the *Official Journal of the European Union*, some substantial errors were spotted. In particular, the wording in relation to the prevention of the entry of unauthorised persons to semen collection centres and germinal product processing establishments created legal uncertainty. Furthermore, an incorrect reference in the text applicable to certain equine animals entering semen collection centres for equine animals unintentionally changed the requirements whose fulfilment centre veterinarians are to ensure. In the interest of legal certainty and clarity, those errors should be corrected.
- (14) Delegated Regulation (EU) 2020/686 should therefore be amended and corrected accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Delegated Regulation (EU) 2020/686 is amended as follows:

- (1) in Article 1(7), point (a) is deleted;
- (2) in Article 2, point (12) is replaced by the following:

‘(12) “embryo collection team” means a germinal product establishment comprised of a group of professionals or a structure approved by the competent authority for the collection, processing, storage and transport of oocytes or *in vivo* derived embryos of bovine, porcine, ovine, caprine or equine animals intended for movement to another Member State, as referred to in Article 4;’
- (3) in Article 3, point (b) is replaced by the following:

‘(b) the group of professionals or the structure supervised by a team veterinarian competent to perform the collection, processing and storage of oocytes or embryos of bovine, porcine, ovine, caprine or equine animals for approval as an embryo collection team;’
- (4) in Article 4(1), point (b)(ii) is replaced by the following:

‘(ii) Part 2, point 2, of Annex I, in respect of the collection, processing, storage and transport of oocytes or embryos of bovine, porcine, ovine, caprine or equine animals;’
- (5) in Article 10, paragraph 2 is replaced by the following:

‘2. In case of a germinal product processed in a germinal product establishment other than the germinal product establishment of collection, the operator of the germinal product establishment of processing shall supplement the information referred to in paragraph 1 with information which permits the identification of the unique approval number of the establishment of processing of that germinal product.’
- (6) in Article 19, paragraph 2 is replaced by the following:

‘2. Operators shall only move donor animals, as referred to in the introductory phrase of paragraph 1, with the prior consent of the centre veterinarian of the semen collection centre of destination.’
- (7) Article 36 is deleted;
- (8) Article 39 is amended as follows:
 - (a) paragraph 1 is deleted;

(b) paragraph 4 is replaced by the following:

‘4. The official veterinarian shall carry out the checks and examinations as provided for in paragraphs 2 and 3 and issue the animal health certificate within the period of 72 hours preceding the time of dispatch of the consignment of germinal products.’;

(9) Article 40 is replaced by the following:

Article 40

Animal health certification requirements for movements of consignments of germinal products of kept terrestrial animals other than bovine, porcine, ovine, caprine or equine animals between Member States

The animal health certificates for movements between Member States of consignments of 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*, shall contain at least the information set out in point 2 of Annex IV.’;

(10) Article 41 is replaced by the following:

Article 41

Requirement for advance notification by operators of movements of consignments of germinal products of kept terrestrial animals other than bovine, porcine, ovine, caprine or equine animals between Member States

Where consignments of germinal products of terrestrial animals other than bovine, porcine, ovine, caprine or equine animals kept at confined establishments or of animals of the family *Camelidae* or *Cervidae* are moved to another Member State, the operator shall notify the competent authority in the Member State of origin of the consignments in advance of the intended movement of those consignments of germinal products.’

Article 2

Annexes I to IV to Delegated Regulation (EU) 2020/686 are amended in accordance with Part A of the Annex to this Regulation.

Article 3

Annex I to Delegated Regulation (EU) 2020/686 is corrected in accordance with Part B of the Annex to this Regulation.

Article 4

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 13 January 2023.

For the Commission
The President
Ursula VON DER LEYEN

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.’.
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