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

of 14.7.2021

**amending Delegated Regulation (EU) 2020/692 supplementing Regulation (EU) 2016/429
of the European Parliament and the Council as regards rules for entry into the Union,
and the movement and handling after entry of consignments of certain animals,
germinal products and products of animal origin**

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Commission Delegated Regulation (EU) 2020/692¹ supplements Regulation (EU) 2016/429 of the European Parliament and the Council² as regards the animal health rules for the entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin.

After its publication on 3 June 2020 in the *Official Journal of the European Union*, certain minor mistakes and omissions were spotted in the provisions of Delegated Regulation (EU) 2020/692. These mistakes and omissions should be corrected, and Delegated Regulation (EU) 2020/692 should be amended accordingly.

In addition, certain provisions of Delegated Regulation (EU) 2020/692 should be amended in order to:

- align them with supplementing rules laid down in other delegated regulations adopted pursuant to Regulation (EU) 2016/429, and Regulation (EU) 2017/625 of the European Parliament and of the Council³;
- to cover certain circumstances that were initially not taken into account;
- to cover certain possibilities that are provided for in Union acts adopted before Regulation (EU) 2016/429, and that should be maintained in the framework of the rules laid down pursuant to Regulation (EU) 2016/429, to ensure a smooth transition from the requirements laid down in those earlier acts concerning the entry into the Union of animals, germinal products and products of animal origin;
- to clarify the species and categories of animals and products of animal origin to which certain requirements should apply or should not apply.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission circulated the contents of this draft Delegated Regulation to members of the Expert Group on Animal Health (E00930).

¹ Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin (OJ L 174, 3.6.2020, p. 379)

² 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') (OJ L 84, 31.3.2016, p. 1)

³ Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

3. LEGAL ELEMENTS OF THE DELEGATED ACT

This Regulation is to be adopted within the framework of Regulation (EU) 2016/429, and in particular pursuant to Articles 234(2), 237(4), 239(2) and 279(2) thereof.

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

of 14.7.2021

amending Delegated Regulation (EU) 2020/692 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin

(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')⁴, and in particular Articles 234(2), 237(4), 239(2) and 279(2) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) 2020/692⁵ supplements the animal health rules laid down in Regulation (EU) 2016/429, as regards the entry into the Union, and the movement and handling after entry, of consignments of certain animals, germinal products and products of animal origin.
- (2) After the publication of Delegated Regulation (EU) 2020/692 on 3 June 2020 in the *Official Journal of the European Union*, certain minor mistakes or omissions were spotted in the provisions of that Delegated Regulation. Those mistakes and omissions should be corrected and Delegated Regulation (EU) 2020/692 should therefore be amended accordingly.
- (3) In addition, certain rules laid down in Delegated Regulation (EU) 2020/692 should be amended in order to ensure that they are consistent with rules laid down in other delegated acts adopted pursuant to Regulation (EU) 2016/429, and Regulation (EU) 2017/625 of the European Parliament and of the Council.⁶

⁴ OJ L 84, 31.3.2016, p. 1.

⁵ Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin (OJ L 174, 3.6.2020, p. 379).

⁶ Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC,

- (4) It is also necessary to amend Delegated Regulation (EU) 2020/692 to cover certain circumstances that were initially omitted from the scope of that act, and to cover certain possibilities that are provided for in Union acts that were adopted prior to Regulation (EU) 2016/429, and that should be maintained in the framework of Regulation (EU) 2016/429. This is important in order to ensure a smooth transition from the requirements laid down in those earlier Union acts concerning the entry into the Union of animals, germinal products and products of animal origin, or to clarify the species and categories of animals and products of animal origin to which certain requirements should apply or should not apply.
- (5) Delegated Regulation (EU) 2020/692 should also ensure a smooth transition from the requirements laid down in earlier Union acts concerning the entry into the Union of aquatic animals and products of animal origin thereof, as they have proven to be effective. Therefore, the aim and substance of those existing rules should be maintained in that Delegated Regulation, but adapted to suit the new legislative framework established by Regulation (EU) 2016/429.
- (6) In addition, the animal health requirements laid down in Delegated Regulation (EU) 2020/692 should not apply to products of animal origin from aquatic animals other than live aquatic animals, except those which are intended for further processing in the Union, given that there are no significant animal health reasons to include such products within the scope of that Delegated Regulation. Article 1(6) of Delegated Regulation (EU) 2020/692, setting out the scope of that act, should therefore be amended.
- (7) The definition of a porcine animal, as currently laid down in Article 2, point (8), of Delegated Regulation (EU) 2020/692 is suitable only for the purpose of the entry into the Union of those animals. Commission Delegated Regulation (EU) 2020/686⁷, which lays down rules on the movement within the Union of germinal products, provides for a different definition of porcine animals, which is appropriate for donors of germinal products. Therefore, the definition of porcine animals in Delegated Regulation (EU) 2020/692 should be amended to cover the entry into the Union of both porcine animals and germinal products of porcine animals.
- (8) The definition of ‘well-boat’ currently laid down in Article 2, point (48), of Delegated Regulation (EU) 2020/692 is not in line with the definition of ‘well-boat’ set out in Article 2, point (2), of Commission Delegated Regulation (EU) 2020/990⁸. In the interests of consistency of Union rules, the definition in Article 2, point (48), of Delegated Regulation (EU) 2020/692 should be amended to bring it into line with the definition set out in Delegated Regulation (EU) 2020/990.
- (9) Delegated Regulation (EU) 2020/692 lays down requirements in relation to the inspection of terrestrial animals prior to their dispatch to the Union, which in the case

89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

⁷ 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)

⁸ Commission Delegated Regulation (EU) 2020/990 of 28 April 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health and certification requirements for movements within the Union of aquatic animals and products of animal origin from aquatic animals (OJ L 221, 10.7.2020, p. 42).

of poultry cover also their flock of origin. It should, however, be clarified that those requirements do not apply to the flock of origin of day-old chicks, in accordance with the requirements applicable until 21 April 2021, laid down in Commission Regulation (EC) No 798/2008⁹. Article 13(1) of Delegated Regulation (EU) 2020/692 should therefore be amended accordingly.

- (10) Delegated Regulation (EU) 2020/692, which applies from 21 April 2021, should ensure a smooth transition from the requirements laid down in earlier Union acts concerning the entry into the Union of terrestrial animals, and germinal products and products of animal origin from terrestrial animals, as they have proved to be effective. Therefore, the aim and substance of those rules should be maintained in that Delegated Regulation, but adapted to suit the new legislative framework established by Regulation (EU) 2016/429. Article 11(1) of Commission Regulation (EU) No 206/2010¹⁰ provided that, following their introduction into the Union, consignments of ungulates, other than ungulates intended for confined establishments, are to remain on the holding of destination for a period of at least 30 days, unless they are dispatched directly to a slaughterhouse. Regulation (EU) No 206/2010 was repealed by Delegated Regulation (EU) 2020/692. However, Delegated Regulation (EU) 2020/692 does not provide for the possibility to move ungulates to a slaughterhouse during the 30-day period after their entry into the Union. Article 26 of Delegated Regulation (EU) 2020/692 should therefore be amended to provide for that possibility, as movements during that period do not give rise to any significant animal health concerns.
- (11) In addition, the derogation from the requirement regarding the 30-day period of residency in the establishment of destination after entry into the Union provided for in Article 26 of Delegated Regulation (EU) 2020/692 that currently applies only to equine animals intended for competition, races and cultural events should be extended to all equine animals, and that Article should be amended accordingly.
- (12) Delegated Regulation (EU) 2020/692 provides for a derogation from the requirements laid down in that act for the entry into the Union of consignments of poultry and hatching eggs of poultry in the case consignments of less than 20 heads of poultry other than ratites, and consignments of less than 20 hatching eggs of poultry other than ratites. Certain requirements in relation to the means of transport, the containers in which they are transported to the Union, vaccination against highly pathogenic avian influenza and disinfection that apply for poultry and hatching eggs, should, however, also apply for the entry into the Union of consignments of less than 20 heads of poultry, other than ratites, and less than 20 hatching eggs of poultry, other than ratites. Articles 49 and 101 of Delegated Regulation (EU) 2020/692 should therefore be amended accordingly.
- (13) Delegated Regulation (EU) 2020/692 provides that all captive birds dispatched to the Union should have been vaccinated against infection with Newcastle disease virus. This, however, is not practically possible and is inconsistent with the requirements for the entry into Member States with status free from infection against Newcastle disease

⁹ Commission Regulation (EC) No 798/2008 of 8 August 2008 laying down a list of third countries, territories, zones or compartments from which poultry and poultry products may be imported into and transit through the Community and the veterinary certification requirements (OJ L 226, 23.8.2008, p. 1).

¹⁰ Commission Regulation (EU) No 206/2010 of 12 March 2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements (OJ L 73, 20.3.2010, p. 1).

virus without vaccination. Article 57 of Delegated Regulation (EU) 2020/692 should therefore be amended to clarify that the requirements as regards the vaccines used against infection with Newcastle disease virus apply in the case where captive birds have been vaccinated against that disease.

- (14) Racing pigeons fall within the definition of ‘captive birds’ laid down in Article 4, point (10), of Regulation (EU) 2016/429. Therefore, the specific animal health requirements for captive birds laid down in Part II, Title 3, Chapter 2, of Delegated Regulation (EU) 2020/692 apply also to those animals. However, those requirements limit the possibility for the entry into the Union of racing pigeons from a third country or territory or zone thereof with the intention that they will fly back to that third country or territory or zone. Moreover, racing pigeons introduced into the Union with the intention to fly back to the third country or territory of origin or zone thereof do not pose the same animal health risk as other captive birds. Delegated Regulation (EU) 2020/692 should therefore be amended to provide for a derogation from the specific animal health requirements for captive birds for the entry into the Union of racing pigeons from a third country or territory or zone thereof where they are normally kept, with the intention to be immediately released with the expectation that they will fly back to that third country or territory or zone thereof.
- (15) Article 74 of Delegated Regulation (EU) 2020/692 lays down the identification requirements for the entry into the Union of dogs, cats and ferrets. As regards the requirements for their means of identification, it refers to implementing acts adopted by the Commission pursuant to Article 120 of Regulation (EU) 2016/429. However, such implementing acts have not yet been adopted, as Article 277 of Regulation (EU) 2016/429 provides that Regulation (EU) No 576/2013 of the European Parliament and of the Council¹¹ is to continue to apply until 21 April 2026 in respect of non-commercial movements of pet animals of those species. Article 74 of Delegated Regulation (EU) 2020/692 should therefore be amended in order to refer to the requirements of Regulation (EU) No 576/2013.
- (16) Due to an omission, there are no provisions in Delegated Regulation (EU) 2020/692 concerning the inspection of consignments of germinal products prior to their dispatch to the Union. In order to ensure that consignments of germinal products comply with the requirements of Delegated Regulation (EU) 2020/692 before they are permitted to enter the Union, that Delegated Regulation should therefore be amended so that it lays down rules related to necessary examinations and checks of those consignments.
- (17) Article 86 of Delegated Regulation (EU) 2020/692 provides that consignments of oocytes and embryos of bovine animals should be allowed to enter the Union if a donor animal comes from an establishment free from enzootic bovine leukosis. Article 87(2) of that Delegated Regulation provides for a derogation for an establishment not free from enzootic bovine leukosis subject to the conditions that the donor animals are less than 2 years of age, and that there has been no clinical case of enzootic bovine leukosis during a period of at least the preceding 3 years. That derogation should apply for bovine donor animals regardless of their age. Article 87(2) of Delegated Regulation (EU) 2020/692 should therefore be amended accordingly.

¹¹ Regulation (EU) No 576/2013 of the European Parliament and of the Council of 12 June 2013 on the non-commercial movement of pet animals and repealing Regulation (EC) No 998/2003 (OJ L 178, 28.6.2013, p. 1)

- (18) Delegated Regulation (EU) 2020/692 provides that hatching eggs of poultry must originate from flocks that have been subjected to a clinical inspection within a period of 24 hours prior to the time of loading of the consignment of hatching eggs for dispatch to the Union. However, third countries and stakeholders have indicated that that requirement unjustifiably increases the administrative burden for competent authorities and operators and constitutes a risk to the biosecurity of the establishments. Considering that those eggs originate in approved establishments that apply strict biosecurity rules, it is appropriate to allow for a wider timeframe for the clinical inspection of the flock of origin of the hatching eggs, similar to what is provided for in Commission Delegated Regulation (EU) 2020/688¹² for the movement of those products between Member States. Therefore, Article 107 of Delegated Regulation (EU) 2020/692 should be amended accordingly.
- (19) Chapter 4 of Title 2 of Part III of Delegated Regulation (EU) 2020/692 lays down requirements for the entry into the Union of specified pathogen-free eggs, including requirements in relation to the establishment of origin of those eggs. Delegated Regulation (EU) 2020/692 should be amended to provide that those establishments in third countries are approved in accordance with the rules that apply for those establishments in the Union.
- (20) Aquatic animals as defined in Article 4, point (3), of Regulation (EU) 2016/429 includes kept animals and wild animals. Aquatic animals may therefore, be permitted to enter the Union from aquaculture establishments and from wild habitats. Hence, they may be dispatched from a ‘place of origin’ or from an ‘establishment of origin’. Delegated Regulation (EU) 2020/692 should permit that possibility and Article 167, points (a) and (d), of Delegated Regulation (EU) 2020/692 should therefore be amended accordingly.
- (21) Article 172 of Delegated Regulation (EU) 2020/692 provides for derogations for certain categories of aquatic animals and products thereof from the requirement to originate from a disease-free third country, territory, zone or compartment. In all cases, however, aquaculture animals and products thereof, that fall within the scope of Delegated Regulation (EU) 2020/692, must originate from an establishment, that is either registered or approved in accordance with Part IV, Title II, Chapter 1, of Regulation (EU) 2016/429. This Regulation should therefore, amend Article 172 of Delegated Regulation (EU) 2020/692 to make it clear that the derogation it provides, applies not to Article 170, but specifically to Article 170(1) of that Delegated Regulation.
- (22) Due to an omission, Article 174(3) of Delegated Regulation (EU) 2020/692 should be amended so that it refers to paragraph Article 170(1)(a)(iii), rather than to Article 170(a)(iii).
- (23) Article 226(3) of Regulation (EU) 2016/429 provides for Member States to have approved national measures for a disease other than a listed disease referred to in Article 9(1), point (d), of that Regulation. Article 175 of Delegated Regulation (EU) 2020/692 and Annex XXIX thereto should be amended to clarify that Member States may take such measures not only for non-listed diseases, but also for diseases listed in Article 9(1), point (e), of Regulation (EU) 2016/429.

¹² 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).

- (24) Due to the lengthy stocking capabilities for semen, oocytes and embryos, Part IV of Delegated Regulation (EU) 2020/692 should lay down certain transitional measures regarding germinal products collected, produced, processed and stored in accordance with Council Directives 88/407/EEC¹³, 89/556/EEC¹⁴, 90/429/EEC¹⁵ and 92/65/EEC¹⁶. Those measures should concern the approval of semen collection centres, semen storage centres, embryo collection teams and embryo production teams under those Directives, and the marking of straws and other packages in which semen, oocytes or embryos are placed, stored and transported. Those measures should also concern the requirements for the collection, production, processing and storage of germinal products, for the animal health of donor animals and for the laboratory and other tests carried out on donor animals and germinal products under those Directives. It is necessary to ensure that there is no disruption in trade in those germinal products, given their importance for the animal breeding sector. Therefore, to ensure the continuity of the entry into the Union of consignments of germinal products collected or produced before 21 April 2021 that fulfil the requirements laid down in Directives 88/407/EEC, 89/556/EEC, 90/429/EEC and 92/65/EEC, certain transitional provisions should be laid down in Delegated Regulation (EU) 2020/692. That Delegated Regulation should be amended accordingly.
- (25) Table 1 of Annex III to Delegated Regulation (EU) 2020/692 lays down, amongst other things, the requirements as regards the residency periods of equine animals before their entry into the Union. In particular, specific residency periods are laid down for equine animals other than registered equine animals, registered equine animals and the re-entry after temporary export of registered horses. Those residency periods should be more detailed to target the risks arising from the entry of equine animals not intended for slaughter, registered horses and equine animals intended for slaughter, as well as for the re-entry after temporary export of registered horses. That Annex should be amended accordingly.
- (26) Table 2 of Annex III to Delegated Regulation (EU) 2020/692 lays down the requirements as regards the residency periods of poultry before their entry into the Union. In particular, specific residency periods are laid down for productive poultry for the production of meat or eggs for consumption and for productive poultry for restocking supplies of game birds, but not for productive poultry for the production of other products. A specific residency period should, therefore, be laid down also for the category of productive poultry for the production of other products. That Annex should be amended accordingly.

¹³ 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).

¹⁴ 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).

¹⁵ 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).

¹⁶ 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).

- (27) Point 2 of Annex XV to Delegated Regulation (EU) 2020/692 lays down the animal health requirements for poultry and hatching eggs originating in a third country or territory or zone thereof where vaccines used against infection with Newcastle disease virus do not meet the specific criteria set out in point 1 of that Annex. Further clarification should, however, be provided on which of those requirements apply to poultry, hatching eggs and their flocks of origin. That Annex should be amended accordingly.
- (28) The rules provided in Delegated Regulation (EU) 2020/692 supplement those laid down in Regulation (EU) 2016/429. As those rules are interrelated, they are laid down together in one single act. In the interest of clarity and for their effective application, it is appropriate for the rules amending Delegated Regulation (EU) 2020/692 to be also laid down in a single delegated act providing a comprehensive set of requirements for the entry into the Union of animals, germinal products and products of animal origin.
- (29) Delegated Regulation (EU) 2020/692 should therefore be amended accordingly.
- (30) Delegated Regulation (EU) 2020/692 applies from 21 April 2021. In the interest of legal certainty, this Regulation should enter into force as a matter of urgency,

HAS ADOPTED THIS REGULATION:

Article 1

Delegated Regulation (EU) 2020/692 is amended as follows:

1. Article 1 is amended as follows:
 - (a) in paragraph 6, the introductory phrase is replaced by the following:

‘6. Part V lays down the animal health requirements for the entry into the Union, as well as the movement and handling after the entry, and derogations from those requirements for the following species of aquatic animals at all life stages as well as their products of animal origin, excluding products of animal origin other than live aquatic animals which are intended for direct human consumption and wild aquatic animals and products of animal origin from those wild aquatic animals landed from fishing vessels intended for direct human consumption.’;
 - (b) paragraph 8 is replaced by the following:

‘8. Part VII lays down transitional and final provisions.’;
2. Article 2 is amended as follows:
 - (a) point (8) is replaced by the following:

‘(8) ‘porcine animal’ means an animal of the species of ungulates belonging to the family *Suidae* listed in Annex III to Regulation (EU) 2016/429 for the purpose of entry into the Union of an animal or an animal of the species *Sus scrofa*, for the purpose of entry into the Union of germinal products.’;
 - (b) point (48) is replaced by the following:

‘(48) ‘well-boat’ means a ‘well-boat’ as defined in Article 2, point 2, of Commission Delegated Regulation (EU) 2020/990*’;

- * Commission Delegated Regulation (EU) 2020/990 of 28 April 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health and certification requirements for movements within the Union of aquatic animals and products of animal origin from aquatic animals (OJ L221, 10.7.2020, p.42).’;

3. in Article 3, point (a)(i) is replaced by the following:

‘(i) in the case of terrestrial animals, germinal products and products of animal origin, a listed third country or territory or zone thereof for the particular species and category of animals, germinal products and products of animal origin;’;

4. in Article 13(1), the second subparagraph is replaced by the following:

‘In the case of poultry, except day-old chicks, and captive birds, that inspection shall also cover the flock of origin of the animals intended for dispatch to the Union.’;

5. Article 26, is replaced by the following:

‘Article 26

Movement and handling of ungulates after their entry into the Union

Following their entry into the Union, ungulates, except equine animals, shall remain in their establishment of destination for a period of at least 30 days from the date of their arrival in that establishment, unless they are moved for slaughter.’;

6. Article 49 is amended as follows:

(a) the introductory phrase is replaced by the following:

‘By way of derogation from Article 14(3), Article 40 and Articles 43 to 48, consignments containing less than 20 heads of poultry other than ratites, shall be permitted to enter the Union provided that such consignments comply with the following requirements:’;

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

‘(c) as regards vaccination against highly pathogenic avian influenza:

- (i) the poultry have not been vaccinated against highly pathogenic avian influenza;
- (ii) the flock of origin of the poultry, except day-old chicks, has not been vaccinated against highly pathogenic avian influenza;
- (iii) where the parent flocks of the day-old chicks have been vaccinated against highly pathogenic avian influenza, guarantees for compliance with the minimum requirements for vaccination programmes and additional surveillance set out in Annex XIII have been provided by the third country or territory of origin;’;

(c) point (e)(iii) is replaced by the following:

‘(iii) *Salmonella Pullorum* and *Salmonella Gallinarum* in case of *Numida meleagris*, *Coturnix coturnix*, *Phasianus colchicus*, *Perdix perdix*, *Anas* spp.’;

(d) the following point (f) is added:

- (f) the day-old chicks come from hatching eggs which prior to incubation have been disinfected in accordance with the instructions of the competent authority of the third country or territory of origin.’;

7. Article 57 is replaced by the following:

Article 57

Specific animal health requirements for the captive birds

Consignments of captive birds shall only be permitted to enter the Union if the animals of the consignment comply with the following requirements:

- (a) they have not been vaccinated against highly pathogenic avian influenza;
- (b) where they have been vaccinated against infection with Newcastle disease virus, the competent authority of the third country or territory of origin has provided guarantees that the vaccines used comply with the general and specific criteria for vaccines against infection with Newcastle disease virus set out in point 1 of Annex XV;
- (c) they have been subjected to a virus detection test for highly pathogenic avian influenza and infection with Newcastle disease virus with negative results, within a period of 7 to 14 days prior to the date of loading for dispatch to the Union.’;

8. In Article 60, point (b)(vi) is renumbered as point (c) as follows:

- (c) release the captive birds from quarantine only on the written authorisation of an official veterinarian.’;

9. Article 62 is replaced by the following:

Article 62

Derogations from the animal health requirements for the entry into the Union of captive birds

1. By way of derogation from requirements laid down in Articles 3 to 10, except point (a)(i) of Article 3, Articles 11 to 19 and Articles 53 to 61, consignments of captive birds which do not comply with those requirements shall be permitted to enter the Union if they originate from third countries or territories specifically listed for the entry into the Union of captive birds based on equivalent guarantees.
2. By way of derogation from the requirements laid down in Article 11 and Articles 54 to 58, consignments of racing pigeons which enter the Union from a third country or territory or zone thereof where they are normally kept, with the intention to be immediately released with the expectation that they will fly back to that third country or territory or zone thereof and which do not comply with those requirements, shall be permitted to enter the Union if they comply with the following requirements:
 - (a) the Member State of destination has determined that the racing pigeons may enter into its territory from that third country or territory or zone thereof in accordance with Article 230(2) of Regulation (EU) 2016/429;
 - (b) they come from a registered establishment, within a 10 km radius of which, including, where appropriate, the territory of any neighbouring country, there has been no outbreak of highly pathogenic avian influenza

- or infection with Newcastle disease virus for a period of at least the preceding 30 days prior to the date of loading for dispatch to the Union;
- (c) they have not been vaccinated against highly pathogenic avian influenza;
 - (d) they have been vaccinated against infection with Newcastle disease virus and the competent authority of the third country or territory of origin has provided guarantees that the vaccines used comply with the general and specific criteria for vaccines against infection with Newcastle disease virus set out in point 1 of Annex XV;
 - (d) they come from an establishment where vaccination against infection with Newcastle disease virus is carried out.
3. By way of derogation from the requirements laid down in Articles 59, 60 and 61, the competent authority of the Member State of entry into the Union may authorise the entry into the Union of racing pigeons which will not be transported directly to a quarantine establishment approved in accordance with Article 14 of Delegated Regulation (EU) 2019/2035 if they are:
- (a) racing pigeons which have entered into the Union from a third country or territory or zone thereof where they are normally kept in accordance with paragraph 2;
 - (b) released immediately, under the control of the competent authority, with the expectation that they will fly back to the third country or territory of origin or zone thereof.’;
10. in Article 74, paragraph 1 is replaced by the following:
- ‘1. Consignments of dogs, cats and ferrets shall only be permitted to enter the Union if each animal in the consignment is individually identified by an injectable transponder as listed in point (e) of Annex III to Delegated Regulation (EU) 2019/2035, which was implanted by a veterinarian and which fulfils the technical requirements referred to in Annex II to Regulation (EU) No 576/2013.’;
11. in Article 80, point (a) is replaced by the following:
- ‘(a) prior to the date of collection, remained in a third country or territory or zone thereof which is listed for the entry into the Union of the particular species and category of germinal product:
- (i) in the case of bovine, ovine and caprine animals, for a period of at least 6 months;
 - (ii) in the case of porcine and equine animals, for a period of at least 3 months.’;
12. in Article 83, point (a)(iii) is replaced by the following:
- ‘(iii) the unique approval number of the germinal product establishment of collection or production, processing and storage of those germinal products.’;
13. after Article 85, the following Article 85a is inserted:

Article 85a

Inspection of consignments of germinal products prior to dispatch to the Union

Consignments of semen, oocytes and embryos of bovine, porcine, ovine, caprine and equine animals shall only be permitted to enter the Union if those consignments were subjected to a visual examination and documentary check, carried out by an official veterinarian in the third country or territory of origin or zone thereof within the period of 72 hours prior to the time of dispatch to the Union as follows:

- (a) a visual examination of the transport container in order to verify compliance with the requirements laid down in Article 84;
- (b) a documentary check of the data submitted by the centre or team veterinarian to ensure that:
 - (i) the information to be certified is supported by the records kept in accordance with:
 - Article 8(1)(a) of Delegated Regulation (EU) 2020/686; and
 - point (d) of Article 8 of this Regulation;
 - (ii) the mark on the straws or other packages, applied in accordance with point (a) of Article 83, corresponds with the number provided in the animal health certificate and on the container in which they are transported;
 - (iii) the animal health requirements referred to in Part III, Title 1, have been fulfilled.’;

14. in Article 87, paragraph 2 is replaced by the following:

- ‘2. By way of derogation from point (b)(iii) of Article 86, consignments of oocytes and embryos of bovine animals shall be permitted to enter the Union if a donor animal comes from an establishment which is 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 in that establishment during a period of at least the preceding 3 years.’;

15. Article 91 is replaced by the following:

Article 91

The establishment of origin of donor ovine and caprine animals

Consignments of semen, oocytes and embryos of ovine and caprine animals shall only be permitted to enter the Union if they were collected from donor animals which come from an establishment that was free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* and they were never previously in any establishment of a lower status.’;

16. in Article 100, point (b)(ii) is replaced by the following:

- ‘(ii) the hatching eggs were transferred directly and as soon as possible to the vessel or aircraft to be used for onward travel to the Union, which complies with requirements laid down in point (a) of Article 102, without leaving the premises of the port or airport.’;

17. in Article 102, in point (a), the introductory phrase is replaced by the following:

‘(a) the hatching eggs must have been transported in means of transport which:’;

18. in Article 107, point (f) is replaced by the following:

‘(f) they have either:

(i) been subjected to a clinical inspection, carried out by an official veterinarian in the third country or territory of origin or zone thereof, within a period of 72 hours prior to the time of loading of the consignment of hatching eggs for dispatch to the Union for the purpose of the detection of signs indicative of the occurrence of diseases, including the relevant listed diseases referred to in Annex I and emerging diseases and they showed no disease symptoms or grounds for suspecting the presence of any of those diseases;

or

(ii) had

– monthly clinical inspections carried out by an official veterinarian in the third country or territory of origin or zone thereof, the most recent carried out within a period of 31 days prior to the time of loading of the consignment of hatching eggs for dispatch to the Union, for the purpose of the detection of signs indicative of the occurrence of diseases, including the relevant listed diseases referred to in Annex I and emerging diseases and they showed no disease symptoms or grounds for suspecting the presence of any of those diseases;

– an evaluation of their current health status carried out by an official veterinarian in the third country or territory of origin or zone thereof, within a period of 72 hours prior to the time of loading of the consignment of hatching eggs for dispatch to the Union, as assessed by up-to-date information supplied by the operator and by documentary checks of the health and production records kept on the establishment, for the purpose of the detection of signs indicative of the occurrence of diseases, including emerging diseases and the relevant listed diseases referred to in Annex I.’;

19. Article 110 is amended as follows:

(a) the introductory phrase is replaced by the following:

‘By way of derogation from Articles 101, 106, 107 and 108, consignments of less than 20 hatching eggs of poultry other than ratites shall be permitted to enter the Union if they comply with the following requirements:’;

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

‘(d) they come from flocks which have been subjected to a clinical inspection, carried out by an official veterinarian in the third country or territory of origin or zone thereof, within a period of 24 hours prior to the time of loading of the consignments of hatching eggs for dispatch to the Union for the purpose of the detection of signs indicative of the occurrence of diseases, including the relevant listed diseases referred to in Annex I and emerging diseases, and the flocks showed no disease

symptoms or grounds for suspecting the presence of any of those diseases;’;

(c) in point (e)(ii), the third hyphen is replaced by the following:

‘– *Salmonella Pullorum* and *Salmonella Gallinarum* in the case of *Numida meleagris*, *Coturnix coturnix*, *Phasianus colchicus*, *Perdix perdix*, *Anas spp.*;’;

(d) the following point (f) is added:

‘(f) the hatching eggs must have been disinfected in accordance with the instructions of the competent authority of the third country or territory of origin.’;

20. in Article 111, point (a)(iii) is replaced by the following:

‘(iii) have been kept for a continuous period of at least six weeks prior to the date of collection of the eggs for dispatch to the Union in establishments which:

- comply with the conditions described in the European Pharmacopoeia;
- are approved by the competent authority of the third country or territory of origin in accordance with requirements which are at least equivalent to those laid down in Article 8 of Delegated Regulation (EU) 2019/2035, the approval of which has not been suspended or withdrawn;’;

21. after Article 119, the following Article 119a is inserted:

Article 119a

Inspection of consignments of germinal products prior to dispatch to the Union

Consignments of semen, oocytes and embryos referred to in Article 117 shall only be permitted to enter the Union if those consignments have been subjected to visual examination and documentary check, carried out by an official veterinarian in the third country or territory of origin or zone thereof within the period of 72 hours prior to the time of dispatch to the Union as follows:

- (a) a visual examination of the transport container in order to verify compliance with the requirements laid down in Article 119;
- (b) a documentary check of the data submitted by the establishment veterinarian responsible for the activities carried out at the confined establishment to ensure that:
 - (i) the information to be certified is supported by the records kept at the confined establishment;
 - (ii) the mark on the straws or other packages, applied in accordance with point (a) of Article 119, corresponds with the number provided in the animal health certificate and on the container in which they are transported;
 - (iii) the animal health requirements referred to in Title 3 of Part III have been fulfilled.’;

22. in Article 125(c), point (i) is replaced by the following:

‘(i) they were cleaned and disinfected, with a disinfectant authorised by the competent authority of the third country or territory of origin, before the loading of the carcasses for dispatch to the game handling establishment;’;

23. in Article 154, the following paragraph 3 is added:
- ‘3. The animals of origin of raw milk, colostrum or colostrum-based products intended for entry into the Union shall not be required to comply with the residency period referred to in paragraph 2, provided that they were introduced into the third country or territory or zone thereof from:
- (a) another third country or territory or zone thereof which is listed for entry into the Union of raw milk, colostrum or colostrum-based products and the animals remained there for at least 3 months prior to milking; or
 - (b) a Member State.’;
24. Article 167 is amended as follows:
- (a) points (a) and (b) are replaced by the following:
 - ‘(a) they were dispatched directly from their place of origin to the Union;
 - (b) they were not unloaded from their container when transported by air, sea, railway or by road, and the water in which they are transported was not changed, in a third country or territory, zone or compartment which is not listed for entry of the particular species and category of aquatic animals into the Union.’;
 - (b) point (d) is replaced by the following:
 - ‘(d) from the time of loading at the place of origin until the time of arrival in the Union, they must not have been transported in the same water or container or well-boat together with aquatic animals which were of a lower health status or which were not intended for entry into the Union.’;
25. in Article 169(3), point (b) is replaced by the following:
- ‘(b) the legible label referred to in point (a) must also contain the following statements, as relevant:
- (i) ‘fish intended for human consumption after further processing in the European Union’;
 - (ii) ‘molluscs intended for human consumption after further processing in the European Union’;
 - (iii) ‘crustaceans intended for human consumption after further processing in the European Union’.’;
26. in Article 172, the introductory phrase is replaced by the following:
- ‘By way of derogation from Article 170(1), the requirements laid down in that Article shall not apply to the following categories of aquatic animals.’;
27. in Article 173, point (b) is replaced by the following:
- ‘(b) fish intended for human consumption after further processing in the Union which were slaughtered and eviscerated prior to dispatch to the Union.’;
28. in Article 174, paragraph 3 is replaced by the following:
- ‘3. The competent authority of the Member State may only grant the authorisation provided for in paragraph 2 of this Article where the release or immersion in natural waters does not jeopardise the health status of the aquatic animals at the

place of release or immersion and in all cases, release into the wild shall comply with the requirement laid down in Article 170(1)(a)(iii).’;

29. Article 175 is amended as follows:

(a) the title is replaced by the following:

‘Article 175

Additional animal health requirements to limit the impact of diseases for which Member States have national measures approved in accordance with Article 226(3) of Regulation (EU) 2016/429’

(b) paragraph 1 is replaced by the following:

‘1. The competent authorities of Member States that have national measures approved in accordance with Article 226(3) of Regulation (EU) 2016/429, against diseases other than the listed diseases which are referred to in Article 9(1)(d) of that Regulation, shall take measures to prevent the introduction of those diseases through the application of additional animal health requirements for the entry into those Member States, of consignments of aquatic animals and products of animal origin from aquatic animals other than live aquatic animals, of species listed in the second column of the table set out in Annex XXIX to this Regulation.’;

30. Part VII is amended as follows:

(a) the title of Part VII is replaced by the following:

**‘PART VII
TRANSITIONAL AND FINAL PROVISIONS’;**

(b) the following Article 182a is inserted after the title of Part VII and before Article 183:

‘Article 182a

Transitional measures

1. Semen collection centres, semen storage centres, embryo collection teams and embryo production teams which have been approved prior to 21 April 2021 in accordance with Council 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 Article 270(2) of Regulation (EU) 2016/429 shall be deemed to be approved germinal product establishments as referred to in Article 82(1) of this Regulation.

In all other respects, they shall be subject to the rules provided for in Article 82(2) this Regulation, and in Article 233 of Regulation (EU) 2016/429.

2. Consignments of semen, oocytes and embryos collected, produced, processed and stored prior to 21 April 2021 shall be allowed to enter into the Union, provided they fulfil, as regards the collection, production, processing and storage of germinal products, animal health requirements of 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 respectively to the species of donor animals.

3. Straws and other packages in which semen, oocytes or embryos, whether or not separated into individual doses, are placed, stored and transported, marked prior to 21 April 2021 in accordance with Directives 88/407/EEC, 89/556/EEC, 90/429/EEC and 92/65/EEC respectively to the species of donor animals, shall be considered to have been marked in accordance with point (a) of Article 83 of this Regulation.

* 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).

** 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).

*** 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).

**** 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).’;

(c) in Article 184, the following title is added:

‘Entry into force and application’;

31. Annexes III, VIII, XV, XXVIII and XXIX are amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 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, 14.7.2021

For the Commission
The President
Ursula VON DER LEYEN