EUROPEAN
COMMISSION

Brussels, XXX
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COMMISSION DELEGATED REGULATION (EU) …/...

of XXX

amending Delegated Regulation (EU) 2020/686 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council as regards the traceability, animal health and certification requirements for movements within the Union of germinal products of certain kept terrestrial animals

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

[Briefly]

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

[Essential part]

3. LEGAL ELEMENTS OF THE DELEGATED ACT

[Briefly]

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(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 Article 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) Articles 16 and 18 of Delegated Regulation (EU) 2020/686 provide that centre veterinarians and team veterinarians should ensure that the donor animals show neither symptoms nor clinical signs of any of the category D diseases and none of the category D diseases relevant for the bovine, porcine, ovine or caprine animals has been reported for a period of at least 30 days in the establishment of origin, quarantine accomodation and semen collection centre. Both, the stakeholders collecting germinal products in the Union and several competent authorities, requested to exclude infection with bluetongue virus (serotypes 1-24) and infection with epizootic

[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).

haemorrhagic disease virus from the category D diseases from this reporting obligation.

(4) Infection with bluetongue virus (serotypes 1-24) and infection with epizootic haemorrhagic disease virus are two very similar diseases from an epidemiological point of view and they share the same listed species. Those are vector born diseases with specific frequent testing requirments in the case the diseases are reported during a period of at least 60 days prior to and during collection of the semen, oocytes or embryos in a Member State or zone thereof. That justifies a different approach to those two diseases than to other category D diseases. Therefore, the reporting obligation in relation to infection with bluetongue virus (serotypes 1-24) and infection with epizootic haemorrhagic disease virus should be deleted and the relevant Article 16 and 18 be amended accordingly.

(5) In addition, infection with bluetongue virus (serotypes 1-24) is has been re-categorisated from a category C+D+E disease to a category D+E disease by Commission Implementing Regulation (EU) 20xx/xxx (PLAN/1496/2025)[3] amending Commission Implementing Regulation (EU) 2018/1882[4]. Amongst other implications, such recategorization implies that the rules for infection with bluetongue virus (serotypes 1-24) related to official disease-free status or to optional eradication programmes including the requirements for movement of germinal products when entering in free zone or into a zone under eradication are being deleted from Commission Delegated Regulation (EU) 2020/689[5] by a separate amendment. Therefore, the requirements related to a official disease-free status and a country or zone carrying out an eradicaton programme for infection with bluetongue virus (serotypes 1-24) will cease to exist and Delegated Regulation (EU) 2020/686 should be amended by removing references to a disease-free status and to an eradicaton programme for that disease.

(6) Article 38 of Delegated Regulation (EU) 2020/686 lays down the animal health requirements for movements to other Member States of germinal products of animals of the families *Camelidae* and *Cervidae,* including requirements realted to infection with bluetongue virus (serotypes 1-24). Those requirments should be aligned to the requirments for donor bovine, ovine and caprine animals as laid down in amended Article 16 of and Chapter II of Part 5 of Annex II to Delegated Regulation (EU) 2020/686.

(7) Part 4 of Annex II to Delegated Regulation (EU) 2020/686 lays down additional animal health requirements for equine donor animals. In accordance with point 1(a)(iii) of Chapter I and point 2(c) of Chapter II of Part 4 of that Annex donor equine

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3 Commission Implementing Regulation (EU) 20xx/xxx of xxx amending the Annex to Implementing Regulation (EU) 2018/1882 concerning the categorisation of infection with bluetongue virus (serotypes 1-24) as a listed disease (OJ L xxx, xx.xx.xxxx, p. xx, ELI: xxx). [PLAN/1496/2025]

4 Commission Implementing Regulation (EU) 2018/1882 of 3 December 2018 on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases (OJ L 308, 4.12.2018, p. 21, ELI: http://data.europa.eu/eli/reg_impl/2018/1882/oj).

5 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, ELI: http://data.europa.eu/eli/reg_del/2020/689/oj).

animals should be subjected to a test for contagious equine metritis (*Taylorella equigenitalis*). In accordance with the Manual of Diagnostic Tests and Vaccines for Terrestrial of the Animals World Organisation Animal Health (WOAH), Chapter 3.6.2 on Contagious Equine Metritis (May 2022 version), for Polymerase Chain Reaction (PCR) testing it is not necessary to use transport medium to convey swabs to the laboratory and such swabs for PCR should be tested no more than 7 days after sampling. Therefore, Part 4 of Annex II to Delegated Regulation (EU) 2020/686 should be amended by deleting a necessity of using a transport medium from the methodology for PCR testing for contagious equine metritis (*Taylorella equigenitalis*).

(8) Chapters II and III of Part 5 of Annex II to Delegated Regulation (EU) 2020/686 lay down requirements as regards infection with bluetongue virus (serotypes 1-24) and infection with the epizootic haemorrhagic disease virus. The requirements for those diseases shlould be amended taking account the re-categorisation from a category C+D+E disease to a category D+E disease of infection with bluetongue virus (serotypes 1-24).

(9) Delegated Regulation (EU) 2020/686 should therefore be amended accordingly.

HAS ADOPTED THIS REGULATION:

Article 1
Amendments to Delegated Regulation (EU) 2020/686

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

1. Article 16 is amended as follows:

   (a) point (d)(ii) is replaced by the following:

   ‘(ii) they have been kept in establishments where no category D diseases, except infection with bluetongue virus (serotypes 1-24) and infection with haemorrhagic epizootic virus, relevant for those animals have been reported;’;

   (b) point (e) is replaced by the following:

   ‘(e) they showed neither symptoms nor clinical signs of any of the category D diseases referred to in point (d)(ii), including infection with bluetongue virus (serotypes 1-24) and infection with haemorrhagic epizootic virus, or of the emerging diseases on the day of collection of the semen, oocytes or embryos;’;

2. Article 18 is amended as follows:

   (a) point (a) is replaced by the following:

   ‘(a) they showed neither symptoms nor clinical signs of any of the category D diseases referred to in Article 16(d)(ii), including infection with bluetongue virus (serotypes 1-24) and infection with haemorrhagic epizootic virus, on the day of their admission to a semen collection centre;’;

   (b) point (b)(i) is replaced by the following:

'(i) none of the category D diseases, except infection with bluetongue virus (serotypes 1-24) and infection with haemorrhagic epizootic virus, relevant for the bovine, porcine, ovine or caprine animals has been reported for a period of at least the preceding 30 days;';

(c) point (c)(i) is replaced by the following:

'(i) during a period which comprises at least 30 days prior to date of collection and at least 30 days following the date of collection of the semen or, in the case of fresh semen, until the date of dispatch of the consignment of semen, none of the category D diseases, except infection with bluetongue virus (serotypes 1-24) and infection with haemorrhagic epizootic virus, relevant for bovine, porcine, ovine, caprine or equine animals have been reported.';

3. Article 38 is amended as follows:

(a) point (g) is deleted;

(b) point (k) is replaced by the following:

'(k) fulfil animal health requirements as regards infection with bluetongue virus (serotypes 1-24) and infection with epizootic haemorrhagic disease virus laid down in Chapters I and II of Part 5 of Annex II;';

4. Annex II is amended in accordance with the Annex to this Regulation.

Article 2

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

It shall apply as of XXXX.

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

Done at Brussels,

For the Commission
The President
[...]