COMMISSION DELEGATED REGULATION (EU) 2023/119

of 9 November 2022

amending Delegated Regulation (EU) 2020/692 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

(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 Articles 3(5), 234(2), 237(4) and 239(2) thereof,

Whereas:

(1) Commission Delegated Regulation (EU) 2020/692 ([2]) 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) The application of the rules laid down in Delegated Regulation (EU) 2020/692 concerning aquatic animals and their products, has indicated that greater clarity is required concerning which commodities are excluded from the scope of that Delegated Regulation. In particular, it should be clarified that wild aquatic animals and products of animal origin from those wild aquatic animals which are landed from fishing vessels and which enter the food chain intended for direct human consumption are excluded from the scope of that Regulation. In addition, it should be clarified that products of animal origin from aquatic animals other than live aquatic animals, which are not intended for further processing in the Union, are excluded from the scope of Delegated Regulation (EU) 2020/692. Article 1(6) of Delegated Regulation (EU) 2020/692 should be amended accordingly.

(3) Several Member States and stakeholders have indicated that following recent developments and specialisations in the germinal products sector, the definition of 'embryo collection teams' in Article 2 of Delegated Regulation (EU) 2020/692 should also include those teams which only collect and handle unfertilised oocytes. That definition should therefore be amended to cover such teams.

(4) In addition, for the purpose of the specific requirements for equine animals as regards African horse sickness and Venezuelan equine encephalomyelitis set out in Annex XI, points 2.1 and 2.2, to Delegated Regulation (EU) 2020/692, it is necessary to lay down a definition of a 'vector-protected establishment' in Article 2 of that Delegated Regulation. There is already a definition of 'vector-protected establishment' in Article 2 of Commission Delegated Regulation (EU) 2020/689 ([3]) in the context of infection with bluetongue virus (serotypes 1-24).

([1]) OJ L 84, 31.3.2016, p. 1.

([2]) 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).

([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).

Therefore, the definition of a 'vector-protected establishment' in Article 2 of Delegated Regulation (EU) 2020/692, for the purpose of African horse sickness and Venezuelan equine encephalomyelitis, should be consistent with the definition of the 'vector-protected establishment' in Article 2 of Delegated Regulation (EU) 2020/689. Article 2 of Delegated Regulation (EU) 2020/692 should therefore be amended accordingly.

(5) Article 3(5) of Regulation (EU) 2016/429 provides that movements of pet animals, other than non-commercial movements, are to comply with the animal health requirements laid down in Parts IV and V thereof. Article 3(5) of that Regulation also empowers the Commission to lay down rules concerning the adaptions that are necessary in order to ensure that Parts IV and V thereof are correctly applied to pet animals, in particular to take account of the fact that pet animals are kept in households by pet keepers. Accordingly, it is necessary to adapt the general requirements regarding the means of transport of terrestrial animals laid down in Article 17 of Delegated Regulation (EU) 2020/692 and the requirements on the movement and handling of terrestrial animals after their entry into the Union laid down in Article 19 of that Delegated Regulation to pet animals kept in households. Articles 17 and 19 of Delegated Regulation (EU) 2020/692 should therefore be amended accordingly.

(6) Article 21(1), point (b) of Delegated Regulation (EU) 2020/692 provides that consignments of ungulates, other than equine animals, are only to be permitted to enter the Union, if the animals of the consignment were individually identified prior to being dispatched from the establishment of origin, by a physical means of identification with a visible, legible and indelible display of, amongst others, the code of the exporting country in accordance with ISO Standard 3166 in the format of two-letter code. It is necessary to provide for a derogation from that requirement in order for the Member States to permit the entry into the Union of such ungulates identified by a physical means of identification displaying the code of the exporting country different from the code conforming to ISO Standard 3166. Such a derogation should only be granted by the Commission and upon request by a third country or territory concerned.

(7) Article 38(2) of Delegated Regulation (EU) 2020/692 provides that, following an outbreak of highly pathogenic avian influenza in a third country or territory, or zone thereof previously considered as free of that disease, that third country or territory, or zone thereof, is again to be considered as free from highly pathogenic avian influenza, when, after a stamping out policy and an adequate cleaning and disinfection has been carried out on all previously infected establishments, the competent authority of the third country or territory has carried out a surveillance programme during a period of at least 3 months following the completion of the stamping out policy and cleaning and disinfection. However, that time frame is not consistent with the one applicable following outbreaks of highly pathogenic avian influenza in a Member State. Therefore, Article 38(2) of Delegated Regulation (EU) 2020/692 should be amended accordingly.

(8) Article 53, point (a), of Delegated Regulation (EU) 2020/692 provides that consignments of captive birds are only to be permitted to enter the Union if the animals in the consignment are identified with an individual identification number, which contains, inter alia, the code of the third country or territory of origin conforming with ISO Standard 3166 in the format of two-letter. As some birds are validly identified in the third countries or territories which are not the third countries or territories from where the birds enter into the Union or with an individual identification number including the code of the third country or territory of origin in the format of three-letter conforming with ISO Standard 3166, Delegated Regulation (EU) 2020/692 should be amended accordingly.

(9) Article 73 of Delegated Regulation (EU) 2020/692 lays down the requirements for the dispatch of dogs, cats and ferrets to the Union. It does not provide for an approval obligation for shelters where consignments of dogs, cats and ferrets are dispatched to the Union, whereas Commission Delegated Regulation (EU) 2020/688 ([4]) provides for

([4]) 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).

such an approval obligation for movements within the Union. Therefore, Delegated Regulation (EU) 2020/692 should be aligned in this regard with Delegated Regulation (EU) 2020/688 and Article 73 of Delegated Regulation (EU) 2020/692 should be amended accordingly.

(10) Article 79 of Delegated Regulation (EU) 2020/692 provides that consignments of semen, oocytes and embryos of bovine, porcine, ovine, caprine and equine animals are only be permitted to enter the Union if they were collected from animals which come from third countries or territories which comply with the animal health requirements laid down in Article 22 thereof. Article 22 of that Delegated Regulation provides such consignments are only to be permitted to enter the Union if they comply, inter alia, with the prohibition on the vaccination of donor bovine, porcine, ovine and caprine animals against, among others, foot-and-mouth disease. However, Commission Delegated Regulation (EU) 2020/686 ([5]), as well as relevant international standards of the World Organisation for Animal Health (WOAH) allow vaccination of bovine, porcine, ovine and caprine animals against foot-and-mouth disease under certain conditions. Therefore, Article 79 of Delegated Regulation (EU) 2020/692 should be amended to provide for a derogation for such vaccination and to align that Article with comparable rules applicable within the Union as well as with international standards.

(11) Article 117 of Delegated Regulation (EU) 2020/692 lays down animal health requirements for the entry into the Union of consignments of germinal products of certain animals intended for confined establishments. Since the date of application of Delegated Regulation (EU) 2020/692 several Member States and stakeholders have questioned the proportionality of those requirements in light of the specificities of those consignments and the differences in related risks to animal health. Therefore, it is appropriate to amend that Article to provide more flexibility for the Member States to manage the risks under their particular circumstances and depending on the animal species concerned while taking into account of the Union lists of authorised third countries, territories or zones thereof laid down by Commission Implementing Regulation (EU) 2021/404 ([6]).

(12) Article 124, point (c)(i), of Delegated Regulation (EU) 2020/692 provides that consignments of fresh meat of kept animals, except those kept as farmed game that have been killed on-the-spot, are only permitted to enter the Union if the fresh meat of the consignment has been obtained from kept animals which, during the transport to the slaughterhouse, did not pass through a third country or territory, or zone thereof, not listed for the entry into the Union of the particular species and category of fresh meat. However, as regards consignments of poultry, compliance with that requirement would in certain cases require the use of less direct roads, affecting normal trade patterns in a disproportionate manner, and also extending the travel time. To resolve this issue while ensuring the application of risk mitigation measures to prevent the spread of diseases, a derogation from that requirement, subject to certain conditions, should be introduced into Delegated Regulation (EU) 2020/692.

(13) Article 150 of Delegated Regulation (EU) 2020/692 lays down requirements for the entry into the Union of consignments of meat products as regards the establishment of origin of the animals from which the fresh meat used for the production thereof was obtained. That provision should be amended to refer to the date of slaughter or killing of the animals instead of the dispatch to the Union of the consignment in order to better link the potential animal health risks to specific products in the consignment.

(14) Article 156 of Delegated Regulation (EU) 2020/692 lays down requirements for the entry into the Union of consignments of dairy products not subject to a risk-mitigating treatment and produced only from raw milk. That provision should be amended to allow the entry into the Union of dairy products produced from dairy products not subject to a risk-mitigating treatment subject to compliance with certain conditions, as the risk is similar.

([5]) 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).

([6]) Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 laying down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and the Council (OJ L 114, 31.3.2021, p. 1).

(15) Article 163 of Delegated Regulation (EU) 2020/692 derogates from Article 3, points (a)(i) and (c)(i), thereof and lays down specific requirements for shelf-stable composite products. That provision should be amended to allow the sourcing of the dairy products from Member States and treated dairy products from third countries or territories, or zones thereof authorised for the entry into the Union of raw milk for the production of shelf-stable composite products. Moreover, the requirements concerning shelf-stable composite products referred to in Article 163(3) should be clarified.

(16) Article 12(2) of Regulation (EU) 2016/429 provides that aquatic animal health professionals may undertake activities assigned to veterinarians under that Regulation, provided they are authorised to do so by the Member State concerned, under national law. In certain third countries and territories, clinical inspections of aquatic animals prior to export to the Union, have in the past, been carried out by aquatic animal health professionals, in addition to veterinarians. It is therefore appropriate to amend Article 166 of Delegated Regulation (EU) 2020/692 to permit aquatic animal health professionals to perform clinical inspections prior to export to the Union, provided they are authorised to do so, under the law of the exporting third country or territory.

(17) Certain aquatic animals are packaged and labelled for human consumption in accordance with Regulation (EC) No 853/2004 of the European Parliament and of the Council ([7]), before they enter the Union. Such aquatic animals present a lower risk for the spread of disease than other aquatic animals which enter the Union, and which are not packaged and labelled in the same way. It is therefore appropriate to amend Article 167, point (a), of Delegated Regulation (EU) 2020/692 to exempt the live aquatic animals which are referred to in Article 172, points (d), (e) and (f), of the same Regulation, from the requirement to be dispatched directly from their place of origin to the Union. This amendment would allow such commodities to be kept in an approved cold store for example, *en route* from their place of origin in a third country or territory, to their place of destination in the Union. A similar exemption should also apply to Article 174(1), point (a), of Delegated Regulation (EU) 2020/692 concerning the handling after entry into the Union of certain products of animal origin from aquatic animals, other than live aquatic animals. Those Articles should therefore be amended accordingly.

(18) Also due to the lower risk of the spread of disease associated with those commodities, consignments of the aquatic animals which are referred to in Article 172, points (d), (e) and (f), of Delegated Regulation (EU) 2020/692, should be exempted from the requirement to be accompanied by a declaration, which is signed by the master of a vessel in which such consignments have been transported, when they enter the Union. Article 168 of that Regulation should therefore, be amended accordingly.

(19) Regulation (EU) 2016/429 provides that Member States may take national measures concerning a disease other than a listed disease referred to in Article 9(1), point (d), of Regulation (EU) 2016/429 subject to certain conditions. Where such measures concern movements of aquatic animals and products of animal origin from aquatic animals between Member States, they are required to be approved in accordance with Article 226(3) of that Regulation. Such measures may apply to listed diseases, which are category E diseases as defined in Commission Implementing Regulation (EU) 2018/1882 ([8]), and to non-listed diseases. Title 2 of Part V of Delegated Regulation (EU) 2020/692 should therefore, be amended to clarify that national measures, which have been approved in accordance with Article 226(3) of Regulation (EU) 2016/429, apply not only to non-listed diseases, but also to category E diseases.

(20) A cross referencing error has been detected in Article 170(1), point (a)(iv), of Delegated Regulation (EU) 2020/692. That Article should therefore be corrected by removing the reference to Article 176 and replacing it by a reference to Article 175 of that Regulation.

(21) Article 178 of Delegated Regulation (EU) 2020/692 lays down the special requirements for the entry into the Union of ungulates, poultry and aquatic animals originating from and returning to the Union following a refusal of entry by a third country or territory. Article 179 of that Regulation lays down the special requirements for the entry into the Union of animals other than ungulates, poultry and aquatic animals originating from and returning to the Union

([7]) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

([8]) 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).

following a refusal of entry by a third country or territory. However, the risk of the introduction of animal diseases into the Union by captive birds is similar to that for poultry. Therefore, the special requirements laid down in Article 178 should also apply to captive birds. Article 178 and 179 of Delegated Regulation (EU) 2020/692 should therefore be amended accordingly.

(22) Annex VIII, point 4, to Delegated Regulation (EU) 2020/692 lays down minimum periods without a reported case or outbreak of certain diseases in the establishment of origin for equine animals. That point omits an option where movement restrictions may be lifted by the competent authority in the case where the 30-day period has elapsed after the last animal of a listed species on the establishment was either killed and destroyed or slaughtered, and the premises in the establishment were cleaned and disinfected. That option is available in the case of movements between Member States of equine animals in accordance with Article 22 of Delegated Regulation (EU) 2020/688 for establishments where surra, dourine or equine infectious anaemia has been reported. At the same time, model animal health certificates laid down in Annex II, Chapters 12 to 18, to Commission Implementing Regulation (EU) 2021/403 ([9]) already include that option of the 30-day period without a reported case of surra, dourine or equine infectious anaemia in the establishment of origin for equine animals. Therefore, it is necessary to align Annex VIII, point 4, to Delegated Regulation (EU) 2020/692. Annex VIII to Delegated Regulation (EU) 2020/692 should be aligned accordingly.

(23) Annex X, point 1, to Delegated Regulation (EU) 2020/692 lays down specific requirements for the entry into the Union of ovine animals as regards infection with *Brucella* as referred to in Article 24(5) of that Delegated Regulation. The requirements concerning a residency period in the establishment of origin should be aligned to those referred to in Article 11, point (b)(iii), of that Delegated Regulation and the relevant entry as regards ovine animals in the table in Annex III to that Delegated Regulation. Annex X to Delegated Regulation (EU) 2020/692 should therefore be amended accordingly.

(24) Annex XI, point 2.1, to Delegated Regulation (EU) 2020/692 lays down specific requirements for African horse sickness to be fulfilled by equine animals entering the Union from third countries or territories, or zones thereof, assigned to a sanitary group E or F. The animals are required to have been kept in isolation in vector-protected facilities for a particular period. It is necessary to align the term 'vector-protected facility', reserved for a confined establishment as referred to in Article 34 of Delegated Regulation (EU) 2020/692, with the term 'vector-protected establishment', defined in Article 2 to that Delegated Regulation. Annex XI to Delegated Regulation (EU) 2020/692 should therefore be amended accordingly.

(25) Annex XI, point 2.2, to Delegated Regulation (EU) 2020/692 lays down specific requirements for Venezuelan equine encephalomyelitis to be fulfilled by equine animals entering the Union from third countries or territories, or zones thereof, assigned to a sanitary group C or D. The animals are required to have been kept in a vector-protected quarantine for a particular period. It is necessary to align the term 'vector-protected quarantine' with the term 'vector-protected establishment', defined in Article 2 to that Delegated Regulation. Annex XI to Delegated Regulation (EU) 2020/692 should therefore be amended accordingly.

(26) In addition, minimum criteria for granting a status of a vector-protected establishment by the competent authority should be specified. It is therefore necessary to laid down those criteria in Annex XI to Delegated Regulation (EU) 2020/692. Those criteria should be consistent with the criteria provided for in Annex V, Part II, Chapter 3, to Delegated Regulation (EU) 2020/689 and in Article 12.1.10, point 1, of the Terrestrial Animal Health Code of the World Organisation for Animal Health (WOAH). Annex XI to Delegated Regulation (EU) 2020/692 should be amended accordingly.

([9]) Commission Implementing Regulation (EU) 2021/403 of 24 March 2021 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates and model animal health/official certificates, for the entry into the Union and movements between Member States of consignments of certain categories of terrestrial animals and germinal products thereof, official certification regarding such certificates and repealing Decision 2010/470/EU (OJ L 113, 31.3.2021, p. 1).

(27) Annex XXI to Delegated Regulation (EU) 2020/692, point 2(b), specifies the timeframe during which the treatment against infestation with *Echinoccocus multilocularis* is to be administered. That time frame has proven difficult to comply with. A certain degree of flexibility may be provided without increasing the risks to public or animal health. Annex XXI to Delegated Regulation (EU) 2020/692 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Delegated Regulation (EU) 2020/692

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

(1) in Article 1, paragraph (6) 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 not intended for further processing in the Union, and wild aquatic animals and products of animal origin from those wild aquatic animals landed from fishing vessels intended for direct human consumption:

(a) fish of listed species belonging to the superclass *Agnatha* and to the classes *Chondrichthyes, Sarcopterygii* and *Actinopterygii*;

(b) aquatic molluscs of listed species belonging to the phylum *Mollusca*;

(c) aquatic crustaceans of listed species belonging to the subphylum *Crustacea*;

(d) aquatic animals of species listed in Annex XXIX to this Regulation which are susceptible to the aquatic diseases for which certain Member States have national measures which have been approved in accordance with Commission Implementing Decision (EU) 2021/260 (*).

(*) Commission Implementing Decision (EU) 2021/260 of 11 February 2021 approving national measures designed to limit the impact of certain diseases of aquatic animals in accordance with Article 226(3) of Regulation (EU) 2016/429 of the European Parliament and of the Council and repealing Commission Decision 2010/221/EU (OJ L 59, 19.2.2021, p. 1).';

(2) Article 2 is amended as follows:

(a) point (36) is replaced by the following:

'(36) "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 of *in vivo* derived embryos intended for entry into the Union;';

(b) the following points are added:

'(50) "animal shelter" means an establishment where former stray, feral, lost, abandoned or confiscated terrestrial animals are kept and whose health status might not be known for all of them at the time of their entry into the establishment;

(51) "vector-protected establishment" means part or all facilities of an establishment that are protected against attacks from, as appropriate, *Culicoides* spp. or Culicidae by appropriate physical and management means, with a status of vector-protected establishment being granted by the competent authority, and complying with the criteria laid down in Annex XI, point 3.';

(3) in Article 17, the following paragraph 3 is added:

'3. Paragraph 1 shall not apply to movements for non-commercial purposes of dogs, cats and ferrets kept as pet animals in households into a Member State from a third country or territory where such non-commercial movements cannot be carried out in accordance with the conditions laid down in Article 245(2) or Article 246(1) and (2) of Regulation (EU) 2016/429.';

(4) in Article 19, the following paragraph 4 is added:

'4. Paragraphs 1 and 2 shall not apply to movements for non-commercial purposes of dogs, cats and ferrets kept as pet animals in households into a Member State from a third country or territory where such non-commercial movements cannot be carried out in accordance with the conditions laid down in Article 245(2) or Article 246(1) and (2) of Regulation (EU) 2016/429';

(5) in Article 21, the following paragraph 5 is added:

'5. By way of derogation from paragraph (1), point (b), based on the request of a third country or territory of origin to the Commission and subject to its agreement, the code of the exporting country referred to in paragraph (1), point (b), may be replaced by a different code in the format of two-letter code.';

(6) in Article 38(2), point (c) is replaced by the following:

'(c) during a period of at least 30 days following the completion of the stamping out policy and cleaning and disinfection referred to in points (a) and (b), the competent authority of the third country or territory has carried out a surveillance programme, providing at least the confidence, by a randomised representative sample of the populations at risk, to demonstrate the absence of infection taking into account the specific epidemiological circumstances in relation to the occurred outbreak(s), with negative results.';

(7) in Article 53, the introductory phrase and point (a) are replaced by the following:

'Consignments of captive birds shall only be permitted to enter the Union if the animals in the consignment are identified with an individual identification number by means of a unique marked closed-ring attached at least to one leg of the animal with a visible, legible and indelible display of an alphanumeric code or an injectable transponder with a legible and indelible display of an alphanumeric code that contains at least the following information:

(a) the code of the third country or territory where they were initially identified conforming with ISO Standard 3166 in the format of two-letter or three-letter;';

(8) in Article 73, the following paragraph 3 is added:

'3. Consignments of dogs, cats and ferrets sourced from an animal shelter shall only be permitted to enter the Union if such consignment have been dispatched from an animal shelter:

(a) approved by the competent authority of the third country or territory in accordance with requirements at least as stringent as those laid down in Article 11 of Delegated Regulation (EU) 2019/2035;

(b) which has a unique approval number assigned by the competent authority of the third country or territory;

(c) listed for that purpose by the competent authority of the third country or territory of dispatch, including the information provided for in Article 21 of Delegated Regulation (EU) 2019/2035.';

(9) Article 79 is replaced by the following:

'*Article 79*

The third country or territory of origin or zone thereof

1. Consignments of semen, oocytes and embryos of bovine, porcine, ovine, caprine and equine animals shall only be permitted to enter the Union if they were collected or produced from animals in third countries or territories, or zones thereof, which comply with the animal health requirements laid down in Article 22.

2. By way of derogation from paragraph 1 of this Article, in connection with the animal health requirement laid down in Article 22(4), point (a), consignments of semen, oocytes and embryos of bovine, porcine, ovine, and caprine animals may be permitted to enter the Union if they were collected or produced in third countries or territories where vaccination against foot and mouth disease has been carried out, provided that they were collected from animals in accordance with the animal health requirements laid down in Annex II, Part 5, Chapter I, point 3 or 4, to Delegated Regulation (EU) 2020/686.';

(10) in Part III, the heading of TITLE 3 is replaced by the following:

'TITLE 3

ANIMAL HEALTH REQUIREMENTS FOR GERMINAL PRODUCTS OF ANIMALS OTHER THAN THOSE REFERRED TO IN ARTICLE 1(4), POINTS (A) AND (B), INTENDED FOR CONFINED ESTABLISHMENTS';

(11) Article 117 is replaced by the following:

'*Article 117*

Requirements for the entry into the Union of consignments of germinal products of animals other than those referred to in Article 1(4), point (a) and (b), intended for confined establishments

Consignments of semen, oocytes and embryos of animals other than those referred to in Article 1(4), point (a) and (b), intended for a confined establishment located in the Union may be permitted to enter the Union provided that:

(a) an assessment has been carried out by the competent authority of the Member State of destination of the risks that the entry of those germinal products may present for the Union;

(b) the donor animals of those germinal products originate from a third country or territory, or zone thereof, authorised for the entry into the Union of the particular species and category of animals either by Commission Implementing Regulation (EU) 2021/404 (*), or pursuant to Article 230(2) of Regulation (EU) 2016/429, by the Member State of destination, depending on the species in question;

(c) the donor animals of those germinal products originate from an establishment in the third country or territory, or zone thereof of origin, which is included in a list established by the competent authority of the Member State of destination from which the entry of animals of specific species into the Union may be authorised;

(d) the germinal products are destined to a confined establishment in the Union, which is approved in accordance with Article 95 of Regulation (EU) 2016/429;

(e) the germinal products are transported directly to the confined establishment referred to in point (d).

(*) Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 laying down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and the Council (OJ L 114, 31.3.2021, p. 1)'.

(12) in Article 124, the following point (e) is added:

'(e) By way of derogation of point (c)(i), during their transport to the slaughterhouse, consignments of poultry may pass through a zone of a third country or territory not listed for entry into the Union of fresh meat of poultry other than ratites, subject to the following conditions:

(i) the establishment of origin of the poultry, the zone of the third country or territory not listed for entry into the Union and the slaughterhouse are located in the same third country or territory;

(ii) the passing through of that zone of the third country or territory is performed without stopping or unloading in that zone;

(iii) the passing through of that zone of the third country or territory is performed prioritising major highways or mainline railways;

(iv) the passing through of that zone of the third country or territory is performed avoiding the vicinity of establishments keeping animals of listed species for the relevant diseases of poultry;

(v) the passing through of that zone of the third country or territory is performed after depopulation and cleaning and disinfection of the establishment(s) affected by outbreak(s) of highly pathogenic avian influenza or infection with Newcastle disease virus;

(vi) following the passing through of that zone of the third country or territory, the poultry shall be brought directly to the slaughterhouse and be slaughtered within a period of 6 hours from the time of their arrival at the slaughterhouse.

If no suitable alternatives are possible and provided that all the conditions listed in (i) to (vi) of this point are complied with, poultry transported to the slaughterhouse may pass through more than one zone referred to in this point.';

(13) Article 150 is replaced by the following:

'*Article 150*

The establishment of origin of the animals from which the fresh meat was obtained

Consignments of meat products shall only be permitted to enter the Union if they have been processed from fresh meat which originates from animals coming from an establishment, or, in the case of wild animals, from a place in and around which, in an area of a 10 km radius, including, where appropriate, the territory of a neighbouring country, none of the listed diseases, relevant for the species of origin of the meat products in accordance with the list set out in Annex I, has been reported during the period of 30 days prior to the date of slaughter or killing of the animals.';

(14) Article 156 is replaced by the following:

'*Article 156*

Dairy products not subject to a risk-mitigating treatment

Consignments of dairy products originating from a third country or territory, or zone thereof, which is listed for entry into the Union of raw milk shall be permitted to enter the Union without having undergone a specific risk-mitigating treatment provided for in Annex XXVII, if the dairy products of the consignment comply with following requirements:

(a) the raw milk or dairy product therefrom, from which they were processed, were obtained from animals of the species *Bos taurus, Ovis aries, Capra hircus, Bubalus bubalis* and *Camelus dromedarius*;

(b) the raw milk or dairy product therefrom, used for the processing of the dairy products complied with the relevant general animal health requirements for the entry into the Union of products of animal origin laid down in Articles 3 to 10 and the specific animal health requirements for the entry into the Union of raw milk laid down in Articles 153 and 154, and therefore was eligible for entry into the Union and it originates from one of the following:

(i) a listed third country or territory, or zone thereof, where the dairy products were processed;

(ii) a third country or territory, or zone thereof, other than a listed third country or territory, or zone thereof, where the dairy products were processed and which is authorised for entry into the Union of raw milk; or

(iii) a Member State.';

(15) Article 163 is replaced by the following:

'*Article 163*

Specific requirements for shelf-stable composite products

1. By way of derogation from Article 3, point (c)(i), consignments of composite products that do not contain meat products, except gelatine and collagen, or colostrum-based products, and that have been treated to become shelf-stable at ambient temperature, shall be permitted to enter the Union accompanied by a declaration, as provided for in paragraph 2 of this Article, if they contain:

(a) dairy products that comply with one of the following conditions:

(i) they have not undergone a risk-mitigating treatment provided for in Annex XXVII, provided that the dairy products have been obtained either in the Union or in a third country or territory, or zone thereof, listed for the entry into the Union of dairy products without undergoing a specific risk-mitigating treatment, in accordance with Article 156, and the third country or territory, or zone thereof, where the composite product is produced, if different, is also listed for entry into the Union of those products without the requirement to apply a specific risk-mitigating treatment;

(ii) they have undergone a risk-mitigating treatment provided for in column A or B of Annex XXVII, relevant for the species of origin of the milk, provided that they have been obtained either in the Union, or in a third country or territory, or zone thereof, listed for entry into the Union of dairy products without undergoing a specific risk-mitigating treatment, in accordance with Article 156, or of dairy products that have undergone a specific risk-mitigating treatment, in accordance with Article 157; and the third country or territory, or zone thereof, where the composite product is produced, if different, is also listed for entry into the Union of those products if they have undergone a specific risk-mitigating treatment;

(iii) they have undergone a risk-mitigating treatment at least equivalent to those referred to in column B of Annex XXVII, regardless of the species of origin of the milk, if the dairy products do not comply with all the requirements provided for in (i) or (ii) of this point or they have been obtained either in the Union, or in a third country or territory, or zone thereof, which is not authorised for the entry into the Union of dairy products but is authorised for the entry into the Union of other products of animal origin in accordance with this Regulation;

(b) egg products that have undergone a risk-mitigating treatment equivalent to those set out in Annex XXVIII.

2. The declaration referred to in paragraph 1 shall:

(a) only accompany consignments of composite products where the final destination of the composite products is in the Union;

(b) be issued by the operator responsible of the entry into the Union of the consignment of composite products, attesting that the composite products in the consignment comply with the requirements laid down in paragraph 1.

3. By way of derogation from of Article 3, point (a)(i), the composite products containing dairy products referred to in paragraph 1, point (a)(iii), of this Article, and the composite products containing egg products that have been treated to become shelf-stable at ambient temperature shall be permitted to enter the Union if they come from a third country or territory, or zone thereof which is not specifically listed for the entry into the Union of those products of animal origin but is listed for the entry into the Union of either:

(a) meat products, dairy products or egg products; or

(b) fishery products in accordance with Article 127 of Regulation (EU) 2017/625';

(16) in Article 166, the following paragraph is added after the introductory phrase:

'However, the clinical inspection referred to in the first paragraph may be performed by an aquatic animal health professional, provided that the aquatic animal health professional is authorised to undertake that activity by the third country or territory concerned under its national law.';

(17) in Article 167, point (a) is replaced by the following:

'(a) other than in the case of the aquatic animals referred to in of Article 172, points (d), (e) and (f), they were dispatched directly from their place of origin to the Union;';

(18) in Article 168, the introductory phrase is replaced by the following:

'Other than in the case of the aquatic animals referred to in Article 172, points (d), (e) and (f), where the dispatch to the Union of consignments of aquatic animals includes transport by vessel or well-boat even for part of the journey, those consignments of aquatic animals transported in accordance with Article 167 shall only be permitted to enter the Union if the aquatic animals of the consignment are accompanied by a declaration, attached to the animal health certificate and signed by the master of the vessel on the day of arrival of the vessel at its port of destination, providing the following information:'.

(19) in Article 169, paragraph 3 is replaced by the following:

'3. Products of animal origin from aquatic animals other than live aquatic animals, which enter the Union intended for further processing shall comply with the following requirements:

(a) they must be identified by a legible label on the exterior of the container, which refers to the certificate that has been issued for that consignment;

(b) the legible label referred to in point (a) must also contain the following statements, as relevant:

(i) "products of animal origin from fish, other than live fish, intended for further processing in the European Union";

(ii) "products of animal origin from molluscs, other than live molluscs, intended for further processing in the European Union";

(iii) "products of animal origin from crustaceans, other than live crustaceans, intended for further processing in the European Union".';

(20) in Article 174, paragraph 1 is replaced by the following:

'1. After their entry into the Union, consignments of:

(a) aquatic animals other than those referred to in Article 172, points (d), (e), and (f), shall be transported directly to their place of destination in the Union;

(b) aquatic animals and products of animal origin from aquatic animals shall be handled appropriately to ensure that natural waters are not contaminated.';

(21) in Part V, the heading of Title 2 is replaced by the following:

'TITLE 2

ANIMAL HEALTH REQUIREMENTS TO LIMIT THE IMPACT OF CERTAIN DISEASES OTHER THAN THOSE WHICH ARE REFERRED TO IN ARTICLE 9(1), POINT (D), OF REGULATION (EU) 2016/429';

(22) in Article 178, the title and the introductory phrase of paragraph 1 are replaced by the following:

'*Article 178*

Special requirements for entry into the Union of ungulates, poultry, captive birds and aquatic animals originating from, and returning to the Union following a refusal of entry by a third country or territory

1. Consignments of ungulates, poultry, captive birds and aquatic animals originating from and returning to the Union following a refusal of entry by the competent authority of a third country or territory shall only be permitted to re-enter the Union if the following requirements are fulfilled:';

(23) in Article 179, the title and the introductory phrase of paragraph 1 are replaced by the following:

'*Article 179*

Special requirements for the entry into the Union of animals other than ungulates, poultry, captive birds and aquatic animals originating from, and returning to the Union following a refusal of entry by a third country or territory

1. Consignments of animals other than ungulates, poultry, captive birds and aquatic animals originating from and returning to the Union following a refusal of entry by the competent authority of a third country or territory shall only be permitted to re-enter the Union if the animals of the consignment are accompanied by the following documents:';

(24) Annexes VIII, X, XI and XXI to Delegated Regulation (EU) 2020/692 are amended in accordance with the Annex to this Regulation.

Article 2

Correction to Delegated Regulation (EU) 2020/692

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

in Article 170(1), point (a)(iv), is replaced by the following:

'(iv) diseases for which certain Member States have taken the national measures referred to in Article 175 of this Regulation, when a consignment contains relevant species listed in Annex XXIX hereto and it is destined for a Member State, zone or compartment which is listed in Annex I or II to Commission Implementing Decision (EU) 2021/260 (*);

(*) Commission Implementing Decision (EU) 2021/260 of 11 February 2021 approving national measures designed to limit the impact of certain diseases of aquatic animals in accordance with Article 226(3) of Regulation (EU) 2016/429 of the European Parliament and of the Council and repealing Commission Decision 2010/221/EU (OJ L 59, 19.2.2021, p. 1)'.

Article 3

Entry into force

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, 9 November 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annexes VIII, X, XI and XXI to Delegated Regulation (EU) 2020/692 are amended as follows:

(1) in Annex VIII, point 4 is replaced by the following:

'4. Minimum periods without a reported case or outbreak of certain listed diseases in the establishment of origin for equine animals as referred to in Article 23(1), point (a)(ii):

	Period	Requirements to be complied with where there has been a previous reported case or outbreak in the establishment
Infection with *Burkholderia mallei* (Glanders)	6 months	Where an infection was reported in the establishment during the period of 3 years prior to the date of dispatch to the Union, following the last outbreak the establishment remained under movement restrictions by the competent authority until: — the infected animals were killed and destroyed, and — the remaining animals were subjected to a test carried out as described in point 3.1 of Chapter 3.6.11 of the World Organisation for Animal Health (WOAH) Terrestrial Manual (Version adopted 2018) with negative results on samples taken at least 6 months after the date on which the infected animals were killed and destroyed and the establishment was cleaned and disinfected.
Venezuelan equine encephalomyelitis	6 months	If they come from an establishment situated in a third country, territory or zone thereof in which Venezuelan equine encephalomyelitis was reported during the period of 2 years prior to the date of dispatch to the Union, they comply with the conditions in the following point (i) and the conditions in either of the following points (ii) or (iii): (i) during the period of at least 21 days prior to date of dispatch to the Union they remained clinically healthy and any animal referred to in point (ii) or (iii) which showed a rise in body temperature, taken daily, was subjected to a diagnostic test for Venezuelan equine encephalomyelitis with the diagnostic method provided for in Part 10(1), point (a), of Annex I to Delegated Regulation (EU) 2020/688, with negative results, and (ii) the animals were kept in isolation in vector-protected establishments for a period of at least 21 days protected from attacks by insect vector, and either — have been vaccinated against Venezuelan equine encephalomyelitis with a complete primary course and revaccinated according to the manufacturer's recommendations not less than 60 days and not more than 12 months prior to the date of dispatch to the Union, or — were subjected to a test for Venezuelan equine encephalomyelitis with the diagnostic method provided for in Part 10(1), point (b), of Annex I to Delegated Regulation (EU) 2020/688, with negative results, carried out on a sample taken not less than 14 days after the date of introduction into the vector-protected establishments;

		(iii) the animals were subjected to: — a test for Venezuelan equine encephalomyelitis with the diagnostic method provided for in Part 10(1), point (b), of Annex I to Delegated Regulation (EU) 2020/688, without an increase in antibody titre, carried out on paired samples taken on two occasions with an interval of 21 days, the second of which was taken during a period of 10 days prior to the date of dispatch to the Union, and — a test for the detection of Venezuelan equine encephalomyelitis virus genome with the diagnostic method provided for in Part 10(2) of Annex I to Delegated Regulation (EU) 2020/688, with negative result, carried out on a sample taken within 48 hours prior to the date of dispatch to the Union, and the animals have been protected from attacks by insect vectors after sampling until such dispatch.
Dourine	6 months	1. Where an infection was reported in the establishment during the period of 2 years prior to the date of dispatch to the Union, following the last outbreak the establishment remained under movement restriction by the competent authority until: — the infected animals were killed and destroyed or slaughtered, or the infected entire male equine animals were castrated, and — the remaining equine animals in the establishment, with the exception of the castrated male equine animals referred to in first indent of this point were kept apart from female equine animals, were subjected to a test for dourine with the diagnostic method provided for in Part 8 of Annex I to Delegated Regulation (EU) 2020/688 with negative results, carried out on samples taken at least 6 months after the measures described in the first indent of this point were completed. 2. By way of derogation from point 1, where an infection was reported in the establishment during the period of 2 years prior to the date of dispatch to the Union, following the last outbreak the establishment remained under movement restrictions by the competent authority for a period of at least 30 days after the last animal of listed species on the establishment was either killed and destroyed or slaughtered, and premises in the establishment were cleaned and disinfected.
Surra (*Trypanosoma evansi*)	6 months	1. Where infection was reported in the establishment during the period of 2 years prior to the date of dispatch to the Union, the establishment remained under movement restriction by the competent authority until: — the infected animals were removed from the establishment, and — the remaining animals had undergone a test for surra (*Trypanosoma evansi*) using one of the diagnostic methods provided for in Part 3 of Annex I to Delegated Regulation (EU) 2020/688 with negative results, carried out on samples taken at least 6 months after the last infected animal had been removed from the establishment.

		2. By way of derogation from point 1, where infection was reported in the establishment during the period of 2 years prior to the date of dispatch to the Union, the establishment remained under movement restrictions by the competent authority for a period of at least 30 days after the last animal of listed species on the establishment was either killed and destroyed or slaughtered, and premises in the establishment were cleaned and disinfected.
Equine infectious anaemia	90 days	1. Where an infection was reported in the establishment during the period of 12 months prior to the date of dispatch to the Union, following the last outbreak the establishment remained under movement restriction by the competent authority until: — the infected animals were killed and destroyed or slaughtered, and — the remaining animals in the establishment were subjected to a test for equine infectious anaemia with the diagnostic method provided for in Part 9 of Annex I to Delegated Regulation (EU) 2020/688 with negative results, carried out on samples taken on two occasions with a minimum interval of 3 months after the measures described in the first indent of this point had been completed and the establishment was cleaned and disinfected. 2. By way of derogation from point 1, where an infection was reported in the establishment during the period of 12 months prior to the date of dispatch to the Union, following the last outbreak the establishment remained under movement restrictions by the competent authority for a period of at least 30 days after the last animal of listed species on the establishment was either killed and destroyed or slaughtered, and premises in the establishment were cleaned and disinfected.
Rabies	30 days	—
Anthrax	15 days	—’

(2) in Annex X, point 1 is replaced by the following:

‘1. **OVINE ANIMALS**

Uncastrated males of ovine animals, other than those intended for slaughter in the Union, must comply with the following requirements:

(a) they have remained for a continuous period of at least 30 days in an establishment where ovine epididymitis (*Brucella ovis*) has not been reported during the period of 12 months prior to the date of dispatch to the Union;

(b) they were subjected to a serological test for ovine epididymitis (*Brucella ovis*), with negative results, during the period of 30 days prior to the date of dispatch to the Union.’;

(3) Annex XI is amended as follows:

(a) point 2.1. is replaced by the following:

‘2.1. **Specific requirements for African horse sickness**

Equine animals must comply with the set of requirements laid down in one of the following points:

(a) the animals were kept in isolation in vector-protected establishments for a period of at least 30 days prior to the date of dispatch to the Union and a serological and an agent identification test for African horse sickness were carried out with negative result in each case on a blood sample taken not less than 28 days after the date of introduction into the vector-protected establishments and within a period of 10 days prior to the date of dispatch to the Union;

(b) the animals were kept in isolation in vector-protected establishments for a period of at least 40 days prior to the date of dispatch to the Union and serological tests to detect antibodies against African horse sickness virus were carried out with no significant increase in antibody titre on blood samples collected on two occasions, with an interval of not less than 21 days, the first sample being collected at least 7 days after the date of introduction into the vector-protected establishments;

(c) the animals were kept in isolation in vector-protected establishments for a period of at least 14 days prior to the date of dispatch to the Union and an agent identification test for African horse sickness virus was carried out with negative result on a blood sample taken not less than 14 days after the date of introduction into the vector-protected establishments and not more than 72 hours before the time of dispatch to the Union, and constant monitoring of the vector protection has proven absence of insect vectors inside the vector-protected establishments;

(d) there is documented evidence that the animals have been vaccinated against African horse sickness with a complete primary course, and revaccinated according to the manufacturer's recommendations, with a licensed vaccine against all serotypes of the African horse sickness virus present in the source population at least 40 days prior to entry into the vector-protected establishments, and the animals were kept in isolation in vector-protected establishments for a period of at least 40 days prior to the date of dispatch to the Union;

(e) the animals were kept in isolation in vector-protected establishments for a period of at least 30 days prior to the date of dispatch to the Union and underwent a serological test for the detection of antibodies against the African horse sickness virus, carried out by the same laboratory, on the same day, on blood samples taken during the isolation period in vector-protected establishments on two occasions with an interval of between 21 and 30 days. The second of these must have been taken within a period of 10 days prior to the date of dispatch to the Union, with negative results in each case or with a negative result in an agent identification test for African horse sickness virus on the second sample.';

(b) point 2.2. is replaced by the following:

'2.2. **Specific requirements for Venezuelan equine encephalomyelitis**

Equine animals must comply with at least one of the following requirements:

(a) the animals have been vaccinated against Venezuelan equine encephalomyelitis with a complete primary course and revaccinated in accordance with the manufacturer's recommendations during a period of not less than 60 days and not more than 12 months prior to the date of dispatch to the Union and were kept in isolation in vector-protected establishments for a period of at least 21 days prior to the date of dispatch to the Union, and during that period they remained clinically healthy, and their body temperature, taken daily, remained within the normal physiological range.

Any other equine animal on the same establishment which showed a rise in body temperature, taken daily, was subjected to a blood test for virus isolation for Venezuelan equine encephalomyelitis with negative results;

(b) the animals have not been vaccinated against Venezuelan equine encephalomyelitis and were kept in isolation in vector-protected establishments for a period of at least 21 days prior to the date of dispatch to the Union, and during that period they remained clinically healthy, and their body temperature, taken daily, remained within the normal physiological range. During isolation period, the animals were

subjected to a diagnostic test for Venezuelan equine encephalomyelitis, with negative results, conducted on a sample taken not less than 14 days after the date of commencement of isolation of the animals in the vector-protected establishments; and the animals remained protected from vector insects until dispatch to the Union.

Any other equine animal on the same establishment that showed a rise in body temperature, taken daily, was subjected to a blood test for virus isolation for Venezuelan equine encephalomyelitis with negative results;

(c) the animals were subjected to a haemagglutination inhibition test for Venezuelan equine encephalomyelitis carried out by the same laboratory on the same day on samples taken on two occasions with an interval of 21 days, the second of which was taken during a period of 10 days prior to the date of dispatch to the Union, without an increase in antibody titre, and an reverse transcription polymerase chain reaction (RT-PCR) test for the detection of Venezuelan equine encephalomyelitis virus genome, carried out with negative result on a sample taken within 48 hours prior to the date of dispatch to the Union, and have been protected from vector attacks from the moment of the RT-PCR sampling until loading for dispatch, by a combined use of approved insect repellents and insecticides on the animals and disinsection of the stable and the means in which they are transported.';

(c) the following point 3 is added:

'3. **VECTOR-PROTECTED ESTABLISHMENT**

Minimum criteria for the granting of a status of vector-protected establishment:

(a) it has appropriate physical barriers at entry and exit points, for example double-door entry-exit system;

(b) the openings of the vector-protected establishment must be vector-screened with mesh of appropriate gauge, impregnated regularly with an approved insecticide according to the instructions of the manufacturer;

(c) vector surveillance and control must be carried out within and around the vector-protected establishment;

(d) measures must be taken to limit or eliminate breeding sites for vectors in the vicinity of the vector-protected establishment;

(e) standard operating procedures must be in place, including descriptions of back-up and alarm systems, for the operation of the vector-protected establishment and for the transport of the animals from that establishment to the place of loading for dispatch to the Union.';

(4) in Annex XXI, point 2(b) is replaced by the following:

'(b) the product must be administered by a veterinarian within a period commencing not more than 48 hours and ending not less than 24 hours prior to the time of dispatch to the Union;'.