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From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	30 January 2020
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

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Subject:	COMMISSION DELEGATED REGULATION (EU) .../... of 30.1.2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of Council as regards rules for aquaculture establishments and transporters of aquatic animals

Delegations will find attached document **C(2020) 415 final**.

Encl.: **C(2020) 415 final**



Brussels, 30.1.2020
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COMMISSION DELEGATED REGULATION (EU) .../...

of 30.1.2020

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)

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, including, *inter alia*, rules for the registration and approval of aquaculture establishments, record-keeping obligations of transporters of aquatic animals, as well as rules on the traceability of kept aquatic animals within the Union.

Regulation (EU) 2016/429 also provides for the Commission to adopt delegated acts under Chapter 1 of Title II of Part IV thereof, supplementing those rules.

The rules laid down in this Delegated Regulation largely replicate rules currently laid down in existing Union acts, in particular in Council Directive 2006/88/EC² and rules adopted on the basis of that act, as they have proven to be effective in preventing the spread of listed diseases within the Union. However, they have been updated in certain respects to take account of experience gained in their application, and the new legislative framework established by Regulation (EU) 2016/429.

Accordingly, this Delegated Regulation lays down the following supplementing rules for:

- (a) the approval of certain aquaculture establishments keeping aquaculture animals posing a significant animal health risk;
- (b) the information to be included in the registers of registered and approved aquaculture establishments to be kept by the competent authorities;
- (c) record-keeping obligations of operators of aquaculture establishments and transporters of aquatic animals intended for those establishments and for release into the wild;
- (d) transitional measures in order to protect the acquired rights and legitimate expectations of stakeholders resulting from pre-existing Union acts.

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. No comments were received from the European Parliament or the Council. A number of meetings have been 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 in the context of 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 28 October 2019 and 25 November 2019. Feedback was received from 2 citizens and the following 7 organisations: Associazione Piscicoltori Italiani (API) (IT), Comité Interprofessionnel des

¹ 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

Produits de L'Aquaculture (CIPA) (FR), Federation of European Aquaculture Producers (FEAP) (BE), European Association of Zoos and Aquaria (EAZA) (NL), Danish Aquaculture Organisation (DK), Ornamental Fish International (OFI) (NL), Department of Environment, Food and Rural Affairs (Defra) (UK).

The main requests and points made were as follows:

- aquaculture establishments keeping fish for release into the wild should not be derogated from the requirement to be approved;
- the public register of establishments should not include information relating to the economic situation of the operators;
- the request for clarification in relation to movements between aquaria and confined establishments;
- the request for clarification in relation to aquaculture establishments which are closed facilities keeping aquaculture animals for ornamental purposes, and the specific movement conditions that would require these establishments to be approved;
- the measures to be considered in the biosecurity plan for aquaculture establishments are somewhat ambitious and inflexible;
- the request for an implementing act to derogate certain low risk businesses from the requirement to be registered.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

This Delegated Regulation is to be adopted within the framework of Regulation (EU) 2016/429, and in particular pursuant to Articles 176(4), 181(2), 185(5), 189(1) and 279(2) thereof.

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

of 30.1.2020

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')⁵, 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/EC⁶ 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

⁵ OJ L 84, 31.3.2016, p. 1.

⁶ 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).

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 Council⁷. 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

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

into account in this risk assessment are set out in Chapter 2 of Part I of Annex VI to Commission Delegated Regulation (EU) .../...⁸ [C(2019) 4056]. 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 Commission Delegated Regulation (EU) .../... [C(2019)4056], 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.
- (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’

⁸ Commission Delegated Regulation (EU) .../... supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes and disease-free status for certain listed and emerging diseases [C(2019) 4056]

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 Commission Delegated Regulation (EU) .../... [C(2019)4056]. 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) 2018/1882⁹ 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 Council¹⁰, 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/EC¹¹.

⁹ 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).

¹⁰ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1.)

¹¹ Commission Decision 2008/392/EC of 30 April 2008 implementing Council Directive 2006/88/EC as regards an Internet-based information page to make information on aquaculture production businesses and authorised processing establishments available by electronic means (OJ L 138, 28.5.2008, p. 12).

- (21) More specific information should, however, also be included in the public register of the competent authority regarding the health status of each approved establishment in order to facilitate safe trade and to ensure stakeholders know whether or not a given aquaculture establishment is free from a specific category B or C disease, is subject to an eradication programme for a specific category B or C disease, is in a surveillance programme for a specific category C disease, or if it has none of those health statuses. Given the scope of the requirements which are set out in this Regulation with regard to the public availability of information on approved aquaculture establishments, this Regulation should repeal Decision 2008/392/EC.
- (22) Articles 186 and 187 of Regulation (EU) 2016/429 lay down the minimum record-keeping obligations for operators of aquaculture establishments. As aquatic animals are generally not individually identifiable, record-keeping in relation to their production and movement is crucial. Whilst there are some common elements between the records kept by operators of different types of aquaculture establishments, specific types of aquaculture establishments should keep records which are particular to them and the type of aquaculture activity they are engaged in. As Article 189(1) of that Regulation provides for the Commission to adopt delegated acts laying down supplementing rules for the record-keeping obligations, different record-keeping requirements should therefore, be set out in this Regulation for each type of approved aquaculture establishment.
- (23) Article 188 of Regulation (EU) 2016/429 lays down the minimum record-keeping obligations for transporters of aquatic animals intended for aquaculture establishments and of aquatic animals which are moved between habitats. Transporters of aquatic animals represent a particular risk for the spread of disease and it is crucial that these operators keep records to ensure the traceability of the aquatic animals they transport, as well as to provide documentary evidence that they are employing appropriate biosecurity measures. Accordingly, this Regulation should lay down supplementing rules for their record-keeping obligations.
- (24) 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

1. This Regulation supplements the rules laid down in Regulation (EU) 2016/429 as regards registered and approved aquaculture establishments keeping aquaculture animals and transporters of aquatic animals.
2. Part II lays down requirements in:
 - (a) Chapter 1 of Title I, on the approval by the competent authority of aquaculture establishments posing a significant risk for diseases affecting aquatic animals, and certain derogations for operators of establishments that pose an insignificant risk for those diseases;

- (b) Chapter 2 of Title I, on the requirements for aquaculture establishments and groups thereof, and the granting of approval by the competent authority;
 - (c) Chapter 1 of Title II, on the information obligations of the competent authority as regards registers of aquaculture establishments registered in accordance with Article 173 of Regulation (EU) 2016/429;
 - (d) Chapter 2 of Title II, on the information obligations of the competent authority as regards registers of approved aquaculture establishments;
 - (e) Chapter 1 of Title III, for the record-keeping obligations of operators of aquaculture establishments and disease control aquatic food establishments registered or approved by the competent authority, in addition to those provided for in Articles 186(1) and 187(1) of Regulation (EU) 2016/429;
 - (f) Chapter 2 of Title III, on the record-keeping obligations of transporters of aquatic animals, in addition to those provided for in Article 188(1) of Regulation (EU) 2016/429.
3. Part III lays down certain transitional measures as regard to Directive 2006/88/EC and Decision 2008/392/EC in relation to the registration and approval of aquaculture establishments.

Article 2

Definitions

For the purposes of this Regulation, the definitions set out in Article 1 of Implementing Regulation (EU) 2018/1882 shall apply.

The following definitions shall also apply:

- (1) 'extensive pond' means a traditional pond or lagoon which is natural or artificial and where the food source for the animals kept in these ponds or lagoons is natural other than in exceptional circumstances, and where no measures are taken to increase the production beyond the natural capacity of the environment;
- (2) 'purification centre' means an establishment with tanks fed by clean seawater in which molluscs are placed for the time necessary to reduce contamination to make them fit for human consumption;
- (3) 'dispatch centre' means an on-shore or off-shore establishment for the reception, conditioning, washing, cleaning, grading, wrapping and packaging of molluscs intended for human consumption;
- (4) 'relaying area' means any freshwater, sea, estuarine or lagoon area with boundaries clearly marked and indicated by buoys, posts or any other fixed means, and used exclusively for the natural purification of molluscs;
- (5) 'in isolation' means keeping aquaculture animals in an aquaculture establishment where they do not come into contact with any other species of aquatic animals either directly through co-habitation or indirectly through the water supply;
- (6) 'closed facility' means an aquaculture establishment, the waste water from which, is subjected to treatment which is capable of inactivating agents of listed diseases or emerging diseases, before it is discharged into open waters;

- (7) 'open facility' means an aquaculture establishment, the waste water from which, is discharged directly into open waters without being treated to inactivate agents of listed diseases or emerging diseases;
- (8) 'epidemiological area' means a defined geographical area where the aquatic animals have the same health status and are exposed to the same risk of contracting a listed disease or an emerging disease;
- (9) 'biosecurity plan' means a documented plan which identifies the routes by which a disease agent can enter an aquaculture establishment, spread within it and transfer from it; it takes account of the specificities of the establishment and identifies measures which will mitigate the biosecurity risks which have been identified;
- (10) 'common biosecurity measures' means the measures included in a biosecurity plan which has been devised for, and implemented by, each aquaculture establishment in a group of aquaculture establishments which has been approved by the competent authority in accordance with Article 177 of Regulation (EU) 2016/429;
- (11) 'unique registration number' means a number assigned to a registered aquaculture establishment or group of aquaculture establishments as referred to in Article 173 of Regulation (EU) 2016/429;
- (12) 'unique approval number' means a number assigned by the competent authority to an aquaculture establishment or group of aquaculture establishments approved by it in accordance with Article 173 of Regulation (EU) 2016/429;
- (13) 'IMO ship identification number' means a unique number assigned to sea-going vessels by the International Maritime Organisation (IMO);
- (14) 'hygiene barrier' means footbaths, hand washes, changes of clothing or other biosecurity measures, the effects of which are to create barriers to the spread of disease into, within or from an aquaculture establishment;
- (15) 'production units' means troughs, ponds, raceways, tanks, cages, pens, or similar structures which contain groups of aquaculture animals in an aquaculture establishment;
- (16) 'increased mortality' means unexplained mortalities above the level considered normal for the aquaculture establishment or group of aquaculture establishments in question, under prevailing conditions;
- (17) 'surveillance programme' means a voluntary programme of testing and control measures undertaken in relation to a category C disease at an aquaculture establishment which is not participating in an eradication programme to achieve disease-free status, but where testing indicates that the aquaculture establishment is not infected with that category C disease.

PART II

REGISTRATION, APPROVAL, REGISTERS AND RECORD-KEEPING

TITLE I

APPROVAL OF OPERATORS OF AQUACULTURE ESTABLISHMENTS BY THE COMPETENT AUTHORITY

CHAPTER 1

Approval of aquaculture establishments posing a significant risk for the spread of disease and derogations from the requirement for approval

Article 3

Derogations from the requirement on operators to apply to the competent authority for approval of aquaculture establishments

1. By way of derogation from Article 176(1)(a) of Regulation (EU) 2016/429, operators of the following types of aquaculture establishments shall not be required to apply to the competent authority for approval of their aquaculture establishments:
 - (a) aquaculture establishments where aquaculture animals are kept solely for release into the wild;
 - (b) extensive ponds where aquaculture animals are kept for direct human consumption or for release into the wild;
 - (c) purification centres which:
 - (i) are approved in accordance with Article 4 of Regulation (EC) No 853/2004; and
 - (ii) receive molluscs only from within the epidemiological area in which the establishment is located;
 - (d) dispatch centres which:
 - (i) are approved in accordance with Article 4 of Regulation (EC) No 853/2004; and
 - (ii) receive molluscs only from within the epidemiological area in which the establishment is located;
 - (e) relaying areas which:
 - (i) are approved in accordance with Article 4 of Regulation (EC) No 853/2004; and
 - (ii) receive molluscs only from within the epidemiological area in which the establishment is located.
2. Derogations from the requirement to apply to the competent authority for approval provided for in paragraph 1 of this Article shall only apply to aquaculture establishments from which aquaculture animals are not moved to another Member

State, other than molluscs for direct human consumption and when the competent authority has completed a risk assessment:

- (a) taking into account at least the risk factors set out in points (a) and (b) of Chapter 2 of Part I of Annex VI to Commission Delegated Regulation (EU) .../... [C(2019)4056]; and
- (b) which has found the risk of the aquaculture animals on the aquaculture establishment either contracting or spreading a listed disease or an emerging disease to be insignificant.

Article 4

Types of aquaculture establishments required to be approved by the competent authority

Operators of the following types of aquaculture establishments shall apply to the competent authority for approval in accordance with Article 176(1)(b) of Regulation (EU) 2016/429:

- (a) quarantine establishments for aquaculture animals;
- (b) aquaculture establishments keeping aquaculture animals of listed species which are vectors in isolation, until such time as they are no longer regarded as being vectors;
- (c) aquaculture establishments which are closed facilities keeping aquaculture animals for ornamental purposes, which because of their movement patterns, create a significant disease risk;
- (d) aquaculture establishments keeping aquaculture animals for ornamental purposes in open facilities;
- (e) vessels or other mobile premises where aquaculture animals are kept temporarily to be treated or to undergo another husbandry related procedure.

CHAPTER 2

Requirements and granting of approval of aquaculture establishments

Article 5

Requirement for approved aquaculture establishments and groups thereof to have a biosecurity plan

The competent authority shall only approve aquaculture establishments referred to in Article 7 and Articles 9 to 19, or groups of aquaculture establishments referred to in Article 8, if their operators have developed and documented a biosecurity plan, which complies with the following requirements:

- (a) it identifies the routes whereby a disease agent can enter the aquaculture establishment or group of aquaculture establishments, spread within it and transfer from it to the environment or to other aquaculture establishments;
- (b) it takes account of the specificities of the individual aquaculture establishment or group of aquaculture establishments and identifies risk-mitigation measures for each biosecurity risk which has been identified;
- (c) it considers or takes into account, where appropriate, the elements set out in point 1(a) of Parts 1 to 7 and Parts 9 to 12, and in point 1(b) of Part 8 of Annex I, when

this plan for the aquaculture establishment or group of aquaculture establishments is being developed.

Article 6

Requirement for approved aquaculture establishments and groups thereof to participate in a risk-based surveillance scheme

1. The competent authority shall only approve aquaculture establishments referred to in Articles 7, 17 and 18 of this Regulation if the operators comply with risk-based surveillance conducted by the competent authority in accordance with Article 26 of Regulation (EU) 2016/429, in the form of a risk-based surveillance scheme as set out in Part 1 and in point 1 of Part 2 of Annex II to this Regulation.
2. The competent authority shall only approve groups of aquaculture establishments referred to in Article 8 of this Regulation when operators comply with risk based surveillance conducted by the competent authority in accordance with Article 26 of Regulation (EU) 2016/429, in the form of a risk- based surveillance scheme as set out in Part 1 and in point 2 of Part 2 of Annex II to this Regulation.
3. When granting approval of aquaculture establishments or groups thereof as provided for in paragraphs 1 and 2, the competent authority shall take account of the following elements, and include them in the risk-based surveillance scheme:
 - (a) the outcome of the surveillance conducted by the operator in accordance with Article 24 of Regulation (EU) 2016/429;
 - (b) the information obtained through the animal health visits carried out by a veterinarian in accordance with Article 25 of Regulation (EU) 2016/429, when the operators make such information available.

Article 7

Requirements for granting approval of aquaculture establishments where aquaculture animals are kept with a view to being moved therefrom either alive or as products of aquaculture animal origin, other than those aquaculture establishments for which specific requirements are laid down in Articles 12 to 19

When granting approval, the competent authority shall ensure that aquaculture establishments where aquaculture animals are kept with a view to being moved therefrom either alive or as products of aquaculture animal origin, other than those aquaculture establishments referred to in Articles 12 to 19, comply with the requirements set out in:

- (a) Article 6(1), in relation to risk-based surveillance;
- (b) point 1 of Part 1 of Annex I, in relation to biosecurity measures;
- (c) point 2 of Part 1 of Annex I, in relation to facilities and equipment.

Article 8

Requirements for granting approval of groups of aquaculture establishments where aquaculture animals are kept with a view to being moved therefrom either alive or as products of aquaculture animal origin

When granting approval, the competent authority shall ensure that groups of aquaculture establishments where aquaculture animals are kept with a view to being moved therefrom

either alive or as products of aquaculture animal origin comply with the requirements set out in:

- (a) Article 6(2), in relation to risk-based surveillance;
- (b) point 1 of Part 2 of Annex I, in relation to biosecurity measures for the aquaculture establishments in the group;
- (c) point 2 of Part 2 of Annex I, in relation to facilities and equipment.

Article 9

Requirements for granting approval of confined aquaculture establishments

When granting approval, the competent authority shall ensure that confined aquaculture establishments comply with the requirements set out in:

- (a) Article 10, in relation to arrangements for facilities where post-mortem examinations are carried out and securing the services of an establishment veterinarian;
- (b) point 1 of Part 3 of Annex I, in relation to biosecurity measures;
- (c) point 2 of Part 3 of Annex I, in relation to surveillance and control;
- (d) point 3 of Part 3 of Annex I, in relation to facilities and equipment.

Article 10

Obligations of operators of confined aquaculture establishments

Before approval is granted by the competent authority, operators of confined aquaculture establishments shall:

- (a) put in place arrangements to perform veterinary post-mortem examinations in appropriate facilities in the confined aquaculture establishment or in a laboratory;
- (b) secure by contract or by another legal instrument, the services of an establishment veterinarian who shall be responsible for:
 - (i) the supervision of the activities of the confined aquaculture establishment and compliance with the requirements for approval laid down in Article 9;
 - (ii) the review of the disease surveillance plan referred to in point 2(a) of Part 3 of Annex I at least annually.

Article 11

Requirements for granting approval of disease control aquatic food establishments

When granting approval, the competent authority shall ensure that disease control aquatic food establishments comply with the requirements set out in:

- (a) point 1 of Part 4 of Annex I, in relation to biosecurity measures;
- (b) point 2 of Part 4 of Annex I, in relation to facilities and equipment.

Article 12

Requirements for granting approval of purification centres other than those referred to in Article 3(1)(c)

When granting approval, the competent authority shall ensure that purification centres other than those referred to in Article 3(1)(c) comply with the requirements set out in:

- (a) point 1 of Part 5 of Annex I, in relation to biosecurity measures;
- (b) point 2 of Part 5 of Annex I, in relation to facilities and equipment.

Article 13

Requirements for granting approval of dispatch centres other than those referred to in Article 3(1)(d)

When granting approval, the competent authority shall ensure that dispatch centres other than those referred to in Article 3(1)(d) comply with the requirements set out in:

- (a) point 1 of Part 6 of Annex I, in relation to biosecurity measures;
- (b) point 2 of Part 6 of Annex I, in relation to facilities and equipment.

Article 14

Requirements for granting approval of relaying areas other than those referred to in Article 3(1)(e)

When granting approval, the competent authority shall ensure that relaying areas other than those referred to in Article 3(1)(e) comply with the requirements set out in:

- (a) point 1 of Part 7 of Annex I, in relation to biosecurity measures;
- (b) point 2 of Part 7 of Annex I, in relation to facilities and equipment.

Article 15

Requirements for granting approval of quarantine establishments

When granting approval, the competent authority shall ensure that quarantine establishments comply with the requirements set out in:

- (a) point 1 of Part 8 of Annex I, in relation to biosecurity measures;
- (b) point 2 of Part 8 of Annex I, in relation to surveillance and control measures;
- (c) point 3 of Part 8 of Annex I, in relation to facilities and equipment.

Article 16

Requirements for granting approval of aquaculture establishments keeping aquaculture animals of listed species which are vectors in isolation, until such time as they are no longer regarded as vectors

When granting approval, the competent authority shall ensure that aquaculture establishments keeping aquaculture animals of listed species which are vectors in isolation, until such time as they are no longer regarded as vectors, comply with the requirements set out in:

- (a) point 1 of Part 9 of Annex I, in relation to biosecurity measures;
- (b) point 2 of Part 9 of Annex I, in relation to surveillance and control measures;
- (c) point 3 of Part 9 of Annex I, in relation to facilities and equipment.

Article 17

Requirements for granting approval of aquaculture establishments which are closed facilities keeping aquaculture animals for ornamental purposes which, because of their movement patterns, create a significant disease risk

When granting approval, the competent authority shall ensure that aquaculture establishments which are closed facilities keeping aquaculture animals for ornamental purposes which, because of their movement patterns, create a significant disease risk, comply with the requirements set out in:

- (a) Article 6(1), in relation to risk-based surveillance;
- (b) point 1 of Part 10 of Annex I, in relation to biosecurity measures;
- (c) point 2 of Part 10 of Annex I, in relation to facilities and equipment.

Article 18

Requirements for granting approval of aquaculture establishments which are open facilities keeping aquaculture animals for ornamental purposes

When granting approval, the competent authority shall ensure that aquaculture establishments which are open facilities keeping aquaculture animals for ornamental purposes comply with the requirements set out in:

- (a) Article 6(1), in relation to risk-based surveillance;
- (b) point 1 of Part 11 of Annex I, in relation to biosecurity measures;
- (c) point 2 of Part 11 of Annex I, in relation to facilities and equipment.

Article 19

Requirements for granting approval of vessels or other mobile premises where aquaculture animals are kept temporarily to be treated or to undergo another husbandry-related procedure

When granting approval, the competent authority shall ensure that vessels or other mobile premises where aquaculture animals are kept temporarily to be treated or to undergo another husbandry-related procedure comply with the requirements set out in:

- (a) point 1 of Part 12 of Annex I, in relation to biosecurity measures;
- (b) point 2 of Part 12 of Annex I, in relation to facilities and equipment.

TITLE II
REGISTERS TO BE KEPT BY THE COMPETENT AUTHORITY OF REGISTERED AND
APPROVED AQUACULTURE ESTABLISHMENTS

CHAPTER 1
Registers of aquaculture establishments kept by the competent
authority

Article 20
Information obligation of the competent authority as regards the register of registered
aquaculture establishments

In addition to the information required by Article 185(2) of Regulation (EU) 2016/429, the competent authority shall include the following information in the register of aquaculture establishments provided for in Article 185(1)(a) of that Regulation, for each aquaculture establishment it registers:

- (a) the unique registration number assigned to it by the competent authority;
- (b) the date of registration by the competent authority;
- (c) the address and geographical coordinates (latitude and longitude) of the location of the aquaculture establishment;
- (d) a description of its facilities and equipment;
- (e) categories of aquaculture animals which are kept in the aquaculture establishment;
- (f) the approximate number or the maximum biomass or both, of the aquaculture animals which may be kept in the aquaculture establishment;
- (g) the period during which aquaculture animals are kept in the aquaculture establishment if it is not continuously occupied, including when relevant, information on seasonal occupation or occupation during particular events;
- (h) the date of any cessation of activity when the operator has informed the competent authority thereof.

CHAPTER 2
Registers of aquaculture establishments approved by the competent
authority

Article 21
Information obligation of the competent authority as regards the register of approved
aquaculture establishments

1. In addition to the information required by Article 185(2) of Regulation (EU) 2016/429, the competent authority shall include the following information in the register of approved aquaculture establishments provided for in Article 185(1)(b) and (c) of that Regulation, for each aquaculture establishment or group of aquaculture establishments it approves:
 - (a) the unique approval number assigned to it by the competent authority

- (b) the date of approval granted by the competent authority or of any suspension or withdrawal of approval by the competent authority;
- (c) the address and geographical co-ordinates (latitude and longitude) of the location of the approved aquaculture establishment or group of aquaculture establishments;
- (d) a description of its relevant facilities and equipment;
- (e) categories of aquaculture animals which are kept in the aquaculture establishment or in the group of aquaculture establishments;
- (f) the approximate number or the maximum biomass, or both, of the aquaculture animals which may be kept in the aquaculture establishment or in the group of aquaculture establishments;
- (g) the period during which aquaculture animals are kept in the aquaculture establishment or group of aquaculture establishments if not continuously occupied, including when relevant, information on seasonal occupation or occupation during particular events;
- (h) the date of any cessation of activity when the operator has informed the competent authority thereof.

2. In addition to the information required by Article 185(3) of Regulation (EU) 2016/429, the competent authority shall include up-to-date information on the health status of the aquaculture animals kept in aquaculture establishments or groups of aquaculture establishments which are approved in accordance with Article 181(1) of that Regulation, in an internet-based information page which is publicly available.

That up-to-date health information shall at least set out the health status of the aquaculture establishment or group of aquaculture establishments for each relevant listed disease and for each relevant category thereof, as follows:

- (a) whether it is free from a category B disease or category C disease;
- (b) if it is in an eradication programme for a category B disease or category C disease;
- (c) if it is in a voluntary surveillance programme for a category C disease; or
- (d) any other information which pertains to a category B, category C or category D disease, other than the information which is set out in points (a), (b) and (c).

TITLE III
**RECORD-KEEPING OBLIGATIONS OF OPERATORS IN ADDITION TO THOSE
PROVIDED FOR IN REGULATION (EU) 2016/429**

CHAPTER 1
***Records to be kept by operators of registered or approved
aquaculture establishments***

Article 22

Record-keeping obligations of operators of registered aquaculture establishments

In addition to the information required by Article 186(1) of Regulation (EU) 2016/429, operators of registered aquaculture establishments shall record and keep the following information:

- (a) the unique registration number assigned to the aquaculture establishment by the competent authority;
- (b) details of any investigations that were carried out following the occurrence of increased mortality or suspicion of the presence of disease;
- (c) self-declaration documents issued in accordance with Article 218 of Regulation (EU) 2016/429, received with consignments of aquaculture animals which have arrived at the aquaculture establishment or which have been sent with such consignments which have been dispatched from the aquaculture establishment, as relevant;
- (d) where relevant, any other documents accompanying aquatic animals.

Article 23

Record-keeping obligations of operators of approved aquaculture establishments where aquaculture animals are kept with a view to their being moved therefrom, either alive or as products of aquaculture animal origin other than those which are referred to in Articles 27 to

34

In addition to the information required by Article 186(1) of Regulation (EU) 2016/429, operators of approved aquaculture establishments where aquaculture animals are kept with a view to being moved therefrom either alive or as products of aquaculture animal origin other than those aquaculture establishments referred to in Articles 27 to 34 of this Regulation, shall record and keep the following information:

- (a) the unique approval number issued to the aquaculture establishment by the competent authority;
- (b) the current risk categorisation of the aquaculture establishment, as assigned by the competent authority;
- (c) details of the implementation and results of the risk-based surveillance provided for in Article 6(1);
- (d) details of movements to the aquaculture establishment including:
 - (i) the unique approval or registration number of the aquaculture establishment of origin of all aquaculture animals which have been received from another aquaculture establishment; or

- (ii) the location of the habitat from which wild aquatic animals have been collected before being dispatched to the aquaculture establishment;
- (e) details of movements from the aquaculture establishment including:
 - (i) aquaculture animals and products of aquaculture animal origin and, in the case of movements of aquaculture animals, including the unique registration or approval number of the aquaculture establishment of destination; or
 - (ii) in the case of movements into the wild, details of the habitat into which the aquaculture animals will be released;
- (f) the name and address of transporters who deliver aquatic animals to or collect aquaculture animals from the establishment;
- (g) the biosecurity plan for the approved aquaculture establishment and evidence of its implementation;
- (h) self-declaration documents issued in compliance with Article 218 of Regulation (EU) 2016/429 received with consignments of aquaculture animals which have arrived at the aquaculture establishment or which have been sent with consignments which have been dispatched from the aquaculture establishment, as relevant;
- (i) where relevant, any other documents accompanying aquatic animals.

Article 24

Record-keeping obligations of operators of an approved group of aquaculture establishments where aquaculture animals are kept with a view to being moved therefrom either alive or as products of aquaculture animal origin

1. In addition to the information required by Article 186(1) of Regulation (EU) 2016/429, operators of aquaculture establishments in a group of aquaculture establishments approved in accordance with point (a) of Article 177 of Regulation (EU) 2016/429 shall record and keep the following information:
 - (a) the unique approval number issued to the aquaculture establishment by the competent authority;
 - (b) the current risk categorisation of the group of aquaculture establishments, as assigned by the competent authority;
 - (c) details of the implementation and results of the risk-based surveillance provided for in Article 6(2);
 - (d) details of movements to the aquaculture establishment including:
 - (i) the unique approval or registration number of the aquaculture establishment of origin for all aquaculture animals which have been received from an aquaculture establishment outside the group; or
 - (ii) the location of the habitat from which wild aquatic animals have been collected before being dispatched to the aquaculture establishment;
 - (e) details of movements from the group of aquaculture establishments including:
 - (i) aquaculture animals and products of aquaculture animal origin from aquaculture animals and, in the case of movements of aquaculture animals, including the unique registration or approval number of the

establishment of destination, where aquaculture animals are dispatched to another establishment outside the group; or

- (ii) in the case of movements into the wild, details of the habitat into which the aquaculture animals will be released;
 - (f) the name and address of transporters who deliver aquatic animals to, or collect aquaculture animals from, the aquaculture establishment;
 - (g) details of the biosecurity plan employed and evidence of its implementation;
 - (h) self-declaration documents issued in compliance with Article 218 of Regulation (EU) 2016/429, received with consignments of aquaculture animals which have arrived at the aquaculture establishment or which have been sent with consignments which have been dispatched from the aquaculture establishment, as relevant;
 - (i) where relevant, any other documents accompanying the aquatic animals.
2. The operator of a group of aquaculture establishments approved in accordance with point (b) of Article 177 of Regulation (EU) 2016/429 shall record or keep the information set out in paragraph 1(a) to (i) of this Article on behalf of each aquaculture establishment in the group.

Article 25

Record-keeping obligations of operators of approved confined aquaculture establishments

In addition to the information required by Article 186(1) of Regulation (EU) 2016/429, operators of approved confined aquaculture establishments shall record and keep the following information:

- (a) the unique approval number issued to the confined aquaculture establishment by the competent authority;
- (b) details of movements to and from the confined aquaculture establishment including the unique registration or approval number of the aquaculture establishment of origin or destination of all aquaculture animals received from or dispatched to another aquaculture establishment;
- (c) the name and address of transporters who deliver aquaculture animals to, or collect aquaculture animals from, the confined aquaculture establishment;
- (d) details of the implementation and results of the disease surveillance plan provided for in point 2 of Part 3 of Annex I;
- (e) the results of clinical and laboratory tests and of post-mortem examinations completed when increased mortalities or suspicion of the presence of disease are investigated;
- (f) where relevant, details of the vaccination or treatment of aquaculture animals provided for in point 2(c) of Part 3 of Annex I;
- (g) details of isolation or quarantine of incoming aquaculture animals, instructions, if any, of the competent authority as regards isolation and quarantine and relevant observations made during any isolation or quarantine period;
- (h) the biosecurity plan for the confined aquaculture establishment;
- (i) where relevant, any other documents accompanying the aquaculture animals.

Article 26

Record-keeping obligations of operators of disease control aquatic food establishments

In addition to the information required by Article 187(1) of Regulation (EU) 2016/429, operators of disease control aquatic food establishments shall record and keep the following information:

- (a) the unique approval number issued to the disease control aquatic food establishment by the competent authority;
- (b) the biosecurity plan for the disease control aquatic food establishment and evidence of its implementation;
- (c) maintenance records for the waste water treatment system used in the disease control aquatic food establishment;
- (d) records to verify the efficacy of the water treatment system;
- (e) the name and address of transporters who deliver aquatic animals to the disease control aquatic food establishment;
- (f) where relevant, any other documents accompanying the aquatic animals.

Article 27

Record-keeping obligations of operators of approved purification centres

In addition to the information required by Article 186(1) of Regulation (EU) 2016/429, operators of approved purification centres shall record and keep the following information:

- (a) the unique approval number issued to the approved purification centre by the competent authority;
- (b) the biosecurity plan for the approved purification centre and evidence of its implementation;
- (c) maintenance records for the waste water treatment system used in the approved purification centre ;
- (d) records to verify the efficacy of the water treatment system;
- (e) where relevant, any other documents accompanying aquatic animals.

Article 28

Record-keeping obligations of operators of approved dispatch centres

In addition to the information required by Article 186(1) of Regulation (EU) 2016/429, operators of approved dispatch centres shall record and keep the following information:

- (a) the unique approval number issued to the approved dispatch centre by the competent authority;
- (b) the biosecurity plan for the approved dispatch centre and evidence of its implementation;
- (c) maintenance records for the waste water treatment system used in the approved dispatch centre;
- (d) records to verify the efficacy of the water treatment system;
- (e) where relevant, any other documents accompanying aquatic animals.

Article 29

Record-keeping obligations of operators of approved relaying areas

In addition to the information required by Article 186(1) of Regulation (EU) 2016/429, operators of approved relaying areas shall record and keep the following information:

- (a) the unique approval number issued to the approved relaying area by the competent authority;
- (b) the biosecurity plan for the approved relaying area and evidence of its implementation;
- (c) where relevant, any other documents accompanying aquatic animals.

Article 30

Record-keeping obligations of operators of approved quarantine establishments for aquaculture animals

In addition to the information required by Article 186(1) of Regulation (EU) 2016/429, operators of approved quarantine establishments for aquaculture animals shall record and keep the following information:

- (a) the unique approval number issued to the quarantine establishment by the competent authority;
- (b) details of movements to the approved quarantine establishment including:
 - (i) the unique registration or approval number of the aquaculture establishment of origin of all aquaculture animals received from another aquaculture establishment; or
 - (ii) the location of the habitat from which aquatic animals have been collected before being dispatched to the approved quarantine establishment;
- (c) details of movements from the approved quarantine establishment including:
 - (i) the unique registration or approval number of the aquaculture establishment of destination; or
 - (ii) the location of the habitat into which aquaculture animals have been released into the wild;
- (d) the name and address of transporters who deliver aquatic animals to, or collect aquaculture animals from, the approved quarantine establishment;
- (e) details of the implementation and results of the disease surveillance provided for in point 2 of Part 8 of Annex I;
- (f) the results of clinical and laboratory tests and of post-mortem examinations provided for in point 2 of Part 8 of Annex I;
- (g) instructions, if any, of the competent authority as regards observations made during any isolation or quarantine period;
- (h) the biosecurity plan for the approved quarantine establishment and evidence of its implementation;
- (i) evidence showing that the environmental parameters in the approved quarantine establishment are conducive to the expression of the relevant listed or emerging disease(s);

- (j) where relevant, any other documents accompanying the aquatic animals.

Article 31

Record-keeping obligations of operators of approved aquaculture establishments keeping aquaculture animals of listed species which are vectors in isolation, until such time as they are no longer regarded as vectors

In addition to the information required by Article 186(1) of Regulation (EU) 2016/429, operators of approved aquaculture establishments keeping aquaculture animals of listed species which are vectors in isolation, until such time as they are no longer regarded as vectors, shall record and keep the following information:

- (a) the unique approval number issued to the aquaculture establishment by the competent authority;
- (b) details of movements to the approved aquaculture establishment including:
 - (i) the unique registration or approval number of the aquaculture establishment of origin of all aquaculture animals received from another aquaculture establishment; or
 - (ii) the location of the habitat from which aquatic animals have been collected before being dispatched to the approved aquaculture establishment;
- (c) details of movements from the approved aquaculture establishment including:
 - (i) the unique registration or approval number of the aquaculture establishment of destination; or
 - (ii) in the case of movements into the wild, details of the habitat into which the aquaculture animals will be released;
- (d) the name and address of transporters who deliver aquatic animals to, or collect aquaculture animals from, the approved aquaculture establishment;
- (e) details of the implementation and results of the disease surveillance provided for in point 2 of Part 9 of Annex I;
- (f) the results of clinical and laboratory tests and of post-mortem examinations provided for in point 2 of Part 9 of Annex I;
- (g) instructions, if any, of the competent authority as regards observations made during the 90 day isolation period referred to in point 2 of Part 9 of Annex I;
- (h) the biosecurity plan for the approved aquaculture establishment and evidence of its implementation;
- (i) where relevant, any other documents accompanying the aquatic animals.

Article 32

Record - keeping obligations of operators of approved aquaculture establishments which are closed facilities keeping aquaculture animals for ornamental purposes

In addition to the information required by Article 186(1) of Regulation (EU) 2016/429, operators of approved aquaculture establishments which are closed facilities keeping aquaculture animals for ornamental purposes shall record and keep the following information:

- (a) the unique approval number issued to the aquaculture establishment by the competent authority;

- (b) the current risk categorisation of the approved aquaculture establishment, as assigned by the competent authority;
- (c) details of the implementation and results of the risk based surveillance provided for in Article 6(1), where relevant;
- (d) details of movements to the approved aquaculture establishment including the unique registration or approval number of the aquaculture establishment of origin of all aquaculture animals received from another aquaculture establishment;
- (e) details of movements from the approved aquaculture establishment, including the unique registration or approval number of the aquaculture establishment of destination other than when these movements take place to households;
- (f) the name and address of transporters who deliver aquatic animals to, or collect aquaculture animals from, the approved aquaculture establishment, other than when these movements take place to households;
- (g) the biosecurity plan for the approved aquaculture establishment and evidence of its implementation;
- (h) self-declaration documents issued in accordance with Article 218 of Regulation (EU) 2016/429, received with consignments of aquaculture animals which have arrived at the approved aquaculture establishment or which have been sent with consignments which have been dispatched from the approved aquaculture establishment, as relevant;
- (i) where relevant, any other documents accompanying aquaculture animals.

Article 33

Record-keeping obligations of operators of approved aquaculture establishments which are open facilities keeping aquaculture animals for ornamental purposes

In addition to the information required by Article 186(1) of Regulation (EU) 2016/429, operators of approved aquaculture establishments which are open facilities keeping aquaculture animals for ornamental purposes shall record and keep the following information:

- (a) the unique approval number issued to the aquaculture establishment by the competent authority;
- (b) the current risk categorisation of the approved aquaculture establishment, as assigned by the competent authority;
- (c) details of the implementation and results of the risk based surveillance provided for in Article 6(1), where relevant;
- (d) details of movements to the approved aquaculture establishment including the unique registration or approval number of the aquaculture establishment of origin of all aquaculture animals which have been received from another aquaculture establishment;
- (e) details of movements from the approved aquaculture establishment including the unique registration or approval number of the aquaculture establishment of destination except when these movements take place to households;
- (f) the name and address of transporters who deliver aquatic animals to, or collect aquaculture animals from, the approved aquaculture establishment, other than when these movements take place to households;

- (g) the biosecurity plan for the approved aquaculture establishment and evidence of its implementation;
- (h) self-declaration documents issued in accordance with Article 218 of Regulation (EU) 2016/429, received with consignments of aquaculture animals which have arrived at the approved aquaculture establishment or which have been sent with consignments which have been dispatched from the approved aquaculture establishment, as relevant;
- (i) where relevant, any other documents accompanying aquatic animals.

Article 34

Record-keeping obligations of operators of approved vessels or other approved mobile premises where aquaculture animals are kept temporarily to be treated or to undergo another husbandry related procedure

In addition to the information required by Article 186(1) of Regulation (EU) 2016/429, operators of approved vessels or other approved mobile premises where aquaculture animals are kept temporarily to be treated or to undergo another husbandry related procedure, shall record and keep the following information:

- (a) the unique approval number issued to the vessel or other mobile premises by the competent authority;
- (b) the dates and times of loading of aquaculture animals at the approved vessel or other approved mobile premises;
- (c) where relevant, the name, address and unique registration or approval number of each aquaculture establishment where aquaculture animals were loaded and unloaded;
- (d) the dates and places at which the vessel or other mobile premises was filled with water before loading and where relevant, exchanged between loading and unloading;
- (e) where relevant, details of the route taken between one aquaculture establishment and another;
- (f) details of each treatment or husbandry related procedure which takes place in the approved vessel or other approved mobile premises;
- (g) the biosecurity plan for the approved vessel or other approved mobile premises and evidence of its implementation;
- (h) where relevant, any other documents accompanying aquaculture animals.

CHAPTER 2

Records to be kept by transporters

Article 35

Record-keeping obligations of transporters of aquatic animals

In addition to the information required by Article 188 of Regulation (EU) 2016/429, transporters of aquatic animals shall record and keep the following information for each means of transport used to move aquatic animals:

- (a) its licence plate number in the case of transport by land, its IMO ship identification number in the case of transport by sea, or any other means of identification which uniquely identifies other means of transport in which aquatic animals are transported;
- (b) the dates and times of loading of aquatic animals at the aquaculture establishment or habitat of origin;
- (c) the name, address and unique registration or approval number of each aquaculture establishment visited;
- (d) the location of each habitat from which wild aquatic animals were collected;
- (e) the dates and times of unloading of aquatic animals at the aquaculture establishment or habitat of destination;
- (f) the dates, times and places of water exchange, when this has occurred;
- (g) the biosecurity plan for the means of transport and evidence of its implementation;
- (h) the reference numbers of the documents accompanying the consignments of aquatic animals.

PART IV

TRANSITIONAL AND FINAL PROVISIONS

Article 36 *Repeal*

Decision [2008/392/EC](#) is repealed with effect from 21 April 2021.

References to the repealed act shall be construed as references to this Regulation.

Article 37 *Transitional measures regarding the information in the registers of existing aquaculture establishments and operators kept by competent authorities*

Member States shall ensure that, for the existing aquaculture establishments and operators referred to in Article 279(1) of Regulation (EU) [2016/429](#) which fall within the scope of Articles 20 and 21 of this Regulation, the information required by Articles 20 and 21 has been included for each such aquaculture establishment and operator in the registers of registered and approved aquaculture establishments kept by competent authorities before 21 April 2021.

Article 38 *Entry into force and application*

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, 30.1.2020

*For the Commission
The President
Ursula von der LEYEN*