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 (Text with EEA relevance)

COMMISSION DELEGATED REGULATION (EU) 2020/990

of 28 April 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 192(2), 197(3), 201(3), 202(3), 205(2), 211(1), 213(1), 216(4), 218(3), 221(1), 222(3), 223(6), and 224(3) thereof,

Whereas:

(1) Regulation (EU) 2016/429 lays down rules for the prevention and control of animal diseases which are transmissible to animals or humans, including rules for the categorisation of listed diseases that are of concern at Union level. Article 5 of that Regulation provides that disease-specific rules for the prevention and control of diseases are to apply to the listed diseases, as referred to in that Article and in Annex II thereto. As listed diseases require different types of management measures, Article 9 of Regulation (EU) 2016/429 provides for disease prevention and control rules, which take account of the potential seriousness of the impact of those various types of listed diseases on public and animal health, the economy, society and the environment.

(2) In particular, Article 9 of Regulation (EU) 2016/429 refers to the different types of listed diseases in points (a) to (e) of paragraph 1 thereof, taking account of the potential risks of cases of those listed diseases. In addition, Article 9(1)(d) of that Regulation provides that listed diseases referred to in Article 9(1)(a), (b), (c) thereof are also to be regarded as listed diseases under Article 9(1)(d), where the risk posed by the disease in question can be effectively and proportionately mitigated by measures concerning movements of animals and products. This distinction between the different categories of listed diseases should be taken into account for the purpose of the rules laid down in this Regulation regarding intra-Union movements of aquatic animals and products of animal origin from aquatic animals, other than live aquatic animals.

(3) Chapters 2 and 3 of Title II of Part IV of Regulation (EU) 2016/429 lay down disease-specific rules that apply to category D diseases and listed species for those diseases, as well as rules for emerging diseases. Those provisions also lay down the animal health requirements for movements within the Union of aquatic animals, including those intended for human consumption, and products of animal origin from aquatic animals, in order to prevent and control the spread of listed and emerging diseases in the Union.

(4) Chapters 2 and 3 of Title II of Part IV of Regulation (EU) 2016/429 also empower the Commission to adopt rules to supplement certain non-essential elements of that Regulation by means of delegated acts. It is therefore appropriate to adopt such supplementing rules in order to ensure the smooth functioning of the new legislative framework for the control and prevention of animal diseases, established by that Regulation. As those supplementing rules are substantially interlinked, in the interest of simplicity and transparency, as well as to facilitate their application, they should be laid down in a single act rather than in a number of separate acts with many cross-references and the risk of duplication.

(5) Commission Implementing Regulation (EU) 2018/1882[(2)] categorises the listed diseases referred to in Article 9(1) of Regulation (EU) 2016/429 into category A, B, C, D and E diseases. It also provides that the disease prevention and control rules for listed diseases referred to in Article 9(1) of Regulation (EU) 2016/429 are to apply to the categories of listed diseases for the listed species and groups of listed species referred to in the table set out in that Implementing Regulation. That table lists intra alia, species and groups of species of aquatic animals and vector species for diseases affecting aquatic animals.

(6) The rules and risk mitigation measures laid down in this Regulation should supplement the animal health requirements laid down in Regulation (EU) 2016/429, as regards movements within the Union of aquatic animals, including those intended for human consumption, and products of animal origin from aquaculture animals, in order to ensure that those commodities do not pose a significant risk for the spread of the aquatic diseases referred to in Annex II to Regulation (EU) 2016/429, and subsequently defined by Commission Implementing Regulation (EU) 2018/1882 as category D diseases, which include as relevant, category A, category B and category C diseases. Commission Delegated Regulation (EU) 2020/689[(3)] lays down rules concerning compulsory and optional eradication programmes for specific listed diseases. As regards category B and C diseases, certain Member States are subject to eradication programmes to stamp out those listed diseases or demonstrate that they have disease-free status as regards those listed diseases. Taking those programmes into account, it is appropriate to provide that movements of aquatic animals and products of animal origin from aquaculture animals other than live aquaculture animals, of listed species for the relevant category B or C disease, should therefore only be allowed, if such movements do not jeopardise the success of those eradication programmes, or disease-free status for those listed diseases, if such has been achieved.

(7) In addition, as regards category C diseases, operators of establishments which are not subject to an optional eradication programme, may implement a voluntary surveillance

programme for a specific category C disease in accordance with the rules laid down in Delegated Regulation (EU) 2020/689. Whilst such establishments will not be declared disease-free, they will have the advantage of receiving only movements of aquaculture animals of listed species for the relevant category C disease, which do not jeopardise the success of the surveillance programme.

(8) Accordingly, this Regulation should lay down the supplementing rules regarding movements of aquatic animals and products of animal origin thereof, which are required to ensure the success of such eradication and surveillance programmes in the Member States, zones or compartments where they are implemented, as well as in Member States, zones and compartments which have achieved disease-free status.

(9) Article 192 of Regulation (EU) 2016/429 lays down disease preventive measures in relation to the transport of aquatic animals and empowers the Commission to lay down supplementing rules for the cleaning and disinfection of the means of transport of aquatic animals, water exchanges, water discharges and biosecurity measures, in order to mitigate the possible risks arising from the transportation of those aquatic animals within the Union. This Regulation should therefore lay down more detailed requirements for the transportation of aquatic animals, including transport by well-boat.

(10) Regulation (EU) 2016/429 provides that consignments of aquatic animals of listed species that enter an area with disease-free status, or an area which is subject to an eradication programme, must be accompanied by an animal health certificate, except in certain very limited circumstances. As certain consignments are transported commercially in mixed lots that could be accompanied by different animal health certificates, it is critical to ensure that each consignment is unloaded at its intended point of destination. The labelling of consignments in such a way that the label clearly links the consignment of aquatic animals to the corresponding animal health certificate is a necessary risk-mitigating step in the interests of traceability, and to ensure that only consignments which are properly certified to be dispatched to disease-free areas, end up in those areas. Therefore, this Regulation should lay down supplementing rules for the labelling of such consignments.

(11) Article 197 of Regulation (EU) 2016/429 provides that aquaculture animals of listed species relevant for category B and C diseases must originate from areas with disease-free status if they are intended for Member States, zones or compartments that are free of those listed diseases, or are subject to an eradication programme for such listed diseases. In certain situations, however, the risks to animal health do not justify such restrictions. This Regulation should therefore, provide for a derogation from such restrictions laid down in from Article 197 of Regulation (EU) 2016/429, while ensuring that the necessary risk-mitigating measures are in place to ensure that such movements of aquaculture animals do not jeopardise the health status or eradication programmes in place.

(12) It is also necessary to lay down supplementing rules providing for derogations in relation to live aquatic animals of listed species, which are intended for human consumption where they are moved to a disease-free Member State, zone or compartment or to one which is subject to an eradication programme and where they

have not originated from a disease-free Member State, zone or compartment. In such cases, those aquatic animals may be of species which are listed as vector species in column 4 of the table in the Annex to Implementing Regulation (EU) 2018/1882, but they have not been in contact with the listed species susceptible to the relevant listed disease as set out in column 3 of that table and therefore they are not considered to be vectors. Another possibility is that those aquatic animals may be destined for slaughter and processing in a disease control aquatic food establishment, having been permitted by the competent authority to leave an area subject to disease control measures regarding a listed or emerging disease. This Regulation should provide that additional risk mitigating measures in relation to packaging and labelling in accordance with Regulation (EC) No 853/2004 of the European Parliament and of the Council[(4)] be applied to molluscs and crustaceans intended for human consumption, thereby ensuring that such aquatic animals may be moved to an area with disease-free status or one which is subject to an eradication programme, without causing a risk for the spread of a relevant listed or emerging disease.

(13) It is also necessary to lay down supplementing rules for movements of aquaculture animals of listed species into confined aquaculture establishments. Aquaculture animals of vector species listed in column 4 of the table in the Annex to Implementing Regulation (EU) 2018/1882, which have not been in contact with the susceptible species listed in column 3 of that table, as well as aquaculture animals which have been quarantined in an establishment approved in accordance with Article 15 of Commission Delegated Regulation (EU) 2020/691[(5)] or quarantined in another confined establishment, including the establishment of destination, should be permitted to be moved into confined establishments. As confined establishments may exchange aquaculture animals amongst themselves with fewer movement requirements than for other types of aquaculture establishments, it is important that the specific rules and derogations laid down in this Regulation ensure that such movements involving confined establishments do not pose a risk for the spread of listed or emerging diseases.

(14) Wild aquatic animals are an important resource that should be protected. Accordingly, Article 199 of Regulation (EU) 2016/429 permits Member States to require that only aquatic animals from disease-free areas may be released into the wild even if the waters into which they are released do not have disease-free status. In addition, Article 205(2) of that Regulation provides for the Commission to adopt delegated acts laying down supplementing rules for movements of aquatic animals for the purposes of sports fishing, including fishing baits. This Regulation should therefore, lay down supplementing rules on a procedure whereby that possibility for Member States can be successfully achieved. As Regulation (EU) 2016/429 does not require animal health certification for such movements of consignments of aquatic animals into areas which are not disease-free, this Regulation should lay down such rules in order to ensure that the competent authorities in both Member States are in a position to trace the movements of such consignments.

(15) Live fishing baits infected with a listed or emerging aquatic disease represent a significant disease risk to wild aquatic animals and potentially therefore, also to aquaculture animals. Accordingly, in order to address that risk, this Regulation should

provide that live fishing baits must only come from an area with disease-free status if they are to be used in a Member State, zone or compartment with disease-free status or in Member States which have taken the measures referred to in Article 199 of Regulation (EU) 2016/429.

(16) Articles 208 and 209 of Regulation (EU) 2016/429 lay down rules in relation to the type of movements of aquatic animals, which must be certified. Experience gained in applying the rules laid down in Council Directive 2006/88/EC[(6)] has however, indicated that some very limited and specific circumstances exist where a derogation from the application of the rules set out in Articles 208 and 209 of Regulation (EU) 2016/429 may be applied as regards category C diseases, with the agreement of the Commission and relevant Member States. Therefore, this Regulation should lay down the conditions under which an animal health certificate should not be required to accompany consignments of aquatic animals of listed species when they are destined for disease-free Member States.

(17) Self-declaration documents are issued by operators in accordance with Article 218 of Regulation (EU) 2016/429, for consignments that are to be moved between Member States but which are not required to be accompanied by an animal health certificate. It is important to lay down rules on the information that such self-declaration documents should contain to ensure the traceability of consignments and support safe trade. Self-declaration documents have an added value in relation to movements of aquaculture animals between aquaculture establishments which are implementing surveillance programmes for a category C disease or diseases. This Regulation should therefore provide that the self-declaration documents contain the necessary information confirming that the aquaculture establishment of origin is participating in a surveillance programme, and that there is no suspicion or confirmation of that category C disease or diseases in the aquaculture establishment.

(18) To ensure compliance with the rules regarding animal health certification laid down in Article 216(3) of Regulation (EU) 2016/429, the official veterinarian is required to carry out documentary checks and a clinical inspection and where relevant, clinical examinations, at the aquaculture establishment of origin, before signing the animal health certificate. The aim of those checks is to ensure that there is no evidence to suggest that a listed or emerging disease is present in the aquaculture establishment and to facilitate safe trade. Supplementing rules concerning those checks should be laid down in this Regulation.

(19) Clinical signs of disease are less obvious in certain categories of aquaculture animals, such as eggs and molluscs. It is therefore, an inappropriate use of resources to require that clinical inspections of such categories of aquaculture animals take place in advance of every movement from an aquaculture establishment. This Regulation should therefore, provide for a derogation from the requirement to carry out clinical inspections of eggs and molluscs every time they are required to be certified, provided certain checks are carried out in relation to documentation, the date of the previous clinical inspection of the aquaculture animals kept in the aquaculture establishment and details of movements to the establishment.