Commission Delegated Regulation (EU) 2020/691 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of Council as regards rules for aquaculture establishments and transporters of aquatic animals (Text with EEA relevance)

COMMISSION DELEGATED REGULATION (EU) 2020/691

of 30 January 2020

supplementing Regulation (EU) 2016/429 of the European Parliament and of Council as regards rules for aquaculture establishments and transporters of aquatic animals

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')[(1)], and in particular Articles 176(4), 181(2), 185(5), 189(1) and 279(2) thereof,

Whereas:

(1) Regulation (EU) 2016/429 lays down rules for the prevention and control of diseases which are transmissible to animals or humans, including, inter alia, rules for aquaculture establishments, and for transporters of aquatic animals. Regulation (EU) 2016/429 also provides for the Commission to adopt delegated acts in order to supplement certain non-essential elements of that Regulation. It is therefore necessary to lay down supplementing rules in order to ensure the smooth functioning of the system established within the new legislative framework of Regulation (EU) 2016/429.

(2) More particularly, the rules laid down in this Regulation should supplement those already laid down in Chapter 1 of Title II of Part IV of Regulation (EU) 2016/429, as regards the approval of aquaculture establishments keeping aquaculture animals posing a significant animal health risk, the registers of aquaculture establishments to be kept by competent authorities, and the record-keeping obligations of operators of aquaculture establishments and transporters of aquatic animals.

(3) In addition, this Regulation takes into account the repeal of Council Directive 2006/88/EC[(2)] by Regulation (EU) 2016/429 with effect from 21 April 2021. Regulation (EU) 2016/429 provides that establishments and operators registered or approved in accordance with that Directive, before the date of application of Regulation (EU) 2016/429, are to be deemed to be registered or approved, as required, in accordance with that Regulation, and subject to the relevant obligations laid down therein.

(4) Accordingly, the rules laid down in this Regulation should supplement the rules laid down in Part IX of Regulation (EU) 2016/429, as regards the necessary transitional

measures to protect the acquired rights and legitimate expectations of stakeholders resulting from pre-existing Union acts with regard to aquaculture establishments.

(5) As the rules laid down in this Regulation all relate to aquaculture establishments and transporters of aquatic animals and are to be applied in tandem, they should be set out in a single act rather than in separate acts with numerous cross-references, in order to facilitate their application, in the interests of transparency, and to avoid a duplication of rules. This is also in keeping with the approach adopted by Regulation (EU) 2016/429.

(6) Article 176(1) of Regulation (EU) 2016/429 provides that operators of aquaculture establishments are to apply to the competent authority for approval where they keep aquaculture animals with a view to those animals being moved therefrom, either alive or as products of aquaculture animal origin. As a wide variety of aquaculture establishments fall within that category, Article 176(2) of Regulation (EU) 2016/429 provides that Member States may exempt operators of specific types of aquaculture establishments from the requirement for approval provided that such aquaculture establishments do not pose a significant disease risk. In addition, Article 176(4) of that Regulation provides that the Commission may adopt delegated acts concerning derogations from the requirement for approval for certain types of aquaculture establishments, again on the condition that those aquaculture establishments do not pose a significant risk.

(7) The level of risk posed by an aquaculture establishment, depends on the activity of that aquaculture establishment and the destination and intended use of the aquaculture animals or products of aquaculture animal origin produced therein. Some aquaculture establishments have already been approved for different purposes, such as aquaculture establishments which have been approved under the hygiene rules in accordance with Regulation (EC) No 853/2004 of the European Parliament and of the Council[3]. In certain situations, aquaculture establishments such as purification and dispatch centres or relaying areas only receive molluscs from within the epidemiological area in which the aquaculture establishment is itself located. These aquaculture establishments therefore, pose an insignificant risk from an animal health perspective. Other aquaculture establishments are also engaged in low risk activities, such as keeping aquaculture animals solely for release into the wild after having produced them from broodstock which originated from the water body on which the aquaculture establishment is located, or keeping aquaculture animals in extensive ponds for human consumption or for release into the wild.

(8) It is necessary to lay down in this Regulation, the specific conditions under which derogations from the requirement for approval should be permitted for aquaculture establishments. In certain cases, derogations should only apply to aquaculture establishments which move aquaculture animals within their own Member State and not to aquaculture establishments which move aquaculture animals between Member States. In all cases, however, derogations from the requirement for an aquaculture establishment to be approved should only be considered when the competent authority has completed a risk assessment which takes into account at least the risk of aquaculture animals on the aquaculture establishment contracting or spreading an aquatic disease via

water or via movements and where the risk has been found to be insignificant. Details of additional risk factors which the competent authority may take into account in this risk assessment are set out in Chapter 2 of Part I of Annex VI to Commission Delegated Regulation (EU) 2020/689[(4)]. Therefore, the supplementing rules laid down in this Regulation should be consistent with those laid down in that Delegated Regulation.

(9) At the same time, certain other types of aquaculture establishments represent a significant risk for the spread of aquatic animal diseases. Such types of aquaculture establishment should be specifically described in this Regulation, and the requirement for the operators of these aquaculture establishments to be approved should be detailed in this Regulation. These include aquaculture establishments keeping ornamental aquaculture animals in open facilities and also in closed facilities where the movement patterns are such that trade within the Union or with third countries potentially present a disease risk. Other types of aquaculture establishments where the risk of disease spread should be mitigated through the requirement for approval by the competent authority, are quarantine establishments, establishments which keep vector species in isolation until such time as they are no longer considered to be vectors, and vessels and other mobile premises where aquaculture animals are treated or undergo other husbandry-related procedures.

(10) Article 177 of Regulation (EU) 2016/429 provides for the competent authority to grant approval of operators for groups of aquaculture establishments. The supplementing rules laid down in this Regulation should therefore apply to such groups where appropriate, and should set out the details of how the rules should apply directly to, and within, the group.

(11) Operators of all aquaculture establishments or groups of aquaculture establishments are required to provide information to the competent authority with a view to obtaining approval in compliance with Article 180 of Regulation (EU) 2016/429. In that regard, operators should provide the competent authority with a written biosecurity plan which will be considered during the approval process. This requirement should apply to both individual aquaculture establishments and groups of aquaculture establishments regardless of their size, but the complexity of the biosecurity plan should depend upon the specificities of the individual aquaculture establishment or group thereof, and on the measures which are required to mitigate the associated disease risks.

(12) Certain aquaculture establishments and groups of aquaculture establishments should, on the basis of the rules laid down in Chapter 1 of Part I to Annex VI of Delegated Regulation (EU) 2020/689, participate in a risk-based surveillance scheme which is put in place by the competent authority in accordance with Article 26 of Regulation (EU) 2016/429. Without such participation, aquaculture establishments or groups of aquaculture establishments should not be approved. In line with Article 27 of Regulation (EU) 2016/429, risk-based surveillance may take into account the surveillance conducted by operators themselves in accordance with Article 24, including the animal health visits referred to in Article 25 of that Regulation. Risk-based surveillance may also be carried out at the same time as surveillance connected with particular listed diseases, in order to maximise resources.

Changes to legislation: *There are currently no known outstanding effects for the Commission Delegated Regulation (EU) 2020/691. (See end of Document for details)*

(13) The frequency of risk-based surveillance should be based on the ranking of the aquaculture establishment by the competent authority as 'high', 'medium' or 'low' risk, following an assessment of the circumstances of the establishment. Factors to be taken into account and considered by the competent authority when risk ranking establishments, as well as the frequency of surveillance which attaches to each risk ranking are set out in Part I of Annex VI to Delegated Regulation (EU) 2020/689. The objective of including aquaculture establishments which keep non-listed species but which participate in a significant amount of trade and which are therefore ranked as 'high' risk, in the risk- based surveillance scheme, is to maximise the chances of identifying and controlling emerging diseases, should they appear in aquaculture animals of those non-listed species.

(14) As risk-based surveillance is also carried out in approved groups of aquaculture establishments, it is important to set out how this should be completed at group level so that the outcome of the surveillance is epidemiologically meaningful. Accordingly, this Regulation should lay down rules concerning the approach which the competent authority should take to carrying out such surveillance.

(15) Apart from the requirement for operators to present a biosecurity plan to the competent authority as part of the approval process, and for certain aquaculture establishments to participate in a risk-based surveillance scheme, the aquaculture establishments that are required to be approved should also meet certain requirements in relation to their facilities and equipment. The particular combination of requirements with regard to biosecurity, surveillance, and facilities and equipment which apply to a specific category of aquaculture establishment or to a specific category of group of aquaculture establishments should therefore, be set out in this Regulation.

(16) Article 178 of Regulation (EU) 2016/429 provides that operators of aquaculture establishments wishing to obtain the status of a confined aquaculture establishment may only move aquaculture animals to or from their aquaculture establishments after they have obtained the approval of that status from the competent authority in accordance with the rules laid down in that Regulation. As these aquaculture establishments may exchange aquaculture animals amongst themselves with fewer movement requirements than for other types of aquaculture establishments, it is appropriate that they should have a contracted veterinarian who will supervise the activities of the aquaculture establishment and be responsible for its health surveillance, so they can provide robust health guarantees to each other. Article 181(2) of Regulation (EU) 2016/429 provides for the Commission to adopt delegated acts laying down supplementing rules for the approval of such aquaculture establishments, and such rules should be laid down in this Regulation.

(17) Article 179 of Regulation (EU) 2016/429 provides for the approval of disease control aquatic food establishments. These aquaculture establishments facilitate the sanitary slaughter and sanitary processing of aquatic animals, which may be infected with a listed or emerging disease. Therefore, they represent a significant disease risk and should be approved by the competent authority. During the periods when these aquaculture establishments are receiving aquatic animals which are infected or

suspected of being infected with a listed or emerging disease, they should comply with stringent biosecurity measures with the aim of ensuring that disease agents are not released into open waters without appropriate treatment. Article 181(2) of that Regulation provides for the Commission to adopt delegated acts laying down supplementing rules for the approval of these aquaculture establishments and accordingly those supplementing rules should be laid down in this Regulation.

(18) Certain purification centres, relaying areas, and dispatch centres for live molluscs should be considered as aquaculture establishments which require approval in accordance with Article 176(1) of Regulation (EU) 2016/429. Those establishments which receive live molluscs from outside their own epidemiological area, represent a higher risk of spreading listed or emerging diseases and should be treated as such during the approval process. This Regulation should therefore lay down supplementing rules in that respect.

(19) Commission Implementing Regulation (EU) 2018/1882[(5)] lays down definitions for categories A, B, C, D and E diseases, and it 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 the Annex to Implementing Regulation (EU) 2018/1882. That table provides that certain species of aquatic animals which are listed in column 4 thereof are only to be considered as vectors when they are kept in an aquaculture establishment where the species listed in column 3 thereof are also kept, or in the case of wild aquatic animals, when they have been exposed to species listed in column 3 in a wild habitat. However, if these species are subsequently kept in isolation from the species listed in column 3 and from infected water sources for an appropriate period of time, they are no longer to be regarded as vectors. If this period of isolation cannot be carried out in a quarantine establishment approved in compliance with Article 15 of this Regulation, then such aquatic animals may instead be kept in another type of aquaculture establishment which does not have all of the biosecurity measures which are required for quarantine establishments, but where they are kept in isolation from potential pathogens until such time as they are no longer to be regarded as vectors. Article 181(2) of Regulation (EU) 2016/429 provides for the Commission to adopt delegated acts laying down supplementing rules for the approval of such aquaculture establishments taking into account those requirements. Accordingly, those requirements should be laid down in this Regulation.

(20) Article 185(5) of Regulation (EU) 2016/429 empowers the Commission to adopt delegated acts regarding additional information to be included in the registers of registered and approved aquaculture establishments kept by the competent authority and public access to those registers. Subject to the data protection requirements laid down in Regulation (EU) 2016/679 of the European Parliament and of the Council[(6)], the information which should be made publicly available by the competent authority should reflect the requirements set out in Article 185(2)(a),(c),(e) and (f) of Regulation (EU) 2016/429 which in turn, largely reflect the details which Member States have already provided in a public register in compliance with Commission Decision 2008/392/EC[(7)].