II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2021/880

of 5 March 2021

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)

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 122(1) and (2), Article 160(1) and (2), Article 162(3) and (4), Article 163(5), Article 164(2), Article 165(3) and Article 279(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 Chapters 1, 2 and 5 of Title I of Part IV of Regulation (EU) 2016/429, as regards the approval of germinal product establishments, the registers of germinal product establishments to be kept by the competent authorities, the record-keeping obligations of operators, the traceability and animal health requirements, and animal health certification and notification 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) Article 11 of Delegated Regulation (EU) 2020/686 lays down the traceability requirements for germinal products of dogs and cats, terrestrial animals other than bovine, porcine, ovine, caprine and equine animals kept at confined establishments, and animals of the families *Camelidae* and *Cervidae*. Establishment where germinal products are collected, produced, processed or stored should be registered or approved by the competent authority and a registration or approval number should be assigned to that establishment. The registration or approval number is a part of the mark on the straws or other packages in which germinal products are placed. Paragraph 1(c) of Article 11 of Delegated Regulation (EU) 2020/686 should be amended to provide a clarity of such requirement.

(6) Article 13 of Delegated Regulation (EU) 2020/686 lays down a derogation for the movements to other Member States of semen of ovine and caprine animals from the establishments where those animals are kept. Donor animals, regardless of whether the place of collection of semen is a semen collection centre or an establishment, should not be used for natural breeding during the period of at least 30 days prior to the date of first collection and during the period of collection of the semen intended for movement to another Member State. Such a requirement should be included in Article 13 of Delegated Regulation (EU) 2020/686.

(7) Articles 30 and 39 of Delegated Regulation (EU) 2020/686 provide for a 10-day validity period of an animal health certificate issued for a consignment of germinal products intended to be moved between Member States. As germinal products are not perishable goods, there should not be any limit to the validity period of these animal health certificates.

(8) Articles 35, 43 and 48 of Delegated Regulation (EU) 2020/686 lay down rules for emergency procedures for the notification of movements of consignments of germinal products between Member States in the event of disturbances caused to the information management system for official controls (IMSOC). Articles 99 and 107 of Commission Delegated Regulation (EU) 2020/688 ([3]) lay down rules on the same matter for movements between Member States of consignments of certain terrestrial animals. However, the wording of the provisions concerned in both Delegated Regulations differ. For the sake of consistency and clarity of procedures, Articles 35, 43 and 48 of Delegated Regulation (EU) 2020/686 should be amended by aligning their wording with that of Articles 99 and 107 of Delegated Regulation (EU) 2020/688.

(9) Part IV of Delegated Regulation (EU) 2020/686 lays down certain transitional measures regarding Council Directives 88/407/EEC ([4]), 89/556/EEC ([5]), 90/429/EEC ([6]) and 92/65/EEC ([7]) in relation to the approval of semen collection centres, semen storage centres, embryo collection teams and embryo production teams and the marking of straws and other packages in which semen, oocytes or embryos are placed, stored and transported. However, in order to enable continuity of the movements between Member States of germinal products fulfilling the requirements laid down in those Directives, which were collected or produced, processed and stored before 21 April 2021, certain additional transitional provisions concerning those movements and the use of animal health certificates issued before 21 April 2021 should be laid down in this Regulation.

(10) Part 1 of Annex II to Delegated Regulation (EU) 2020/686 lays down additional animal health requirements for bovine donor animals. In accordance with point 1(b)(i) and point 2(a) of Chapter I of Part 1 of that Annex bovine semen donors are to be subjected to an intradermal tuberculin test for infection with *Mycobacterium tuberculosis* complex (*M. bovis, M. caprae* and *M. tuberculosis*). However, there is also a gamma-interferon assay listed in point 2 of Part 2 of Annex I to Delegated Regulation (EU) 2020/688 as another diagnostic method for infection with *Mycobacterium tuberculosis* complex (*M. bovis, M. caprae* and *M. tuberculosis*). Therefore, Delegated Regulation (EU) 2020/686 should be amended in order to provide for the possibility of using of both diagnostic methods.

([3]) Commission Delegated Regulation (EU) 2020/688 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health requirements for movements within the Union of terrestrial animals and hatching eggs (OJ L 174, 3.6.2020, p. 140).

([4]) Council Directive 88/407/EEC of 14 June 1988 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the bovine species (OJ L 194, 22.7.1988, p. 10).

([5]) Council Directive 89/556/EEC of 25 September 1989 on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species (OJ L 302, 19.10.1989, p. 1).

([6]) Council Directive 90/429/EEC of 26 June 1990 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the porcine species (OJ L 224, 18.8.1990, p. 62).

([7]) Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC (OJ L 268, 14.9.1992, p. 54).

(11) Points 1 and 2 of Annex IV to Delegated Regulation (EU) 2020/686 lay down information that is to be contained in the animal health certificate for germinal products. The date of dispatch of the consignment has been unintentionally omitted from that information and therefore it should be inserted in those provisions. In addition, point 1(f)(i) of Annex IV to that Delegated Regulation requires the breed of donor animal to be specified in the animal health certificate for germinal products of bovine, porcine, ovine, caprine and equine animals. Such information is unnecessary from an animal health point of view and therefore should be removed from the required information to be contained in the animal health certificate for germinal products of bovine, porcine, ovine, caprine and equine animals.

(12) After the publication of Delegated Regulation (EU) 2020/686 in the *Official Journal of the European Union*, some clerical errors and unintentional omissions were spotted. In the interest of legal certainty and clarity, those errors and omissions should be corrected.

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

(14) As Delegated Regulation (EU) 2020/686 applies from 21 April 2021, this Regulation should also apply from that date,

HAS ADOPTED THIS REGULATION:

Article 1

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

(1) Article 1(9) is amended as follows:

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

'(b) the marking of straws and other packages in which semen, oocytes or embryos are placed, stored and transported;';

(b) the following points (c) and (d) are added:

'(c) the use of animal health certificates issued before 21 April 2021;

(d) the movements between Member States of semen, oocytes and embryos collected, produced, processed and stored before 21 April 2021.';

(2) in Article 2, point (28) is replaced by the following:

'(28) "IMSOC" means an information management system for official controls for the integrated operation of the mechanisms and tools through which data, information and documents concerning official controls and other official activities are managed, handled, and automatically exchanged as referred to in Article 131 of Regulation (EU) 2017/625;';

(3) in Article 11(1), point (c) is replaced by the following:

'(c) one of the following:

(i) where the establishment of collection or production, processing and storage of those germinal products was assigned with a unique registration number, the unique registration number which shall include the ISO 3166-1 alpha-2 code of the country in which the establishment is registered;

(ii) where the establishment of collection or production, processing and storage of those germinal products is a confined establishment, the unique approval number which shall include the ISO 3166-1 alpha-2 code of the country in which the approval is granted;';

(4) Article 13 is amended as follows:

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

'(h) ensure that the consignment of semen is transported in accordance with Articles 28 and 29;';

(b) the following point (i) is added:

'(i) ensure that donor animals were not used for natural breeding during the period of at least 30 days prior to the date of first collection of semen intended for movements between Member States and during the period of collection of that semen.';

(5) in Article 17, point (b) is replaced by the following:

'(b) they must not be moved between Member States until the movement restrictions applied to either the semen collection centre or the establishment where the semen, oocytes or embryos were collected have been removed by the competent authorities; and';

(6) in Article 20, paragraph 3 is replaced by the following:

'3. By way of derogation from paragraph 1(a)(iii), the team veterinarian may accept a donor animal of oocytes and embryos which came from an establishment which was not free from enzootic bovine leukosis provided that the official veterinarian responsible for the establishment of origin has certified that there has been no clinical case of enzootic bovine leukosis during a period of at least the preceding 3 years.';

(7) in Article 22, point (a) is deleted;

(8) in Article 27(1), point (b) is replaced by the following:

'(b) the mark on the straws or other packages, applied in accordance with Article 10, and the number of the seal applied on the container in which the straws or other packages are transported, correspond with the mark and the number provided either in the animal health certificate or in the self-declaration document.';

(9) in Article 30, paragraph 3 is deleted;

(10) Article 32(2) is amended as follows:

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

'(e) the marking of the germinal products, as required by Article 10;';

(b) the following points (f), (g) and (h) are added:

'(f) the species of donor animals;

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

(h) the declaration that the consignment fulfils the animal health requirements laid down in Chapter 1.';

(11) Article 35 is replaced by the following:

'*Article 35*

Emergency procedures for the notification of movements of consignments of germinal products of bovine, porcine, ovine, caprine and equine animals between Member States in the event of power cuts and other disturbances of the IMSOC

In the event of power cuts and other disturbances of the IMSOC, the competent authority of the place of origin of the consignment of germinal products of bovine, porcine, ovine, caprine and equine animals to be moved between Member States shall comply with the contingency arrangements set out in Article 46 of Commission Implementing Regulation (EU) 2019/1715 *.

* Commission Implementing Regulation (EU) 2019/1715 of 30 September 2019 laying down rules for the functioning of the information management system for official controls and its system components ("the IMSOC Regulation") (OJ L 261, 14.10.2019, p. 37).';

(12) Article 39 is amended as follows:

(a) in paragraph 1(b), point (ii) is replaced by the following:

'(ii) the mark on the straws or other packages, applied in accordance with Article 11, and the number of the seal applied on the container in which the straws or other packages are transported, correspond with the mark and the number provided in the animal health certificate;';

(b) in paragraph 2(b), point (ii) is replaced by the following:

'(ii) the mark on the straws or other packages, applied in accordance with Article 11, and the number of the seal applied on the container in which the straws or other packages are transported, correspond with the mark and the number provided in the animal health certificate;';

(c) in paragraph 3(b), point (ii) is replaced by the following:

'(ii) the mark on the straws or other packages, applied in accordance with Article 11, and the number of the seal applied on the container in which the straws or other packages are transported, correspond with the mark and the number provided in the animal health certificate;';

(d) paragraph 5 is deleted;

(13) Article 43 is replaced by the following:

'*Article 43*

Emergency procedures for the notification of movements of consignments of germinal products of kept terrestrial animals other than bovine, porcine, ovine, caprine and equine animals between Member States in the event of power cuts and other disturbances of the IMSOC

In the event of power cuts and other disturbances of the IMSOC, the competent authority of the place of origin of the consignment of germinal products of kept terrestrial animals other than bovine, porcine, ovine, caprine and equine animals to be moved between Member State shall comply with the contingency arrangements set out in Article 46 of Implementing Regulation (EU) 2019/1715.';

(14) Article 46(2) is amended as follows:

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

'(c) the date of dispatch of the consignment;';

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

'(g) available results of the tests referred to in Article 45(2)(b);';

(c) the following points (h) and (i) are added:

'(h) the number of the seal applied on the transport container;

(i) the declaration that the consignment fulfils requirements laid down in Article 44 or 45, including that the prior written consent of the competent authority of the Member State of destination to accept the consignment of germinal products has been obtained.';

(15) Article 48 is replaced by the following:

'*Article 48*

Emergency procedures for the notification of movements between Member States of germinal products intended for scientific purposes or for storage in gene banks in the event of power cuts and other disturbances of the IMSOC

In the event of power cuts and other disturbances of the IMSOC, the competent authority of the place of origin of the consignment of germinal products intended for scientific purposes or for storage in gene banks to be moved between Member State shall comply with the contingency arrangements set out in Article 46 of Implementing Regulation (EU) 2019/1715.';

(16) Article 49 is replaced by the following:

'*Article 49*

Transitional measures

1. Semen collection centres, semen storage centres, embryo collection teams and embryo production teams which have been approved before 21 April 2021 in accordance with Directives 88/407/EEC, 89/556/EEC, 90/429/EEC and 92/65/EEC referred to in the 6th, 7th, 8th and 12th indents of the first subparagraph of Article 270(2) of Regulation (EU) 2016/429 shall be considered to have been approved in accordance with Article 97 of Regulation (EU) 2016/429 and Article 4 of this Regulation.

In all other respects, they shall be subject to the rules provided for in Regulation (EU) 2016/429, and in this Regulation.

2. Semen, oocytes and embryos collected, produced, processed and stored before 21 April 2021 shall be allowed to be moved between Member States, provided they fulfil, as regards the collection, production, processing and storage of germinal products, animal health requirements for donor animals and laboratory and other tests carried out on donor animals and germinal products, the requirements laid down in Directives 88/407/EEC, 89/556/EEC, 90/429/EEC and 92/65/EEC.

3. Straws and other packages in which semen, oocytes or embryos, whether or not separated into individual doses, are placed, stored and transported, marked before 21 April 2021 in accordance with Directives 88/407/EEC, 89/556/EEC, 90/429/EEC and 92/65/EEC shall be considered to have been marked in accordance with Article 121 of Regulation (EU) 2016/429 and Article 10 of this Regulation.

4. Animal health certificates issued before 21 April 2021 in accordance with Directives 88/407/EEC, 89/556/EEC, 90/429/EEC and 92/65/EEC shall be considered to have been issued in accordance with Article 162 of Regulation (EU) 2016/429 and Articles 30 and 31 of this Regulation.';

(17) Annexes I to IV to Delegated Regulation (EU) 2020/686 are 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 from 21 April 2021.

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

Done at Brussels, 5 March 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

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

(1) Annex I is amended as follows:

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

'(v) each straw or other package in which semen is placed is clearly marked in accordance with the requirements laid down in Article 10;';

(b) in Part 4, point 1(a)(iv) is replaced by the following:

'(iv) each straw or other package in which semen, oocytes or embryos are placed is clearly marked in accordance with the requirements laid down in Article 10;';

(c) in Part 5, point 1(a)(iv) is replaced by the following:

'(iv) each straw or other package in which semen, oocytes or embryos are placed is clearly marked in accordance with the requirements laid down in Article 10;';

(2) Annex II is amended as follows:

(a) in Chapter I of Part 1, point 1(b)(i) is replaced by the following:

'(i) for infection with *Mycobacterium tuberculosis* complex (*M. bovis, M. caprae* and *M. tuberculosis*), a test referred to in Part 2 of Annex I to Delegated Regulation (EU) 2020/688;';

(b) in Chapter I of Part 1, point 1(b)(iii) is replaced by the following:

'(iii) for enzootic bovine leukosis, a serological test referred to in point (a) of Part 4 of Annex I to Delegated Regulation (EU) 2020/688, unless the derogation provided for in Article 20(2)(a) of this Regulation applies;';

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

'(a) for infection with *Mycobacterium tuberculosis* complex (*M. bovis, M. caprae* and *M. tuberculosis*), a test referred to in Part 2 of Annex I to Delegated Regulation (EU) 2020/688;';

(d) in Chapter I of Part 3, points 1(b), 1(c) and 1(d) are replaced by the following:

'(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, and any male caprine animal kept with them together, have been subjected with negative results to a serological test for ovine epididymitis (*Brucella ovis*), or any other test for ovine epididymitis (*Brucella ovis*) of an equivalent documented sensitivity and specificity;

(c) the animals have been subjected to the following tests carried out on samples taken within a period of 30 days preceding the commencement of the period of quarantine referred to in point (a), 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 Delegated Regulation (EU) 2020/688;

(ii) in the case of ovine animals, and any male caprine animals kept with them together, a serological test for ovine epididymitis (*Brucella ovis*), or any other test for ovine epididymitis (*Brucella ovis*) of an equivalent documented sensitivity and specificity;

(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 Delegated Regulation (EU) 2020/688;

(ii) in the case of ovine animals, and any male caprine animals kept with them together, a serological test for ovine epididymitis (*Brucella ovis*), or any other test for ovine epididymitis (*Brucella ovis*) of an equivalent documented sensitivity and specificity.';

(e) in Chapter I of Part 3, the introductory phrase of point 2 is replaced by the following:

'2. All ovine and caprine 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:';

(f) in Chapter II of Part 5, point 1(a) is replaced by the following:

'(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 free from infection with bluetongue virus (serotypes 1-24), where no case of infection with bluetongue virus (serotypes 1-24) has been confirmed during the last 24 months in the targeted animal population;';

(g) in Chapter II of Part 5, point 2(a) is replaced by the following:

'(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 free from infection with bluetongue virus (serotypes 1-24),where no case of infection with bluetongue virus (serotypes 1-24) has been confirmed during the last 24 months in the targeted animal population;';

(3) Annex III is amended as follows:

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

'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) a mixture of lincomycin-spectinomycin (150/300 μg), penicillin (500 IU) and streptomycin (500 μg); or

(b) a mixture of gentamicin (250 μg), tylosin (50 μg), lincomycin-spectinomycin (150/300 μg); or

(c) a mixture of amikacin (75 μg) and divekacin (25 μg); or

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

(b) in Part 1, point 4 is replaced by the following:

'4. In respect of semen of bovine animals, antibiotics or mixtures of antibiotics referred to in point 3(a), (b) and (c) or antibiotics or mixtures of antibiotics with a bactericidal activity at least equivalent to that of the antibiotics or their mixtures referred to in point 3(a), (b) and (c), or semen diluents containing such antibiotics or mixtures of antibiotics, shall be added and be effective in particular against campylobacters, leptospires and mycoplasmas.';

(c) in Part 1, point 5 is replaced by the following:

'5. In respect of semen of porcine animals, antibiotics or mixtures of antibiotics referred to in point 3(a), (b) and (c) or antibiotics or mixtures of antibiotics with a bactericidal activity at least equivalent to that of the antibiotics or their mixtures referred to in point 3(a), (b) and (c), or semen diluents containing such antibiotics or mixtures of antibiotics, shall be added and be effective in particular against leptospires.';

(4) Annex IV is amended as follows:

(a) in point 1(f), point (i) is replaced by the following:

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

(b) in point 1, point (i) is replaced by the following:

'(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;';

(c) in point 1, the following point (j) is added:

'(j) the date of dispatch of the consignment.';

(d) in point 2, point (i) is replaced by the following:

'(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;';

(e) in point 2, the following point (j) is added:

'(j) the date of dispatch of the consignment.'.