Commission Implementing Regulation (EU) 2020/2236 of 16 December 2020 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 for the entry into the Union and movements within the Union of consignments of aquatic animals and of certain products of animal origin from aquatic animals, official certification regarding such certificates and repealing Regulation (EC) No 1251/2008 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/2236

of 16 December 2020

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health (Animal Health Law)⁽¹⁾, and in particular Articles 213(2), 224(4), 238(3) and 239(3) thereof,

Having regard to 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)⁽²⁾, and in particular Article 90 thereof,

Whereas:

(1) Regulation (EU) 2016/429 lays down rules on animal diseases that are transmissible to animals or to humans, including rules for the animal health certificates required to accompany the entry into the Union and movements within the Union of consignments of aquatic animals and certain products of animal origin from aquatic animals. It also empowers the Commission to adopt implementing acts laying down rules for model

- forms of those animal health certificates, as well rules concerning the information to be contained in certain documents and declarations required for the entry into the Union of such consignments.
- (2) In addition, that Regulation empowers the Commission to lay down special rules concerning model forms of animal health certificates, declarations and other documents for aquatic animals for which the application of the rules set out in that Regulation may not be adequate, taking into account, inter alia, the final destination of the consignment. Regulation (EU) 2016/429 also provides that those animal health certificates may include other information required under other Union legislation. Accordingly, the model animal health certificate should be set out in this Regulation.
- (3) Article 213(2) and Article 224(4) of Regulation (EU) 2016/429 also empower the Commission to lay down by means of implementing acts, rules concerning the model animal health certificates, for certain movements of aquatic animals and certain products thereof. Therefore, the model of certificates for the movements of such consignments within the Union should be set out this Regulation.
- (4) Articles 238(3) and 239(3) of Regulation (EU) 2016/429 empower the Commission to lay down by means of implementing acts, rules concerning models of animal health certificates, declarations and other documents for the entry into the Union of aquatic animals of which the Union is not the final destination. Accordingly, the model animal health certificate should be set out in this Regulation.
- (5) Model animal health certificates set out in this Regulation should contain relevant guarantees in order to ensure that consignments of aquatic animals and of certain products of animal origin from aquatic animals entering the Union and moving within the Union do not pose a significant risk for animal or public health. Such guarantees depend on, inter alia, the relevant diseases listed in Article 5 and in Annex II to Regulation (EU) 2016/429 as well as on their categorisation as provided for in Article 9(1) of that Regulation and in the Annex to Commission Implementing Regulation (EU) 2018/1882⁽³⁾.
- (6) Regulation (EU) 2017/625 lays down rules for the performance of official controls and other official activities performed by the competent authorities of the Member States in order to verify compliance by operators with Union rules in the areas referred to in Article 1(2) of that Regulation, which include, inter alia, food and food safety, as well as animal health and welfare. Official certificates are defined in Regulation (EU) 2017/625 as a paper or electronic document signed by the certifying officer, and providing assurance concerning compliance with one or more requirements laid down in the rules referred to in Article 1(2) thereof. That Regulation empowers the Commission to lay down by means of implementing acts, rules concerning model official certificates and for the issuance of such certificates.
- (7) Point (c) of the first paragraph of Article 90 of Regulation (EU) 2017/625 empowers the Commission to lay down by means of implementing acts rules concerning the procedures to be followed for the issuance of replacement certificates. Therefore, it is appropriate to establish common requirements as regards the replacement of animal health certificates in this Regulation.

- (8) To avoid misuse and abuse, it is important to lay down rules concerning the cases where a replacement animal health certificate may be issued and the requirements that need to be met for replacing animal health certificates. The cases should be limited to administrative errors, or in cases where the initial certificate has been damaged or lost.
- (9) Commission Delegated Regulation (EU) 2020/691⁽⁴⁾ lays down supplementing rules regarding registered and approved aquaculture establishments keeping aquaculture animals and transporters of aquatic animals. In particular, that Regulation provides supplementary rules as regards the approval of aquaculture establishments keeping aquaculture animals which pose a significant risk for the transmission of diseases affecting aquatic animals. Therefore, certain model animal health certificates set out in this Regulation should include the relevant guarantees in order to ensure that the establishment has been approved in accordance with the rules laid down in Delegated Regulation (EU) 2020/691. In addition, this Regulation should also have regard to the definitions laid down in Delegated Regulation (EU) 2020/691.
- (10) In addition, Commission Delegated Regulations (EU) 2020/692⁽⁵⁾ and (EU) 2020/990⁽⁶⁾ lay down rules supplementing those laid down in Regulation (EU) 2016/429. Delegated Regulation (EU) 2020/692 lays down, inter alia, relevant animal health requirements for entry into the Union of aquatic animals and certain products of animal origin from aquatic animals. Therefore, model animal health certificates set out in this Regulation should take into account relevant guarantees laid down in those Regulations. In addition, this Regulation should also have regard to the definitions laid down in Delegated Regulation (EU) 2020/692.
- (11) Delegated Regulation (EU) 2020/990 lays down specific rules regarding movements within the Union of consignments of aquatic animals and products of animal origin from aquatic animals, including requirements for animal health and certification in this regard. In particular, that Regulation lays down certain rules on the contents of animal health certificates for aquatic animals and certain products of animal origin from aquatic animals. Therefore, the model animal health certificates set out in this Regulation should take into account the supplementing rules laid down in Regulations (EU) 2020/990. In addition, this Regulation should also have regard to the definitions laid down in Delegated Regulation (EU) 2020/990.
- (12) Implementing Regulation (EU) 2018/1882 lays down the definition of 'category D disease' for which measures are needed to prevent such disease from spreading. Furthermore, that Implementing Regulation lays down that the disease prevention and control rules for the listed diseases referred to in Article 9(1) of Regulation (EU) 2016/429 shall apply to the categories of listed diseases for the listed species and groups of listed species referred to in the table set out in the Annex to that Regulation. That table lists, inter alia, vector species for diseases affecting aquatic animals. Accordingly, this should be taken into account in the model animal health certificates set out in this Regulation.
- (13) Model animal health certificates for movements within the Union and the entry into the Union of consignments of aquatic animals and certain products of animal origin from aquatic animals should contain details of the consignment and specific animal health

- information certified by an official veterinarian. In the case of movements within the Union, model animal health certificates should also contain a part designated to record official controls carried out during such movements and at the place of destination, as well as the results of those official controls.
- (14) Commission Implementing Regulation (EU) 2020/2235⁽⁷⁾ lays down the model animal health certificates, model official certificates and model animal health/official certificates for the movement within the Union of consignments of animals and products. That Implementing Regulation provides for the compatibility of such certificates with the Trade Control and Expert System (TRACES) and it facilitates the system of certification in the Union. Therefore, the model animal health certificates set out in this Regulation for the movement within the Union of consignments of aquatic animals and certain products of animal origin from aquatic animals should be drawn up on the basis of the model animal health certificate for the movement within the Union of animals and products set out in Chapter 1 of Annex I to Implementing Regulation (EU) 2020/2235.
- (15) Furthermore, in order to ensure consistency and to improve the efficiency of animal health certification, the model animal health certificate for the entry into the Union of consignments of aquatic animals set out in this Regulation should be drawn up on the basis of the model animal health certificate for the entry into the Union of animals, products of animal origin, composite products, germinal products, animal by-products, sprouts for human consumption and seeds intended for the production of sprouts for human consumption set out in Chapter 3 of Annex I to Implementing Regulation (EU) 2020/2235.
- (16) Regulation (EU) 2017/625 provides that consignments of animals and goods are to be accompanied by an official certificate issued either on paper or in electronic form. Furthermore, Regulation (EU) 2016/429 provides that animal health certificates issued in electronic form, including those animal health certificates accompanying consignments entering the Union, may replace animal health certificates issued on paper. Therefore, it is appropriate to establish common requirements as regards the issuance of animal health certificates for consignments of aquatic animals and certain products of animal origin from aquatic animals, both in paper and in electronic form, in addition to the requirements laid down in Article 217 of Regulation (EU) 2016/429 and Chapter VII of Title II of Regulation (EU) 2017/625. These common requirements should be set out in this Regulation.
- (17) Regulation (EU) 2017/625 provides that the Information Management System for Official Controls (IMSOC) is to allow for the production, handling and transmission of official certificates, including in electronic form. Commission Implementing Regulation (EU) 2019/1715⁽⁸⁾ provides that the TRACES is the IMSOC component enabling the entire process of certificate production to be performed electronically, thus preventing possible fraudulent or deceptive practices in respect of the animal health or official certificates. Therefore, in order to ensure an adequate level of security of electronic means of electronic certification and taking into account the aim to harmonise

- the process of certification, model animal health certificates set out in this Regulation should be compatible with TRACES.
- (18) Commission Regulation (EC) No 1251/2008⁽⁹⁾ lays down specific rules for certification requirements for the placing on the market and import into Union of aquaculture animals and products thereof. However, the rules laid down in that Regulation have already been replaced by the rules laid down in Delegated Regulations (EU) 2020/990 and (EU) 2020/692, and the model certificates laid down in Regulation (EC) No 1251/2008 are to be replaced by the model animal health certificates laid down in this Regulation. Accordingly, in order to avoid a duplication of rules, Regulation (EC) No 1251/2008 should be repealed.
- (19) It is appropriate to introduce a transitional period to take into account the specific situation of competent authorities in third countries that need to make the necessary arrangements to ensure compliance with this Regulation and the specific situation of shipments of consignments of aquatic animals and products of animal origin from aquatic animals accompanied by animal health certificates issued in accordance with Regulation (EC) No 1251/2008 before the date of application of this Regulation.
- (20) As Regulation (EU) 2016/429 applies with effect from 21 April 2021, this Regulation should also apply from that date.
- (21) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

- This Regulation lays down rules concerning the animal health certificates provided for in Regulation (EU) 2016/429 and official certification provided for in Regulation (EU) 2017/625 as regards the issuance and replacement of animal health certificates required for the entry into the Union⁽¹⁰⁾ and movements within the Union of certain consignments of aquatic animals and of products of animal origin from aquatic animals.
- 2 It establishes model animal health certificates and a model declaration for the following:
 - a model animal health certificates for movements within the Union of consignments of certain categories of aquatic animals and certain products of animal origin from aquaculture animals (Annex I);
 - b a model animal health certificate for the entry into the Union of consignments of aquatic animals intended for certain aquaculture establishments, for release into the wild, or for other purposes excluding human consumption (Annex II);
 - c a model declaration by the master of vessel: addendum for transport of consignments of certain aquatic animals entering the Union by sea (Annex III).