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COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	28 April 2020
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2020) 2568 final
Subject:	COMMISSION DELEGATED REGULATION (EU) .../... of 28.4.2020 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

Delegations will find attached document C(2020) 2568 final.

Encl.: C(2020) 2568 final



Brussels, 28.4.2020
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COMMISSION DELEGATED REGULATION (EU) .../...

of 28.4.2020

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)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

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 lays down rules on transmissible animal diseases and animal health requirements for movements within the Union of aquatic animals and products of animal origin from aquatic animals.

Chapters 2 and 3 of Title II of Part IV of Regulation (EU) 2016/429 empower the Commission to adopt delegated acts supplementing the principal rules laid down in that basic act (the supplementing rules). Since those supplementing rules are all interrelated, they should be laid down in a single delegated act, in the interests of consistency and transparency, and to avoid duplication of Union rules.

The supplementing rules are largely based on those laid down in Council Directive 2006/88/EC², and they establish animal health and certification requirements for movements within the Union of aquatic animals, including certain aquatic animals intended for human consumption, and products of animal origin from aquaculture animals other than live aquaculture animals. The supplementing rules have been adapted to suit the new legislative framework established by Regulation (EU) 2016/429, and take account of updates of international standards and scientific progress as well as the experience gained through the application of Council Directive 2006/88/EC.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission had several meetings and exchanges with the Expert Group on animal health (E00930)³. The draft Delegated Regulation was also made available to the European Parliament and the Council for comments, but no comments were received from those two Institutions. A number of meetings were also held with a range of stakeholders within the framework of the Animal Health Advisory Committee⁴, where the main elements of the draft act were illustrated and discussed. The Commission has taken account of the input received during these consultation activities.

In addition, stakeholders' comments on the draft Delegated Regulation were collected in the context of the Better Regulation feedback mechanism during the period between 16 January and 13 February, 2020. Feedback was received from the following organisations: Comité Interprofessionnel des Produits de l'Aquaculture (FR), Dansk Akvakultur (DK), Federation of European Aquaculture Producers

¹ Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L 84, 31.3.2016, p. 1).

² Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals (OJ L 328, 24.11.2006, p. 14).

³ https://ec.europa.eu/food/animals/health/expert_group_en

⁴ https://ec.europa.eu/food/animals/health/advisory_committees_en

(FEAP) (BE), European Association of Zoos and Aquaria (EAZA) (NL), Ornamental Fish International (OFI) (BE), ANSES (FR), Canadian Food Inspection Agency.

The main requests and points made were as follows:

- the approach to determining when vector species should be regarded as vectors of listed diseases as set out in Annex I was questioned. It was further questioned why no vector species have been listed for HPR deleted-ISAV;
- the request to replace clinical inspections of consignments of aquatic animals and their eggs prior to certification with the surveillance system which pertains to disease-free status;
- the acknowledgement that the draft Delegated Regulation sets out requirements for movements of aquaculture animals to confined establishments, but that it would benefit from the addition of requirements concerning movements between confined establishments;
- the requirement for self-declaration documents will create a burden for businesses which trade in non-susceptible ornamental aquatic animals;
- the request to consider whether *Esox lucius* is a species that is susceptible to IHN as well as VHS;
- the request for an explanation as to why a number of derogations which apply to movements of aquatic animals and their products within the Union, do not apply to aquatic animals and their products entering the Union from third countries.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

3.1. Summary of the proposed rules

This Delegated Regulation will supplement the rules laid down in Chapters 2 and 3 of Title II of Part IV of Regulation (EU) 2016/429, and more particularly, it will include the following rules concerning category D diseases:

- (a) biosecurity and labelling rules for the means of transport and containers transporting aquatic animals;
- (b) animal health requirements for movements of aquatic animals intended for aquaculture establishments and for the release of aquaculture animals into the wild;
- (c) animal health requirements for movements of live aquatic animals intended for human consumption;
- (d) animal health requirements for movements of aquatic animals intended for certain specific uses or purposes;
- (e) animal health certification and notification requirements for movements of aquatic animals and products of animal origin from aquaculture animals other than live aquaculture animals, and the roles and responsibilities of the competent authorities in the Member States and operators for such certification and notification requirements;
- (f) the content of self-declaration documents for movements of aquaculture animals between Member States, including specific rules for aquaculture

establishments which participate in surveillance programmes for category C diseases;

- (g) the movement conditions under which listed species referred to in column 4 of the table in the Annex to Commission Implementing Regulation (EU) 2018/1882⁵ are to be regarded as vectors of specific listed diseases.

3.2. Legal basis

This Delegated Regulation is to be adopted pursuant to Regulation (EU) 2016/429, 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.

⁵ 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).

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

of 28.4.2020

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)

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')⁶ 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

⁶ OJ L 84, 31.3.2016, p.1

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) 2018/1882⁷ 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) .../...⁸[Publications Office please insert reference to SANTE/7066/2019, C(2019)4056] 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

⁷ 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)

⁸ Commission Delegated Regulation (EU) 2019/... of ... supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules on surveillance, eradication programmes and disease-free status for certain listed and emerging diseases (OJ L..., dd/mm/yyyy, p. [...]).

programme for a specific category C disease in accordance with the rules laid down in Delegated Regulation (EU) xxx/xxx [Publications Office please insert reference to SANTE/7066/2019, C(2019)4056]. 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 Council⁹ 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)...../..... [Publications Office please insert reference to SANTE/7208/2019, C(2020)415]¹⁰ 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

⁹ 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).

¹⁰ Commission Delegated Regulation (EU)/..... [Publications Office please insert reference to SANTE/7208/2019, C(2020)415]

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/EC¹¹ 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.

¹¹ Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals (OJ L 328, 24.11.2006, p.14)

- (20) Experience gained in the application of Directive 2006/88/EC indicates that certain other derogations from the requirement to carry out a clinical inspection within 72 hours prior to the time of dispatch should also be laid down in this Regulation. These derogations are intended to allow flexibility to the competent authority to carry out the clinical inspection within a period of 7 days before the time of dispatch in certain limited circumstances where the probability of disease manifestation or the risk of the spread of a listed or emerging disease are estimated to be low.
- (21) Articles 219 and 220 of Regulation (EU) 2016/429 lay down the obligations on operators other than transporters, and on the competent authorities in the Member States, in relation to the notification of movements of aquatic animals between Member States. This Regulation should lay down supplementing rules concerning the information, which operators should provide to the competent authority in advance of any such movement, as well as the information the competent authority in the Member State of origin should notify to the competent authority of the Member State of destination. This advance notification of movements between Member States should apply both to aquaculture animals and to wild aquatic animals.
- (22) In the case of movements of aquaculture animals of listed species between an establishment in one Member State which is participating in a surveillance programme for a certain category C disease, and an establishment in another Member State which is participating in a surveillance programme for the same category C disease, it is important to lay down rules concerning the information which must be notified in advance, to ensure that the establishment of destination receives aquaculture animals with the appropriate health status. This Regulation should therefore lay down rules concerning the information, which should be notified to the competent authority in the Member State of origin by the operator of the establishment of origin, as well as the information, which that competent authority should notify to the competent authority in the Member State of destination.
- (23) As the notification of movements between Member States is an important step in ensuring the traceability of aquatic animals and products of animal origin from aquaculture animals other than live aquaculture animals, and in supporting safe trade, this Regulation should lay down detailed rules concerning the requirements for advance notification including details of the information which should be supplied by operators as well as emergency procedures for such notifications. Articles 219(2), 220(2) and 221(1) of Regulation (EU) 2016/429 and Article 46 of Commission Implementing Regulation (EU) 2019/1715¹² describe the information to be supplied by operators and competent authorities in relation to such notifications and the emergency procedures to be put place by the competent authority in the event of power cuts or other disturbances to TRACES.
- (24) Article 222(3) of Regulation (EU) 2016/429 provides for the Commission to adopt delegated acts in relation to the obligations of operators as regards movements of products of animal origin from aquatic animals other than live aquatic animals, including the risk-mitigation measures that should be applied to such products at the places of origin and destination. Article 222(4) of that Regulation provides that the

¹² Commission Implementing Regulation (EU) 2019/ 1715 of 30 September 2019 laying down rules for the functioning of the information management system for official controls and its system components ('the IMSOC Regulation' (OJ L261,14.10.2019, p.37)

rules set out in that Article, do not apply to products of animal origin from wild aquatic animals harvested or caught for direct human consumption. Accordingly, the supplementing rules laid down in this Regulation should apply only to products of animal origin from aquaculture animals and should lay down measures to be taken when certain products of animal origin from aquaculture animals of listed species, other than live aquaculture animals, enter an area with disease-free status for further processing, or if they have been authorised by the competent authority to leave an establishment or zone which is subject to emergency measures or movement restrictions. The supplementing rules should also lay down the animal health certification and notification requirements which should apply to such movements in order to ensure the traceability of such products.

- (25) The rules laid down in this Regulation in relation to movements of live aquatic animals, should refer to the species listed in columns 3 and 4 of the table in the Annex to Implementing Regulation (EU) 2018/1882, with certain derogations for the vector species set out in column 4. However, given the lower level of risk associated with products of animal origin from aquaculture animals other than live aquaculture animals, the rules laid down in this Regulation as regards the movement of such products should apply only to those susceptible species listed in column 3 of the table in the Annex to Implementing Regulation (EU) 2018/1882, and should not apply to the vector species set out in column 4 of the same table.
- (26) Products of animal origin from aquaculture animals other than live aquaculture animals are required in certain circumstances, to be accompanied by an animal health certificate in accordance with Article 223 of Regulation (EU) 2016/429. Details of the content of such animal health certificates should be laid down in this Regulation.
- (27) This Regulation should apply from 21 April 2021 in accordance with the date of application of Regulation (EU) 2016/429,

HAS ADOPTED THIS REGULATION:

PART I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1 *Subject matter and scope*

This Regulation supplements the rules laid down in Chapters 2 and 3 of Title II of Part IV of Regulation (EU) 2016/429, as regards intra-Union movements of aquatic animals and products from aquatic animals.

In particular, it lays down rules concerning:

- (a) the obligations on operators, including transporters, for the transport of aquatic animals;
- (b) supplementary animal health requirements for movements of aquatic animals intended for specific uses or purposes, including certification and notification requirements;
- (c) the production, processing and distribution of products of animal origin from aquaculture animals, other than live aquaculture animals.

Article 2 *Definitions*

For the purposes of this Regulation, the definitions in Article 4 of Regulation (EU) 2016/429 and in Article 2 of Delegated Regulation (EU) .../....[Publications Office please insert reference to SANTE/7208/2019, C(2019)415] apply.

The following definitions also apply:

- (1) ‘container’ means any crate, box, receptacle or other rigid structure used for the transport of aquatic animals or eggs of aquatic animals which is not the means of transport;
- (2) ‘well-boat’ means a vessel which has a well or tank for the storage, transport or treatment of live aquaculture animals in water;
- (3) ‘vector species’ means species listed in column 4 of the table set out in the Annex to Implementing Regulation (EU) 2018/1882, which fulfil the conditions to be regarded as vectors as set out in column 3 of Annex I to this Regulation;
- (4) ‘fishing bait’ means any aquatic animal used to attract or catch another aquatic animal;
- (5) ‘national measures’ means national measures designed to limit the impact of diseases other than listed diseases as referred to in Article 226 of Regulation (EU) 2016/429;
- (6) ‘habitat’ means aquatic areas distinguished by geographical, abiotic and biotic features whether entirely natural or semi-natural;
- (7) ‘disease-free Member State, zone or compartment’ means a Member State, zone or compartment thereof which has been declared disease-free in accordance with Article 36(4) or 37(4) of Regulation (EU) 2016/429;
- (8) ‘eradication programme’ means a compulsory eradication programme established in accordance with Article 31(1) of Regulation (EU) 2016/429, or an optional eradication programme established in accordance with Article 31(2) of that Regulation;
- (9) ‘registered aquaculture establishment’ means an establishment which has been registered by the competent authority in accordance with Article 173 of Regulation (EU) 2016/429;
- (10) ‘approved aquaculture establishment’ means an establishment which has been approved by the competent authority in accordance with Article 176 of Regulation (EU) 2016/429;
- (11) ‘approved group of aquaculture establishments’ means a group of aquaculture establishments approved by the competent authority in accordance with Article 177 of Regulation (EU) 2016/429.

PART II

MOVEMENTS OF AQUATIC ANIMALS

Chapter 1

General requirements on operators for the transport of aquatic animals

Article 3

General obligations on operators as regards biosecurity requirements for the transport of aquatic animals

1. Operators, including transporters, shall ensure that aquatic animals are:
 - (a) loaded and transported in water which does not alter their health status;
 - (b) not transported in the same water or in the same container as aquatic animals of a lower health status, from the time of loading to the time of arrival at their place of destination.
2. Operators, including transporters, shall ensure that:
 - (a) the means of transport and containers are designed and constructed in such a way that cleaning and disinfection can be carried out effectively between consignments in order not to jeopardise the health status of the aquatic animals during transport;
 - (b) the container, when it is not a single use item, or the vessel, as well as other transport equipment, are cleaned and disinfected between consignments.
3. Operators, including transporters, shall ensure that the cleaning and disinfection required by paragraph 2(b) is carried out in accordance with a protocol agreed by the competent authority of the place of origin, which must include details of where and when the cleaning and disinfection is to take place and the type of disinfecting agents that must be used.

Article 4

General obligations on operators as regards requirements for water exchanges and discharges during the transport of aquatic animals

1. Operators, including transporters, shall ensure that where water exchange is necessary, it only takes place as follows:
 - (a) in the case of transport on land: at exchange points where the exchange does not alter the health status of the aquatic animals being transported, or those at the place of destination or en route to that destination;
 - (b) in the case of transport by well-boat: at a distance of at least 10 km from any aquaculture establishments which are located en route from the place of loading to the place of destination.
2. Operators, including transporters, shall ensure that water exchanges as referred to in paragraph 1, do not take place in areas which are subject to movement restrictions or emergency measures.

Article 5

Obligations on operators as regards specific transport and labelling requirements concerning means of transport and containers in which aquatic animals are transported

1. Operators, including transporters, of consignments of aquatic animals that are accompanied by an animal health certificate as referred to in Article 208 or Article 209 of Regulation (EU) 2016/429, shall ensure that the means of transport or containers in which those aquatic animals are transported, are identified by means of a legible label which must:

- (a) be displayed in a visible position on the container or the means of transport, as practicable;
 - (b) contain the necessary information to clearly link the consignment to the animal health certificate.
2. By way of derogation from paragraph 1(b), in the case of transport by well-boat, the label may be replaced by an entry in the ship's manifest that contains the necessary information to clearly link the consignment to the animal health certificate referred to in paragraph 1.

Chapter 2

Supplementary animal health requirements for movements of aquatic animals

SECTION 1

MOVEMENTS OF AQUATIC ANIMALS INTENDED FOR AQUACULTURE ESTABLISHMENTS OR RELEASE INTO THE WILD

Article 6

Derogations from the requirement for aquaculture animals of listed species to originate from a disease-free Member State, zone or compartment

By way of derogation from Article 197(1) and (2) of Regulation (EU) 2016/429, operators, including transporters, may move aquaculture animals of listed species which are relevant for the category B diseases or category C diseases for which the Member State, zone or compartment of destination has obtained disease-free status, or for which it is subject to an eradication programme, from Member States, zones or compartments which are not free of those listed diseases, under the following circumstances:

- (a) the aquaculture animals are of one of the species listed in column 4 of the table in the Annex to Implementing Regulation (EU) 2018/1882 and they are not regarded as being vectors of the category B or category C diseases in question; or
- (b) the aquaculture animals are of one of the species listed in column 4 of the table in the Annex to Implementing Regulation (EU) 2018/1882 and are vectors , but they are regarded as being free from the category B or category C diseases in question, as they have completed quarantine in a quarantine establishment approved in accordance with Article 15 of Delegated Regulation (EU)/.... [Publications Office please insert reference to SANTE/7208/2019, C(2020)415], under the requirements set out in point (2) of Part 8 of Annex I to that Delegated Regulation; or
- (c) the aquaculture animals are of one of the species listed in column 4 of the table in the Annex to Implementing Regulation (EU) 2018/1882 and are vectors , but they have been kept in an aquaculture establishment approved in accordance with Article 16 of Delegated Regulation (EU)/.... [Publications Office please insert reference to SANTE/7208/2019, C(2020)415] under the requirements set out in point (2) of Part 9 of Annex I to that Delegated Regulation, and are no longer regarded as vectors of the category B or category C diseases in question; or
- (d) the aquaculture animals are destined for a confined establishment for scientific purposes.

Article 7

Obligations on operators as regards disease prevention and risk mitigating measures for movements of wild aquatic animals to aquaculture establishments

By way of derogation from Article 197(1) and (2) of Regulation (EU) 2016/429 in conjunction with Article 200(1) thereof, operators including transporters, may move wild aquatic animals of listed species which are relevant for the category B or category C diseases, for which the Member State, zone or compartment of destination has obtained disease-free status or for which it is subject to an eradication programme, from Member States, zones or compartments which are not free of those listed diseases, provided that those wild aquatic animals are destined for an aquaculture establishment and the following circumstances apply:

- (a) they are regarded as being free of the category B or category C diseases in question, as they have completed quarantine in a quarantine establishment approved in accordance with Article 15 of Delegated Regulation (EU)/.... [Publications Office please insert reference to SANTE/7208/2019, C(2020)415] under the requirements set out in point (2) of Part 8 of Annex I to that Delegated Regulation; or
- (b) in the case of wild aquatic animals of species listed in column 4 of the table in the Annex to Implementing Regulation (EU) 2018/1882 and which are vectors, they have been kept in an aquaculture establishment approved in accordance with Article 16 of Delegated Regulation (EU)/.... [Publications Office please insert reference to SANTE/7208/2019, C(2020)415] under the requirements set out in point (2) of Part 9 of Annex I to that Delegated Regulation, and are no longer regarded as vectors.

SECTION 2

MOVEMENTS OF LIVE AQUATIC ANIMALS INTENDED FOR HUMAN CONSUMPTION

Article 8

Derogations from the movement requirements of live aquatic animals of listed species intended for human consumption in a Member State, zone or compartment, which has obtained disease-free status or which is subject to an eradication programme

By way of derogation from Article 201(1) of Regulation (EU) 2016/429 in conjunction with Article 202(1) thereof, when live aquatic animals are intended for human consumption, Member States may authorise operators to move animals of listed species for the category B or category C diseases for which the Member State, zone or compartment of destination has obtained disease-free status, or for which it is subject to an eradication programme, when one or more of the following circumstances apply:

- (a) the live aquatic animals are of one of the species listed in column 4 of the table in the Annex to Implementing Regulation (EU) 2018/1882 and they are not vectors of the category B or category C diseases in question ; or
- (b) the live aquatic animals are destined for a disease control aquatic food establishment for slaughter and subsequent processing having originated from an area which is subject to movement restrictions or emergency measures as referred to in Article 191(2)(b)(i) and (ii) of Regulation (EU) 2016/429, and where such movements are authorised by the competent authority, and take place in accordance with the conditions set out in that authorisation; or
- (c) the live aquatic animals are molluscs or crustaceans which are packed and labelled for human consumption in accordance with the specific requirements for those animals as set out in Sections VII and VIII of Annex III to Regulation (EC) No 853/2004 and they would no longer be able to survive as live animals if returned to the aquatic environment; or
- (d) the live aquatic animals are molluscs or crustaceans which are packed and labelled for human consumption in accordance with the specific requirements for those animals as set out in Sections VII and VIII of Annex III to Regulation (EC) No 853/2004 and they are intended for further processing without temporary storage at the place of processing; or

- (e) the live aquatic animals are molluscs or crustaceans which are intended for human consumption without further processing, and they are packed for retail sale in accordance with the specific requirements for those animals as set out in Sections VII and VIII of Annex III to Regulation (EC) No 853/2004.

SECTION 3

MOVEMENTS OF AQUATIC ANIMALS INTENDED FOR OTHER SPECIFIC USES AND PURPOSES

Article 9

Animal health requirements for movements of aquaculture animals to confined establishments

1. Operators shall only move aquaculture animals of listed species from a confined establishment to a confined establishment in another Member State if those animals do not pose a significant risk of the spread of diseases for which they are listed, based on the results of the surveillance plan referred to in Article 9(c) of Delegated Regulation (EU) .../.... [Publications Office please insert reference to SANTE/7208/2019, C(2020)415].
2. Operators shall only move aquaculture animals of listed species, which are relevant for category D diseases, from aquaculture establishments other than a confined establishment into a confined establishment if those aquaculture animals comply with one or more of the following requirements:
 - (a) they originate from a disease-free Member State, zone or compartment;
 - (b) they are quarantined under appropriate conditions in one of the following:
 - (i) a quarantine establishment approved in accordance with Article 15 of Delegated Regulation (EU) .../.... [Publications Office please insert reference to SANTE/7208/2019, C(2020)415]; or
 - (ii) a quarantine facility in another confined establishment; or
 - (iii) the quarantine facility of the confined establishment of final destination;
 - (c) they are aquaculture animals of one of the species listed in column 4 of the table in the Annex to Implementing Regulation (EU) 2018/1882 and they are vectors, but they have been kept in an aquaculture establishment approved in accordance with Article 16 of Delegated Regulation (EU) .../.... [Publications Office please insert reference to SANTE/7208/2019, C(2020)415] under the requirements set out in point (2) of Part 9 of Annex I to that Delegated Regulation, and are no longer regarded as vectors.
3. By way of derogation from paragraph 2, operators may move aquaculture animals that do not comply with the requirements laid down in that paragraph into a confined establishment for scientific purposes.

Article 10

Supplementary requirements for the release of aquatic animals into the wild

Operators shall only move aquatic animals for release into the wild in a Member State which has taken measures in accordance with Article 199 of Regulation (EU) 2016/429 and those aquatic animals are for sports fishing, including fishing bait as referred to in Article

205(2)(a)(iii) thereof, if they originate from a Member State, zone or compartment with disease-free status, and they comply with the following requirements:

- (a) the Member State of destination has notified the Commission and other Member States that it applies measures in accordance with Article 199 of Regulation (EU) 2016/429 for aquatic animals for sports fishing, including fishing bait as referred to in Article 205(2)(a)(iii) thereof;
- (b) the competent authority in the Member State of origin has authorised the movement;
- (c) the competent authorities in the Member State of origin and the Member State of destination have measures in place to ensure the traceability of the aquatic animals moved in accordance with this Article.

Article 11

Animal health requirements for movements of aquatic animals for use as live fishing bait

Operators shall only move live fishing bait that are aquatic animals of listed species relevant for category D diseases, other than those listed in column 4 of the table in the Annex to Implementing Regulation (EU) 2018/1882 and which are not regarded as vectors, into a Member State, zone or a compartment which has disease-free status, or which is subject to an eradication programme to obtain disease-free status for one or more of those relevant category D diseases, if such live fishing baits originate from a disease-free Member State, zone or compartment.

Chapter 3

Animal health certificates, self-declarations and movement notification

SECTION 1

GENERAL RULES AS REGARDS ANIMAL HEALTH CERTIFICATION

Article 12

Derogations from the animal health certificate requirement for certain species of aquaculture animals

By way of derogation from the animal health certification requirements laid down in Article 208(1) of Regulation (EU) 2016/429, operators may move aquaculture animals of listed species relevant for category C diseases without an animal health certificate, subject to compliance with the following conditions:

- (a) the competent authority of the Member State of destination has notified the Commission and the other Member States that such movements are authorised subject to compliance with the conditions laid down in points (c) and (d);
- (b) the competent authority of the Member State of origin has authorised the movement;
- (c) the category C disease in question has never occurred in either the Member State of origin or the Member State of destination;
- (d) both the competent authority of the Member State of origin and of destination have systems in place to ensure the traceability of the aquaculture animals moved in accordance with the conditions laid down in points (a), (b) and (c).

SECTION 2

RULES ON THE CONTENTS OF ANIMAL HEALTH CERTIFICATES AND SELF-DECLARATION DOCUMENTS FOR AQUATIC ANIMALS

Article 13

Rules on the contents of animal health certificates for the various species and categories of aquatic animals of listed species

1. Operators shall ensure that the animal health certificates referred to in Article 208(1) of Regulation (EU) 2016/429 for aquaculture animals and in Article 209 thereof for aquatic animals other than aquaculture animals, contain the following:
 - (a) the general information specified in paragraph 1 or 2 of Part A of Annex II, as relevant for aquaculture animals or wild aquatic animals;
 - (b) the specific animal health guarantees in accordance with paragraph 2 of this Article as relevant for the species and category of aquatic animals in question;
 - (c) details of the purpose for which the aquatic animals are to be used in accordance with paragraph 3 of Part A of Annex II.
2. The specific animal health guarantees for aquatic animals of relevant species referred to in paragraph 1(b) shall be the following:
 - (a) the aquatic animals being moved show no disease symptoms; and they originate from either:
 - (i) an aquaculture establishment or habitat where there are no increased mortalities with an undetermined cause; or
 - (ii) a part of the aquaculture establishment or habitat which is independent of the epidemiological unit where increased mortalities or other disease symptoms have occurred, where the competent authority of the Member State of destination and where relevant, the competent authority of the Member State(s) of transit, if there are any such Member States, have given consent for such a movement to occur; or
 - (iii) an aquaculture establishment which is subject to the movement restrictions or emergency measures set out in Article 191(2)(b)(i) and (ii) of Regulation (EU) 2016/429 and a derogation from those movement restrictions or emergency measures is authorised by the competent authority and the movement takes place in accordance with the conditions of that authorisation;
 - (b) the aquatic animals being moved originate from a Member State, zone or compartment which complies with one of the following:
 - (i) it has disease-free status for the category B or category C diseases for which the Member State, zone or compartment of destination has obtained disease-free status or for which it is subject to an eradication programme ; or
 - (ii) it is subject to an eradication programme for a category B disease or category C disease, when the aquatic animals are destined for an aquaculture establishment which is also subject to an eradication programme for the same category B disease or category C disease;

- (c) where the Member States of destination have taken national measures, the aquatic animals of the relevant species comply with the health guarantees which are necessary to comply with those national measures;
- (d) where the aquaculture animals are moved from aquaculture establishments other than those referred to in paragraph 2(a)(iii), a documentary check of the mortality, movements, health and production records of the aquaculture establishment has been completed and it indicates that there is no suspicion of a listed disease or emerging disease in the aquaculture establishment.

Article 14

Information to be contained in self-declaration documents for different species and categories of aquaculture animals

1. Operators shall ensure that self-declaration documents for movements of aquaculture animals from their place of origin in one Member State to their place of destination in another Member State, issued in accordance with Article 218 of Regulation (EU) 2016/429, contain the following information:
 - (a) the specific information referred to in paragraphs 2 and 3 of this Article, as relevant for the category of aquaculture animal in question;
 - (b) the general information specified in paragraph 1 of Part B of Annex II;
 - (c) details of the purpose for which the aquaculture animals are to be used in accordance with paragraph 2 of Part B of Annex II.
2. In addition to the requirements of paragraph 1, operators shall ensure that self-declaration documents for aquaculture animals of listed species include the following specific information:
 - (a) a declaration that the aquaculture animals being moved show no disease symptoms and they originate from either:
 - (i) an aquaculture establishment where there are no increased mortalities with an undetermined cause; or
 - (ii) a part of the aquaculture establishment which is independent of the epidemiological unit where increased mortalities or other disease symptoms have occurred, where the Member State of destination and the Member State(s) of transit, if there are any such Member States, have given consent for such a movement to occur;
 - (b) where the aquaculture animals are intended for an aquaculture establishment which is participating in a surveillance programme for a specified category C disease, a declaration that the aquaculture animals originate from an aquaculture establishment:
 - (i) which is participating in a surveillance programme for that specified category C disease; and
 - (ii) where there has been no suspicion or confirmation of the presence of that specified category C disease and this is supported by the sampling and laboratory data referred to in paragraph 1(f) of Part B of Annex II.
3. In addition to the requirements of paragraph 1 of this Article, operators shall ensure that the self-declaration documents for aquaculture animals of non-listed species and for aquaculture animals of species listed in column 4 of the table in the Annex to

Implementing Regulation (EU) 2018/1882 which are not regarded as vectors of the relevant category C disease, contain information indicating that the aquaculture animals being moved show no disease symptoms; and they originate from either:

- (a) an aquaculture establishment or a habitat where there are no increased mortalities with an undetermined cause; or
- (b) a part of the aquaculture establishment which is independent of the epidemiological unit where increased mortalities or other disease symptoms have occurred where the Member State of destination and the Member State(s) of transit, if there are any such Member States, have given consent for such a movement.

SECTION 3

RULES ON THE RESPONSIBILITY OF THE COMPETENT AUTHORITY FOR ANIMAL HEALTH CERTIFICATION

Article 15

Rules concerning the responsibility of the competent authority for animal health certification

1. Before signing an animal health certificate as provided for in Article 216(2)(a) of Regulation (EU) 2016/429, the official veterinarian shall carry out the following checks and examinations in the aquaculture establishment:
 - (a) a documentary check of the mortality records, movement records and health and production records kept at the aquaculture establishment; and
 - (b) a clinical inspection and where relevant, a clinical examination of:
 - (i) the aquaculture animals to be moved;
 - (ii) any moribund aquaculture animals which are observed in production units other than those in which the aquaculture animals referred to in point (i) are kept;
 - (iii) aquaculture animals from any production unit in the aquaculture establishment where the documentary check has raised any suspicion of the presence of a listed disease or an emerging disease.
2. By way of derogation from paragraph 1(b), in the case of eggs and molluscs, a clinical inspection may be omitted when a consignment is to be moved from the aquaculture establishment within a period of 4 weeks from the date on which the last clinical inspection was completed, provided that a documentary check as referred to in paragraph 1(a) is carried out within the 72 hours prior to the time the consignment is to be moved, and this documentary check indicates that:
 - (a) no movements of listed species have taken place to the aquaculture establishment since the last clinical inspection was carried out; and
 - (b) there is no suspicion of listed or emerging diseases in the aquaculture establishment.
3. The official veterinarian shall, after completing the checks, inspections and where relevant, examinations provided for in paragraph 1, issue an animal health certificate for the consignment of aquaculture animals or eggs within a period of 72 hours before the time of departure of the consignment from the establishment of origin.

4. The animal health certificate, as provided for in Article 216(2)(a) of Regulation (EU) 2016/429, shall be valid for a period of 10 days from the date on which it is issued by the official veterinarian.

By way of derogation from the first subparagraph, in the case of transport by waterway or sea of aquaculture animals, that period of 10 days may be extended by the period of the duration of the journey by waterway or sea.

Article 16

Derogations from certain requirements in relation to clinical examinations and certification prior to movement

1. By way of derogation from Article 15(3), the period within which the official veterinarian shall carry out the clinical inspection and where relevant, the clinical examination, and issue an animal health certificate for aquaculture animals of listed species other than those referred to in Article 15(2), may be extended from a period of 72 hours to a period of 7 days prior to the date of departure from the aquaculture establishment of origin, under the following circumstances:
 - (a) multiple movements of the same species of aquaculture animals occur from the same aquaculture establishment of origin to the same aquaculture establishment of destination and the movements take place not more than 7 days apart;
 - (b) a documentary check of the mortality records, movement records, health and production records is made prior to the movement of each consignment, and a clinical inspection and where necessary, a clinical examination, is carried out within the period of 72 hours prior to the time of the first movement and at least every 7 days thereafter, until such time as the last of the movements referred to in point (a) have taken place;
 - (c) each consignment is fully traceable.
2. The official veterinarian shall issue an animal health certificate as provided for in Article 216(2)(a) of Regulation (EU) 2016/429, for each consignment which is moved during the 7 day period between clinical inspections as referred to in paragraph 1 of this Article, subject to compliance with the following conditions:
 - (a) no movements of listed species have taken place to the aquaculture establishment since the last clinical inspection was carried out; and
 - (b) there is no suspicion of a listed disease or emerging disease in the aquaculture establishment.

SECTION 4

DETAILED RULES ON THE NOTIFICATION OF MOVEMENTS OF AQUATIC ANIMALS

Article 17

Advance notification of movements to another Member State of aquaculture animals from an aquaculture establishment subject to a surveillance programme for a category C disease

Operators of establishments implementing a surveillance programme for a specified category C disease in accordance with Article 3(2)(b)(iv) of Delegated Regulation (EU)[Publications Office please insert reference to SANTE/7066/2019, C(2019)4056], who are moving aquaculture animals to another aquaculture establishment implementing a

surveillance programme for the same category C disease in another Member State, shall notify the competent authority in their Member State of origin in advance of the intended movement.

Article 18

Information obligation of operators concerning the notification of movements of aquatic animals to another Member State

Operators required to notify the competent authority in their Member State of origin of movements of consignments of aquatic animals to another Member State, in accordance with Article 219 of Regulation (EU) 2016/429, shall provide that competent authority with the following information concerning such consignments set out in:

- (a) paragraphs 1 and 3 of Part A of Annex II concerning aquaculture animals, other than those referred to in point (c) of this Article to be moved to another Member State;
- (b) paragraphs 2 and 3 of Part A of Annex II concerning wild aquatic animals to be moved to another Member State;
- (c) Part B of Annex II concerning the aquaculture animals referred to in Article 17, to be moved to another Member State.

Article 19

Information obligation of the competent authority concerning the notification of movements of aquatic animals to another Member State

1. The competent authority of the Member State of origin required to notify the competent authority of the Member State of destination of movements of consignments of aquatic animals to another Member State, in accordance with Article 220(1) of Regulation (EU) 2016/429, shall provide the competent authority with the following information concerning such consignments set out in:
 - (a) paragraphs 1 and 3 of Part A of Annex II concerning aquaculture animals, other than those referred to in point (c) of Article 18 to be moved to another Member State;
 - (b) paragraphs 2 and 3 of Part A of Annex II concerning wild aquatic animals to be moved to another Member State.
2. The competent authority of the Member State of origin shall notify the competent authority of the Member State of destination of movements of the aquaculture animals referred to in Article 17, confirm the participation of the aquaculture establishment in the surveillance programme referred to in that Article and provide the information set out in Part B of Annex II.

Article 20

The emergency procedures for the notification of movements of aquatic animals between the Member States in the event of power cuts and other disturbances of TRACES

In the event of the unavailability of TRACES, the competent authority of the Member State of origin of the aquatic animals to be moved to another Member State, shall comply with the contingency arrangements established pursuant to Article 46 of Implementing Regulation (EU) 2019/1715.

Article 21

Designation of regions for the management of notifications of movements

Member States shall designate regions of their territory for the management of notifications of movements of aquatic animals to other Member States, as provided for in Articles 17, 18 and 19.

When designating those regions, the Member States shall ensure that:

- (a) all parts of their territory are covered by at least one designated region;
- (b) each designated region falls within the responsibility of a competent authority designated for animal health certification purposes in that designated region;
- (c) the competent authority responsible for the designated region has access to TRACES;
- (d) the personnel of the competent authority responsible for the designated region possess the appropriate ability and knowledge, and have received specific training, or have equivalent practical experiences in the use of TRACES for the production, handling and transmission of the information provided for in Articles 17, 18 and 19.

PART III PRODUCTION, PROCESSING AND DISTRIBUTION OF PRODUCTS OF ANIMAL ORIGIN FROM AQUACULTURE ANIMALS, OTHER THAN LIVE AQUACULTURE ANIMALS

Article 22

Obligations of operators moving products of animal origin from aquaculture animals other than live aquaculture animals, for further processing in a Member State, zone or compartment which has obtained disease-free status or is subject to an eradication programme

1. When they are intended for further processing, operators shall only move products of animal origin from aquaculture animals other than live aquaculture animals, of species listed in column 3 of the table in the Annex to Implementing Regulation (EU) 2018/1882 for the category B or category C diseases for which the Member State, zone or compartment of destination has obtained disease-free status, or for which it is subject to an eradication programme, if they originate from a Member State, zone or compartment which is free from the diseases in question.
2. By way of derogation from paragraph 1, the following products of animal origin from aquaculture animals of listed species other than live aquaculture animals, shall not be required to comply with that paragraph 1:
 - (a) fish intended for human consumption which are slaughtered and eviscerated before the movement;
 - (b) products of animal origin which are destined for a disease control aquatic food establishment.

Article 23

Obligations of operators moving products of animal origin from aquaculture animals other than live aquaculture animals, from certain establishments and zones

Operators shall only move products of animal origin from aquaculture animals other than live aquaculture animals, originating from establishments and zones that are subject to the emergency measures concerning the listed and emerging diseases referred to in Article 222(2)(a) of Regulation (EU) 2016/429, or the movement restrictions referred to in Article 222(2)(b) thereof, to another Member State, zone or compartment, subject to compliance with the following conditions:

- (a) the movements are authorised by the competent authority of the place of destination; and
- (b) the products of animal origin in question comply with the conditions attached to the authorisation referred to in point (a).

Article 24

Specific transport and labelling requirements for products of animal origin from aquaculture animals, other than live aquaculture animals

Operators, including transporters, shall ensure that consignments of products of animal origin from aquaculture animals other than live aquaculture animals, as referred to in Articles 22 and

23 of this Regulation, that are required to be accompanied by an animal health certificate in accordance with Article 223(1) of Regulation (EU) 2016/429, comply with the following requirements:

- (a) the consignments are traceable during transport;
- (b) the consignments are identified by means of a legible label which is displayed in a visible position in the means of transport or container, as practicable, or in the case of transport by sea, by an entry in the ship's manifest; and the label or manifest must contain the information necessary to link the consignment to the animal health certificate.

Article 25

Contents of animal health certificates for products of animal origin from aquaculture animals, other than live aquaculture animals, as referred to in Article 22

The animal health certificate issued by the competent authority for movements of products of animal origin from aquaculture animals, other than live aquaculture animals, in accordance with Article 223(4) of Regulation (EU) 2016/429 shall, for the products referred to in Article 22 of this Regulation, in addition to the information set out in Article 224 of that Regulation, contain the following:

- (a) the general information specified in paragraph 1 of Annex III;
- (b) details of the purpose for which the products of animal origin are to be used in accordance with paragraph 2 of Annex III;
- (c) an attestation signed by the official veterinarian certifying that the products of animal origin from the aquaculture animals in question comply with the requirements laid down in Article 22(1).

Article 26

Contents of animal health certificates for products of animal origin from aquaculture animals other than live aquaculture animals, as referred to in Article 23

The animal health certificate issued by the competent authority of the Member State of origin for movements of products of animal origin from aquaculture animals other than live aquaculture animals, in accordance with Article 223(4) of Regulation (EU) 2016/429 shall, in addition to the information set out in Article 224 of that Regulation, contain:

- (a) the general information specified in paragraph 1 of Annex III;
- (b) details of the purpose for which the products of animal origin are to be used in accordance with paragraph 2 of Annex III;
- (c) an attestation signed by the official veterinarian as referred to in paragraph 3 of Annex III certifying compliance with the conditions laid down in point (b) of Article 23.

Article 27

Information obligation of operators concerning the notification of movements of products of animal origin from aquaculture animals other than live aquaculture animals between Member States

Operators, in notifications of movements of products of animal origin from aquaculture animals other than live aquaculture animals to other Member States, as provided for in Article

225(1) of Regulation (EU) 2016/429, shall provide the competent authority of the Member State of origin with the information set out in Annex III to this Regulation for each consignment of products of animal origin from aquaculture animals other than live aquaculture animals.

Article 28

Information obligation of the competent authority concerning the notification of movements of products of animal origin from aquaculture animals other than live aquaculture animals between Member States

The competent authority of the Member State of origin, notifying the competent authority of the Member State of destination of movements of products of animal origin from aquaculture animals other than live aquaculture animals, in accordance with Article 225(2) of Regulation (EU) 2016/429, shall provide the information set out in Annex III to this Regulation for each consignment of products of animal origin from aquaculture animals other than live aquaculture animals.

Article 29

Emergency procedures

In the event of the unavailability of TRACES, the competent authority of the Member State of origin of the products of animal origin from aquaculture animals other than live aquaculture animals, to be moved to another Member State, shall comply with the contingency arrangements established pursuant to Article 46 of *Implementing Regulation (EU) 2019/1715*.

PART IV FINAL PROVISIONS

Article 30

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 21 April 2021.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 28.4.2020

For the Commission

The President

Ursula VON DER LEYEN