

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

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) Regulation (EU) 2016/429 lays down rules for the prevention and control of diseases which are transmissible to animals or humans, including, inter alia, rules for aquaculture establishments, and for transporters of aquatic animals. Regulation (EU) 2016/429 also provides for the Commission to adopt delegated acts in order to supplement certain non-essential elements of that Regulation. It is therefore necessary to lay down supplementing rules in order to ensure the smooth functioning of the system established within the new legislative framework of Regulation (EU) 2016/429.
- (2) More particularly, the rules laid down in this Regulation should supplement those already laid down in Chapter 1 of Title II of Part IV of Regulation (EU) 2016/429, as regards the approval of aquaculture establishments keeping aquaculture animals posing a significant animal health risk, the registers of aquaculture establishments to be kept by competent authorities, and the record-keeping obligations of operators of aquaculture establishments and transporters of aquatic animals.
- (3) In addition, this Regulation takes into account the repeal of Council Directive 2006/88/EC <sup>(2)</sup> by Regulation (EU) 2016/429 with effect from 21 April 2021. Regulation (EU) 2016/429 provides that establishments and operators registered or approved in accordance with that Directive, before the date of application of Regulation (EU) 2016/429, are to be deemed to be registered or approved, as required, in accordance with that Regulation, and subject to the relevant obligations laid down therein.
- (4) Accordingly, the rules laid down in this Regulation should supplement the rules laid down in Part IX of Regulation (EU) 2016/429, as regards the necessary transitional measures to protect the acquired rights and legitimate expectations of stakeholders resulting from pre-existing Union acts with regard to aquaculture establishments.
- (5) As the rules laid down in this Regulation all relate to aquaculture establishments and transporters of aquatic animals and are to be applied in tandem, they should be set out in a single act rather than in separate acts with numerous cross-references, in order to facilitate their application, in the interests of transparency, and to avoid a duplication of rules. This is also in keeping with the approach adopted by Regulation (EU) 2016/429.
- (6) Article 176(1) of Regulation (EU) 2016/429 provides that operators of aquaculture establishments are to apply to the competent authority for approval where they keep aquaculture animals with a view to those animals being moved therefrom, either alive or as products of aquaculture animal origin. As a wide variety of aquaculture establishments fall within that category, Article 176(2) of Regulation (EU) 2016/429 provides that Member States may exempt operators of specific types of aquaculture establishments from the requirement for approval provided that such aquaculture establishments do not pose a significant disease risk. In addition, Article 176(4) of that Regulation provides that the Commission may adopt delegated acts concerning derogations from the requirement for approval for certain types of aquaculture establishments, again on the condition that those aquaculture establishments do not pose a significant risk.

<sup>(1)</sup> OJ L 84, 31.3.2016, p. 1.

<sup>(2)</sup> 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).

- (7) The level of risk posed by an aquaculture establishment, depends on the activity of that aquaculture establishment and the destination and intended use of the aquaculture animals or products of aquaculture animal origin produced therein. Some aquaculture establishments have already been approved for different purposes, such as aquaculture establishments which have been approved under the hygiene rules in accordance with Regulation (EC) No 853/2004 of the European Parliament and of the Council <sup>(3)</sup>. In certain situations, aquaculture establishments such as purification and dispatch centres or relaying areas only receive molluscs from within the epidemiological area in which the aquaculture establishment is itself located. These aquaculture establishments therefore, pose an insignificant risk from an animal health perspective. Other aquaculture establishments are also engaged in low risk activities, such as keeping aquaculture animals solely for release into the wild after having produced them from broodstock which originated from the water body on which the aquaculture establishment is located, or keeping aquaculture animals in extensive ponds for human consumption or for release into the wild.
- (8) It is necessary to lay down in this Regulation, the specific conditions under which derogations from the requirement for approval should be permitted for aquaculture establishments. In certain cases, derogations should only apply to aquaculture establishments which move aquaculture animals within their own Member State and not to aquaculture establishments which move aquaculture animals between Member States. In all cases, however, derogations from the requirement for an aquaculture establishment to be approved should only be considered when the competent authority has completed a risk assessment which takes into account at least the risk of aquaculture animals on the aquaculture establishment contracting or spreading an aquatic disease via water or via movements and where the risk has been found to be insignificant. Details of additional risk factors which the competent authority may take into account in this risk assessment are set out in Chapter 2 of Part I of Annex VI to Commission Delegated Regulation (EU) 2020/689 <sup>(4)</sup>. Therefore, the supplementing rules laid down in this Regulation should be consistent with those laid down in that Delegated Regulation.
- (9) At the same time, certain other types of aquaculture establishments represent a significant risk for the spread of aquatic animal diseases. Such types of aquaculture establishment should be specifically described in this Regulation, and the requirement for the operators of these aquaculture establishments to be approved should be detailed in this Regulation. These include aquaculture establishments keeping ornamental aquaculture animals in open facilities and also in closed facilities where the movement patterns are such that trade within the Union or with third countries potentially present a disease risk. Other types of aquaculture establishments where the risk of disease spread should be mitigated through the requirement for approval by the competent authority, are quarantine establishments, establishments which keep vector species in isolation until such time as they are no longer considered to be vectors, and vessels and other mobile premises where aquaculture animals are treated or undergo other husbandry-related procedures.
- (10) Article 177 of Regulation (EU) 2016/429 provides for the competent authority to grant approval of operators for groups of aquaculture establishments. The supplementing rules laid down in this Regulation should therefore apply to such groups where appropriate, and should set out the details of how the rules should apply directly to, and within, the group.
- (11) Operators of all aquaculture establishments or groups of aquaculture establishments are required to provide information to the competent authority with a view to obtaining approval in compliance with Article 180 of Regulation (EU) 2016/429. In that regard, operators should provide the competent authority with a written biosecurity plan which will be considered during the approval process. This requirement should apply to both individual aquaculture establishments and groups of aquaculture establishments regardless of their size, but the complexity of the biosecurity plan should depend upon the specificities of the individual aquaculture establishment or group thereof, and on the measures which are required to mitigate the associated disease risks.
- (12) Certain aquaculture establishments and groups of aquaculture establishments should, on the basis of the rules laid down in Chapter 1 of Part I to Annex VI of Delegated Regulation (EU) 2020/689, participate in a risk-based surveillance scheme which is put in place by the competent authority in accordance with Article 26 of Regulation (EU) 2016/429. Without such participation, aquaculture establishments or groups of aquaculture establishments should not be approved. In line with Article 27 of Regulation (EU) 2016/429, risk-based surveillance may take into account the surveillance conducted by operators themselves in accordance with Article 24, including the animal health visits referred to in Article 25 of that Regulation. Risk-based surveillance may also be carried out at the same time as surveillance connected with particular listed diseases, in order to maximise resources.

<sup>(3)</sup> 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).

<sup>(4)</sup> Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 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 (see page 211 of this Official Journal).

- (13) The frequency of risk-based surveillance should be based on the ranking of the aquaculture establishment by the competent authority as 'high', 'medium' or 'low' risk, following an assessment of the circumstances of the establishment. Factors to be taken into account and considered by the competent authority when risk ranking establishments, as well as the frequency of surveillance which attaches to each risk ranking are set out in Part I of Annex VI to Delegated Regulation (EU) 2020/689. The objective of including aquaculture establishments which keep non-listed species but which participate in a significant amount of trade and which are therefore ranked as 'high' risk, in the risk-based surveillance scheme, is to maximise the chances of identifying and controlling emerging diseases, should they appear in aquaculture animals of those non-listed species.
- (14) As risk-based surveillance is also carried out in approved groups of aquaculture establishments, it is important to set out how this should be completed at group level so that the outcome of the surveillance is epidemiologically meaningful. Accordingly, this Regulation should lay down rules concerning the approach which the competent authority should take to carrying out such surveillance.
- (15) Apart from the requirement for operators to present a biosecurity plan to the competent authority as part of the approval process, and for certain aquaculture establishments to participate in a risk-based surveillance scheme, the aquaculture establishments that are required to be approved should also meet certain requirements in relation to their facilities and equipment. The particular combination of requirements with regard to biosecurity, surveillance, and facilities and equipment which apply to a specific category of aquaculture establishment or to a specific category of group of aquaculture establishments should therefore, be set out in this Regulation.
- (16) Article 178 of Regulation (EU) 2016/429 provides that operators of aquaculture establishments wishing to obtain the status of a confined aquaculture establishment may only move aquaculture animals to or from their aquaculture establishments after they have obtained the approval of that status from the competent authority in accordance with the rules laid down in that Regulation. As these aquaculture establishments may exchange aquaculture animals amongst themselves with fewer movement requirements than for other types of aquaculture establishments, it is appropriate that they should have a contracted veterinarian who will supervise the activities of the aquaculture establishment and be responsible for its health surveillance, so they can provide robust health guarantees to each other. Article 181(2) of Regulation (EU) 2016/429 provides for the Commission to adopt delegated acts laying down supplementing rules for the approval of such aquaculture establishments, and such rules should be laid down in this Regulation.
- (17) Article 179 of Regulation (EU) 2016/429 provides for the approval of disease control aquatic food establishments. These aquaculture establishments facilitate the sanitary slaughter and sanitary processing of aquatic animals, which may be infected with a listed or emerging disease. Therefore, they represent a significant disease risk and should be approved by the competent authority. During the periods when these aquaculture establishments are receiving aquatic animals which are infected or suspected of being infected with a listed or emerging disease, they should comply with stringent biosecurity measures with the aim of ensuring that disease agents are not released into open waters without appropriate treatment. Article 181(2) of that Regulation provides for the Commission to adopt delegated acts laying down supplementing rules for the approval of these aquaculture establishments and accordingly those supplementing rules should be laid down in this Regulation.
- (18) Certain purification centres, relaying areas, and dispatch centres for live molluscs should be considered as aquaculture establishments which require approval in accordance with Article 176(1) of Regulation (EU) 2016/429. Those establishments which receive live molluscs from outside their own epidemiological area, represent a higher risk of spreading listed or emerging diseases and should be treated as such during the approval process. This Regulation should therefore lay down supplementing rules in that respect.
- (19) Commission Implementing Regulation (EU) 2018/1882 <sup>(5)</sup> 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

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<sup>(5)</sup> 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).

aquatic animals may instead be kept in another type of aquaculture establishment which does not have all of the biosecurity measures which are required for quarantine establishments, but where they are kept in isolation from potential pathogens until such time as they are no longer to be regarded as vectors. Article 181(2) of Regulation (EU) 2016/429 provides for the Commission to adopt delegated acts laying down supplementing rules for the approval of such aquaculture establishments taking into account those requirements. Accordingly, those requirements should be laid down in this Regulation.

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

<sup>(6)</sup> 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.)

<sup>(7)</sup> 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).

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) 2020/689; 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 coordinates (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 I

#### *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 III***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 January 2020.

*For the Commission*

*The President*

Ursula VON DER LEYEN

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## ANNEX I

**REQUIREMENTS FOR GRANTING APPROVAL OF AQUACULTURE ESTABLISHMENTS, AS REFERRED TO IN CHAPTER 2 OF TITLE I OF PART II**

## PART 1

**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 as referred to in Article 7**

1. The requirements in relation to biosecurity measures of aquaculture establishments where aquaculture animals are kept with a view to being moved therefrom either alive or as products of aquaculture animal origin as referred to in point (b) of Article 7, shall be the following:
  - (a) operators shall implement a biosecurity plan in accordance with Article 5, which must take the following elements into consideration:
    - (i) disinfection points must be installed at critical locations in the aquaculture establishment;
    - (ii) where the following functional units exist within the same aquaculture establishment, they must be separated using appropriate hygiene barriers:
      - hatchery units,
      - fattening units,
      - processing units,
      - dispatch centre;
    - (iii) work clothing and footwear for personnel must be kept solely for use at the aquaculture establishment and cleaned and disinfected regularly;
    - (iv) equipment must not be shared between aquaculture establishments but where this is unavoidable, an appropriate protocol for cleaning and disinfection of the equipment must be followed;
    - (v) visitors to the aquaculture establishment must be controlled in cases where they pose a disease risk; these visitors must either:
      - wear protective clothing and footwear provided at the aquaculture establishment, or
      - clean and disinfect any protective clothing and footwear they bring onto the aquaculture establishment on arrival and in the case of non-disposable clothing and footwear, on departure;
    - (vi) dead animals must be removed from all production units at a frequency that ensures infective pressure is kept to a minimum but which is practicable given the production method used, and disposed of in compliance with Article 13 of Regulation (EC) No 1069/2009 of the European Parliament and of the Council <sup>(1)</sup>;
    - (vii) as far as possible, equipment in the aquaculture establishment must be cleaned and disinfected at the end of each production cycle;
    - (viii) where aquaculture establishments receive fertilised eggs from other establishments, and where biologically feasible, these eggs must be disinfected appropriately on arrival and all packaging must be disinfected or disposed of in a biosecure manner;
    - (ix) the cleaning and disinfection records of transporters must be verified before aquatic animals are loaded or unloaded at the aquaculture establishment;
  - (b) operators shall nominate a named person to be in charge of implementing the biosecurity plan for the aquaculture establishment with other personnel reporting to that individual in relation to biosecurity matters.

<sup>(1)</sup> Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

2. The requirements in relation to facilities and equipment of aquaculture establishments as referred to in point (c) of Article 7, shall be the following:
  - (a) suitable equipment and facilities must be available for the purpose of maintaining appropriate husbandry conditions for the aquaculture animals kept on the aquaculture establishment;
  - (b) the aquaculture establishment must provide for good standards of hygiene and allow adequate health monitoring to be carried out;
  - (c) as far as possible, equipment and facilities must be made from materials which can be appropriately cleaned and disinfected;
  - (d) appropriate predator control measures must be put in place, taking into account the risk of disease spread these predators pose and the environmental constraints of the aquaculture establishment;
  - (e) appropriate equipment must be available for the cleaning and disinfection of facilities, equipment and means of transport.

## PART 2

### **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 as referred to in Article 8**

1. The requirements in relation to biosecurity measures of groups of aquaculture establishments where aquaculture animals are kept with a view to being moved therefrom as referred to in point (b) of Article 8, shall be the following:
  - (a) operators shall implement a biosecurity plan in accordance with Article 5, and in developing their biosecurity plan, the operators must take the following elements into consideration:
    - (i) disinfection points must be installed at critical locations in each aquaculture establishment in the group;
    - (ii) where the following functional units exist within the same aquaculture establishment, they must be separated using appropriate hygiene barriers:
      - hatchery units,
      - fattening units,
      - processing units,
      - dispatch centre;
    - (iii) work clothing and footwear for personnel must be kept solely for use at each aquaculture establishment and cleaned and disinfected regularly;
    - (iv) equipment must not be shared between aquaculture establishments but where this is unavoidable, an appropriate protocol for cleaning and disinfection of the equipment must be followed;
    - (v) visitors to the aquaculture establishment must be controlled where they pose a disease risk; these visitors must either:
      - wear protective clothing and footwear provided at each aquaculture establishment, or
      - clean and disinfect any protective clothing and footwear they bring onto the aquaculture establishment on arrival and in the case of non-disposable clothing and footwear, on departure;
    - (vi) dead aquaculture animals must be removed from all production units at a frequency that ensures infective pressure is kept to a minimum but which is practicable given the production method used, and disposed of in compliance with Article 13 of Regulation (EC) No 1069/2009;
    - (vii) as far as possible, equipment in each aquaculture establishment must be cleaned and disinfected at the end of each production cycle;

- (viii) where aquaculture establishments receive fertilised eggs from other establishments, and where biologically feasible, these eggs must be disinfected appropriately on arrival and all packaging must be disinfected or disposed of in a biosecure manner;
    - (ix) the cleaning and disinfection records of transporters must be verified before aquaculture animals are loaded or unloaded at the aquaculture establishment;
  - (b) responsibility for the implementation of the measures set out in the biosecurity plan shall be with:
    - (i) the operator of each individual aquaculture establishment in a group of aquaculture establishments approved in accordance with point (a) of Article 177 of Regulation (EU) 2016/429;
    - (ii) the operator of a group of aquaculture establishments approved in accordance with point (b) of Article 177 of Regulation (EU) 2016/429.
- 2. The requirements in relation to facilities and equipment of groups of aquaculture establishments as referred to in point (c) of Article 8, shall be the following:
  - (a) suitable equipment and facilities must be available for the purpose of maintaining appropriate husbandry conditions for the aquaculture animals kept in each aquaculture establishment in the group;
  - (b) each aquaculture establishment in the group must have good standards of hygiene and allow health monitoring to be carried out;
  - (c) equipment and facilities in each aquaculture establishment in the group must be made from materials which can be readily cleaned and disinfected;
  - (d) appropriate predator control measures must be put in place in each aquaculture establishment in the group, taking into account the risk of disease spread these predators pose and the environmental constraints of the aquaculture establishment;
  - (e) appropriate equipment must be available in each aquaculture establishment in the group for cleaning and disinfection of facilities, equipment and means of transport.

### PART 3

#### **Requirements for granting approval of confined aquaculture establishments referred to in Article 9**

- 1. The requirements in relation to the biosecurity measures of confined aquaculture establishments as referred to in point (b) of Article 9, shall be the following:
  - (a) operators shall implement the biosecurity plan in accordance with Article 5, which must take the following elements into consideration:
    - (i) disinfection points must be installed at critical locations in the confined aquaculture establishment;
    - (ii) where different functional units exist within the same confined aquaculture establishment, they must be kept separate using hygiene barriers;
    - (iii) work clothing and footwear for personnel must be kept at the confined aquaculture establishment and cleaned and disinfected regularly;
    - (iv) visitors must wear protective clothing and footwear provided by the operator;
    - (v) equipment shall not be shared with other aquaculture establishments;
    - (vi) dead animals must be removed at a frequency that ensures infective pressure is kept to a minimum, and disposed of in compliance with Article 13 of Regulation (EC) No 1069/2009;
    - (vii) the equipment in the confined aquaculture establishment must be cleaned and disinfected at an appropriate frequency;

- (viii) where confined aquaculture establishments receive fertilised eggs from other establishments, where biologically feasible and where it does not interfere with research objectives, these eggs must be disinfected appropriately on arrival, and all packaging must be disinfected or disposed of in a biosecure manner;
    - (ix) the cleaning and disinfection records of transporters must be verified before aquaculture animals are loaded or unloaded at the establishment;
  - (b) operators shall nominate a named person to be in charge of implementing the biosecurity plan for the confined aquaculture establishment with other personnel reporting to that individual in relation to biosecurity matters.
2. The requirements in relation to surveillance and control measures of confined aquaculture establishments as referred to in point (c) of Article 9, shall be the following:
- (a) a disease surveillance plan must be implemented, which must include appropriate controls for diseases of aquaculture animals, and it must be updated according to the number and species of the aquaculture animals present in the confined aquaculture establishment, and to the epidemiological situation in and around the confined aquaculture establishment as regards listed and emerging diseases;
  - (b) aquaculture animals suspected of being infected with listed or emerging disease agents must be subjected to clinical, laboratory or post-mortem testing;
  - (c) the vaccination and treatment of aquaculture animals against transmissible diseases is carried out as appropriate.
3. The requirements in relation to facilities and equipment of confined aquaculture establishments as referred to in point (d) of Article 9, shall be the following:
- (a) the boundaries of the confined aquaculture establishments must be clearly demarcated and the access of aquatic animals and humans to animal facilities must be controlled;
  - (b) where necessary, adequate facilities suited for the quarantine of aquaculture animals introduced from other establishments must be available;
  - (c) adequate means for isolating aquaculture animals must be available;
  - (d) tanks and other holding facilities must be of a suitable standard and constructed so that:
    - (i) contact with aquatic animals outside is prevented and that inspections and any necessary treatments can be easily carried out;
    - (ii) floors, walls and all other material or equipment can be readily cleaned and disinfected;
  - (e) suitable equipment and facilities must be available for the purpose of maintaining appropriate husbandry conditions for the aquaculture animals kept in the confined aquaculture establishment;
  - (f) the confined aquaculture establishment must provide for good standards of hygiene and allow adequate health monitoring to be carried out;
  - (g) appropriate equipment must be available for the cleaning and disinfection of facilities, equipment and means of transport;
  - (h) appropriate predator control measures must be put in place, taking into account the risk of disease spread these predators pose;
  - (i) appropriate disinfection equipment must be in place to ensure that all wastewater which is discharged from the confined aquaculture establishment is treated to a level which ensures that any infectious agents of listed or emerging diseases which are present are fully inactivated before discharge.



## PART 4

**Requirements for granting approval of disease control aquatic food establishments referred to in Article 11**

1. The requirements in relation to biosecurity measures of disease control aquatic food establishments as referred to in point (a) of Article 11, shall be the following:
  - (a) operators shall implement the biosecurity plan for the disease control aquatic food establishment in accordance with Article 5, which must take account of at least the following elements when animals which are infected with a listed or emerging disease are slaughtered or processed on the premises:
    - (i) visitors to the establishment must be avoided, but when such visits are unavoidable, they must be controlled and protective clothing and footwear must be provided by the operator which are safely disposed of or cleaned and disinfected after use;
    - (ii) the personnel of the disease control aquatic food establishment must wear work clothing and footwear which must be cleaned and disinfected at an appropriate frequency;
    - (iii) an appropriate disinfection system must be in place to ensure that waste water from the disease control aquatic food establishment is appropriately treated so that any disease agents which are present are inactivated before the water is discharged;
    - (iv) an appropriate system must be in place to ensure the collection and appropriate disposal of animal by-products; such by-products shall be processed as Category 1 or Category 2 material in compliance with Article 12 or Article 13 of Regulation (EC) No 1069/2009;
    - (v) appropriate cleaning and disinfecting operations must be completed prior to the arrival of any new consignment of aquatic animals for processing;
    - (vi) appropriate measures must be in place to ensure that all means of transport and their containers which are used to deliver aquatic animals to a disease control aquatic food establishment are cleaned and disinfected before they leave the establishment.
2. The requirements in relation to facilities and equipment of disease control aquatic food establishments as referred to in point (b) of Article 11, shall be the following:
  - (a) floors, walls and all other material or equipment must be easily cleaned and disinfected;
  - (b) appropriate disinfection equipment must be in place to ensure that all waste water which is discharged from the disease control aquatic food establishment is treated to a level which ensures that any infectious agents of listed or emerging diseases which are present are fully inactivated before discharge;
  - (c) appropriate equipment, compatible with the type of production activities conducted, must be available for the cleaning and disinfection of facilities, equipment and means of transport;
  - (d) appropriate predator control measures must be put in place, taking into account the risk of disease spread these predators pose.

## PART 5

**Requirements for granting approval of purification centres as referred to in Article 12**

1. The requirements in relation to biosecurity measures of purification centres as referred to in point (a) of Article 12, shall be the following:
  - (a) operators shall implement the biosecurity plan in accordance with Article 5, which must take the following elements into consideration:
    - (i) disinfection points must be installed at critical locations in the purification centre;
    - (ii) the work clothing and footwear for personnel must be kept solely for use at the purification centre and cleaned and disinfected regularly;
    - (iii) equipment must not be shared between establishments but where this is unavoidable, an appropriate protocol for cleaning and disinfection of the equipment must be put in place;

- (iv) visitors to the purification centre must be controlled where they pose a risk for the spread of disease; these visitors must either:
    - wear protective clothing and footwear provided at the purification centre; or
    - clean and disinfect any protective clothing and footwear they bring onto the purification centre on arrival and in the case of non-disposable clothing and footwear, on departure;
  - (v) equipment in the purification centre must be cleaned and disinfected at the end of the purification cycle;
  - (vi) wastewater from the purification centre must not be discharged without appropriate treatment directly into water bodies when the health status of aquatic animals may be jeopardised with respect to listed or emerging diseases.
2. The requirements in relation to facilities and equipment of purification centres as referred to in point (b) of Article 12, shall be the following:
- (a) the purification centre must provide for good standards of hygiene;
  - (b) equipment and facilities must be made from materials which can be appropriately cleaned and disinfected;
  - (c) appropriate equipment must be available for cleaning and disinfection of facilities, equipment and means of transport;
  - (d) appropriate predator control measures must be put in place, taking into account the risk of disease spread these predators pose;
  - (e) appropriate disinfection equipment must be put in place to ensure that wastewater which is discharged from the purification centre is treated when required to ensure that any agents of listed or emerging diseases which are present are inactivated prior to discharge.

#### PART 6

#### **Requirements for granting approval of dispatch centres as referred to in Article 13**

1. The requirements in relation to biosecurity measures of dispatch centres as referred to in point (a) of Article 13, shall be the following:
- (a) operators shall implement the biosecurity plan in accordance with Article 5, which must take the following elements into consideration:
    - (i) disinfection points must be installed at critical locations in the dispatch centre;
    - (ii) work clothing and footwear for personnel must be kept solely for use at the dispatch centre and cleaned and disinfected regularly;
    - (iii) equipment must not be shared between establishments but where this is unavoidable, an appropriate protocol for cleaning and disinfection of the equipment must be put in place;
    - (iv) visitors to the dispatch centre must be controlled in cases where they pose a risk for the spread of disease; these visitors must either:
      - wear protective clothing and footwear provided at the establishment, or
      - clean and disinfect any protective clothing and footwear they bring onto the establishment on arrival and in the case of non-disposable clothing and footwear, on departure;
    - (v) equipment in the dispatch centre must be cleaned and disinfected at the end of the dispatch operation;
    - (vi) wastewater from the dispatch centre must not be discharged without appropriate treatment directly into water bodies when the health status of aquatic animals may be jeopardised with respect to listed or emerging diseases.
2. The requirements in relation to facilities and equipment of dispatch centres as referred to in point (b) of Article 13, shall be the following:
- (a) the dispatch centre must provide for good standards of hygiene;
  - (b) equipment and facilities must be made from materials which can be appropriately cleaned and disinfected;

- (c) appropriate equipment must be available for cleaning and disinfection of facilities, equipment and means of transport;
- (d) appropriate predator control measures must be put in place, taking into account the risk of disease spread these predators pose;
- (e) appropriate disinfection equipment must be in place to ensure that waste water which is discharged from the dispatch centre is treated when required to ensure that any agents of listed or emerging diseases which are present are inactivated prior to discharge.

## PART 7

**Requirements for granting approval of relaying areas as referred to in Article 14**

1. The requirements in relation to biosecurity measures of relaying areas as referred to in point (a) of Article 14, shall be the following:
  - (a) operators shall implement the biosecurity plan in accordance with Article 5, which must take the following elements into consideration:
    - (i) disinfection points must be installed at critical locations in the relaying area;
    - (ii) work clothing and footwear for personnel must be kept solely for use at the relaying area and cleaned and disinfected regularly;
    - (iii) equipment must not be shared between aquaculture establishments but in cases where this is unavoidable, an appropriate protocol for cleaning and disinfection of the equipment must be put in place;
    - (iv) visitors to the relaying area must be controlled in cases where they pose a risk for the spread of disease; these visitors must either:
      - wear protective clothing and footwear provided at the relaying area, or
      - clean and disinfect any protective clothing and footwear they bring onto the relaying area on arrival and in the case of non-disposable clothing and footwear, on departure;
    - (v) as far as possible, equipment in the relaying area must be cleaned and disinfected at the end of the purification cycle.
2. The requirements in relation to facilities and equipment of relaying areas as referred to in point (b) of Article 14, shall be the following:
  - (a) as far as possible, the relaying area must provide for good standards of hygiene;
  - (b) as far as possible, equipment and facilities must be made from materials which can be appropriately cleaned and disinfected;
  - (c) appropriate equipment must be available for cleaning and disinfection of facilities where relevant, and equipment and means of transport;
  - (d) appropriate predator control measures must be put in place, taking into account the risk of disease spread these predators pose and the environmental constraints of the relaying area.

## PART 8

**Requirements for granting approval of quarantine establishments as referred to in Article 15**

1. The requirements in relation to biosecurity measures of quarantine establishments for aquatic animals as referred to in point (a) of Article 15 shall be the following:
  - (a) the quarantine establishment must be located at a secure distance from other quarantine establishments, aquaculture establishments or groups of aquaculture establishments by a distance specified by the competent authority on the basis of a risk assessment which must take into account the epidemiology of the relevant listed and emerging diseases;

- (b) the operator shall implement the biosecurity plan which is provided for in Article 5 and which must include at least the following elements:
    - (i) disinfection points must be installed at critical locations as identified in the biosecurity plan;
    - (ii) where they exist within the same quarantine establishment, measures must be taken to ensure that quarantine units remain epidemiologically separate from each other;
    - (iii) work clothing and footwear for personnel must be kept at the quarantine establishment and cleaned and disinfected regularly;
    - (iv) equipment must not be shared between quarantine units within the quarantine establishment, but in cases where this is unavoidable, an appropriate protocol for cleaning and disinfection of the equipment must be put in place; equipment must not be shared with other establishments;
    - (v) only authorised persons may enter the quarantine establishment;
    - (vi) persons entering the quarantine establishment must wear the protective clothing and footwear provided and these must be safely disposed of or cleaned and disinfected after use;
    - (vii) dead animals must be removed from all quarantine units at a frequency that ensures infective pressure is kept to a minimum and disposed of as Category 1 or Category 2 material in compliance with Article 12 or Article 13 of Regulation (EC) No 1069/2009;
    - (viii) all equipment in the quarantine establishments must be cleaned and disinfected at the end of each quarantine period;
    - (ix) the required quarantine period must start when the last aquatic animal in the cohort to be quarantined is introduced;
    - (x) each quarantine unit must be emptied of animals, cleaned and disinfected at the end of the quarantine period and be kept free of animals for a period of at least seven days before new aquatic animals are introduced;
    - (xi) precautions must be taken to prevent cross-contamination between incoming and outgoing consignments of aquatic animals;
    - (xii) animals released from the quarantine establishment must meet the requirements for movements of aquaculture animals between Member States;
  - (c) a named person must be in charge of implementing the biosecurity plan for the quarantine establishment with other personnel reporting to that individual in relation to biosecurity matters, where necessary.
2. The requirements in relation to surveillance and control measures of quarantine establishments for aquaculture animals, as referred to in point (b) of Article 15, shall be the following:
- (a) environmental conditions which are conducive to the clinical expression of the relevant listed or emerging disease must be kept in the quarantine establishment throughout the entire quarantine period;
  - (b) all aquaculture animals that die or show symptoms of disease *during* the quarantine period must be clinically inspected by a veterinarian and testing of samples must be carried out at a laboratory designated by the competent authority for that purpose;
  - (c) fish, molluscs and crustaceans of listed species must be quarantined under the conditions set out in point (a) for a period of at least 90 days;
  - (d) within a period of 15 days from the date of expiry of the quarantine period, samples must be taken from a number of aquaculture animals that will ensure the detection of the relevant pathogen with a 95 % confidence if the target prevalence is 2 %. These aquaculture animals may be taken from the cohort which is undergoing quarantine or from co-habiting sentinel aquaculture animals which are susceptible to the relevant listed or emerging disease and which are used as a diagnostic aid during the quarantine period.
3. The requirements in relation to facilities and equipment of quarantine establishments for aquaculture animals, as referred to in point (c) of Article 15, shall be the following:
- (a) the water supply to the quarantine establishment must be free of agents of the relevant listed or emerging disease;

- (b) the waste water from the quarantine establishment must be treated appropriately to ensure that the infectious agent(s) of listed and emerging diseases are inactivated before discharge;
- (c) the waste water treatment system must be fitted with a fail-safe backup mechanism to ensure its continuous operation and the complete containment of the relevant infectious agent(s);
- (d) the quarantine establishments must be clearly demarcated and the access of animals and humans must be controlled;
- (e) staff responsible for carrying out veterinary checks must have sufficiently equipped premises at their disposal, where necessary, including changing rooms and showers;
- (f) adequate means for isolating aquaculture animals must be available for use when required;
- (g) floors, walls and all other material or equipment must be constructed so that they can be adequately cleaned and disinfected;
- (h) an appropriate system must be in place to ensure the collection and appropriate disposal of animal by-products in compliance with Article 13 of Regulation (EC) No 1069/2009;
- (i) appropriate predator control measures are put in place, taking into account the risk of disease spread that these predators pose;
- (j) the part of the quarantine establishment accommodating the aquaculture animals must be of a suitable standard and so constructed that contact with water and animals outside is prevented and that inspection and any necessary husbandry procedures can be easily carried out.

#### PART 9

##### **Requirements for granting approval of aquaculture establishments keeping aquaculture animals of vector species in isolation, until such time as they are no longer regarded as vectors, as referred to in Article 16**

1. The requirements in relation to biosecurity measures 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, as referred to in point (a) of Article 16 shall be the following:
  - (a) operators shall implement the biosecurity plan in accordance Article 5, which must include at least the following elements:
    - (i) disinfection points must be installed at critical locations in the aquaculture establishment;
    - (ii) where different isolation units exist within the same aquaculture establishment, appropriate measures must be taken to ensure they remain epidemiologically separate from each other;
    - (iii) work clothing and footwear for personnel must be kept solely for use at the aquaculture establishment and cleaned and disinfected regularly;
    - (iv) equipment must not be shared between isolation units within the aquaculture establishment but where this is unavoidable, an appropriate protocol for cleaning and disinfection of the equipment must be put in place; equipment must not be shared with other establishments;
    - (v) only authorised persons must enter the aquaculture establishment;
    - (vi) persons entering the aquaculture establishment must wear the protective clothing and footwear provided and these must be safely disposed of or cleaned and disinfected after use;
    - (vii) dead animals must be removed from all production units in the establishment at a frequency that ensures infective pressure is kept to a minimum, and must be disposed of in compliance with Article 13 of Regulation (EC) No 1069/2009;
    - (viii) all equipment in the aquaculture establishment, or in the relevant isolation unit, if the aquaculture establishment consists of more than one such unit, must be cleaned and disinfected at the end of each isolation period;
    - (ix) the isolation period referred to in point 2 shall only start when the last animal in the cohort is introduced to the aquaculture establishment, or when there are a number of isolation units in the aquaculture establishment, the isolation period shall only start when the last animal in the cohort is introduced to the isolation unit;



- (x) each isolation unit in the aquaculture establishment must be emptied of animals, and cleaned and disinfected at the end of the isolation period;
  - (xi) precautions must be taken to prevent cross-contamination between incoming and outgoing consignments of aquatic animals;
  - (xii) animals released from the aquaculture establishment in which the isolation period has been undergone shall meet the requirements for movements of aquatic animals between Member States.
- (b) operators shall ensure that a named person is charged with implementing the biosecurity plan for the aquaculture establishment with other personnel reporting to that individual in relation to biosecurity matters, where necessary.
2. The requirements in relation to surveillance and control measures of establishments keeping aquaculture animals of listed species which are vectors in isolation until such time as they are no longer regarded as vectors, as referred to in point (b) of Article 16, shall be the following:
- (a) fish, molluscs and crustaceans of listed species shall be kept in isolation for a period of at least 90 days;
  - (b) all aquaculture animals that die or show symptoms of disease during the 90 day isolation period must be clinically inspected by a veterinarian and testing of samples must be carried out at a laboratory designated by the competent authority for that purpose.
3. The requirements in relation to facilities and equipment 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, as referred to in point (c) of Article 16, shall be the following:
- (a) adequate means of keeping aquaculture animals in isolation must be available;
  - (b) the water supply to the aquaculture establishment must be free of listed species and of agents of the relevant listed and emerging diseases;
  - (c) where this is necessary so as not to jeopardise the health status of receiving waters, the waste water from the aquaculture establishment must be treated appropriately to ensure that the infectious agent(s) of listed and emerging diseases are inactivated before discharge;
  - (d) the access of animals to the aquaculture establishment is controlled;
  - (e) floors, walls and all other material or equipment are constructed so that they can be adequately cleaned and disinfected;
  - (f) an appropriate system is in place to ensure the collection and appropriate disposal of animal by-products in compliance with Article 13 of Regulation (EC) No 1069/2009;
  - (g) appropriate predator control measures are put in place, taking into account the risk of disease spread that these predators pose.

#### PART 10

##### **Requirements for granting approval of aquaculture establishments which are closed facilities keeping aquaculture animals for ornamental purposes as referred to in Article 17**

1. The requirements in relation to biosecurity measures of aquaculture establishments which are closed facilities keeping aquaculture animals for ornamental purposes which, because of their movement patterns, create a significant disease risk, as referred to in Article 17 shall be the following:
- (a) the operator shall implement the biosecurity plan in accordance with Article 5, which must take the following elements into consideration:
    - (i) disinfection points must be installed at critical locations in the establishment;
    - (ii) work clothing and footwear for personnel must be kept solely for use at the aquaculture establishment and cleaned and disinfected regularly;

- (iii) visitors to the aquaculture establishment must be controlled in cases where they pose a disease risk. These visitors must either:
    - wear protective clothing and footwear provided at the aquaculture establishment, or
    - clean and disinfect any protective clothing and footwear they bring onto the aquaculture establishment on arrival and in the case of non-disposable clothing and footwear, on departure;
  - (iv) dead animals must be removed from all production units at a frequency that ensures infective pressure is kept to a minimum and disposed of in compliance with Article 13 of Regulation (EC) No 1069/2009.
  - (b) a named person must be in charge of implementing the biosecurity plan for the aquaculture establishment with other personnel reporting to that individual in relation to biosecurity matters, where necessary.
2. The requirements in relation to facilities and equipment of the aquaculture establishments which are closed facilities keeping aquaculture animals for ornamental purposes which, because of their movement patterns, create a significant disease risk, as referred to in point (c) of Article 17, shall be the following:
- (a) suitable equipment and facilities must be available for the purpose of maintaining appropriate husbandry conditions for the animals kept in the establishment;
  - (b) the aquaculture establishment must provide for good standards of hygiene and allow health monitoring to be carried out;
  - (c) the equipment and facilities must be made from materials which can be readily cleaned and disinfected;
  - (d) appropriate equipment must be available for cleaning and disinfection of facilities, equipment and means of transport;
  - (e) appropriate predator control measures must be put in place, taking into account the risk of disease spread that these predators pose;
  - (f) an appropriate system must be in place to ensure the collection and appropriate disposal of animal by-products in compliance with Article 13 of Regulation (EC) No 1069/2009.

#### PART 11

##### **Requirements for granting approval of aquaculture establishments which are open facilities keeping aquaculture animals for ornamental purposes as referred to in Article 18**

1. The requirements in relation to biosecurity measures of aquaculture establishments which are open facilities keeping aquaculture animals for ornamental purposes as referred to in point (b) of Article 18, shall be the following:
- (a) the operator shall implement the biosecurity plan in accordance with Article 5, which must take the following elements into consideration:
    - (i) disinfection points must be installed at critical locations in the aquaculture establishment;
    - (ii) where they exist within the same aquaculture establishment, functional units must be kept separate using appropriate hygiene measures;
    - (iii) work clothing and footwear for personnel must be kept at the aquaculture establishment and cleaned and disinfected regularly;
    - (iv) equipment must not be shared between aquaculture establishments but in cases where this unavoidable, an appropriate protocol for cleaning and disinfection of the equipment must be put in place;
    - (v) visitors to the aquaculture establishment must be controlled in cases where they pose a disease risk. These visitors must either:
      - wear protective clothing and footwear provided at the aquaculture establishment, or
      - clean and disinfect any protective clothing and footwear they bring onto the aquaculture establishment on arrival and in the case of non-disposable clothing and footwear, on departure;

- (vi) dead animals must be removed from all production units at a frequency that ensures infective pressure is kept to a minimum and disposed of in compliance with Article 13 of Regulation (EC) No 1069/2009;
  - (vii) as far as possible, equipment in the aquaculture establishment must be cleaned and disinfected at the end of each production cycle;
  - (viii) the cleaning and disinfection records of transporters must be verified before animals are loaded or unloaded at the aquaculture establishment;
- (b) operators shall ensure that a named person is charged with implementing the biosecurity plan for the aquaculture establishment with other personnel reporting to that individual in relation to biosecurity matters, where necessary.
2. The requirements in relation to facilities and equipment of aquaculture establishments which are open facilities keeping aquaculture animals for ornamental purposes as referred to in point (c) of Article 18, shall be the following:
- (a) suitable equipment and facilities must be available for the purpose of maintaining appropriate husbandry conditions for the animals kept in the aquaculture establishment;
  - (b) the establishment must provide for good standards of hygiene and allow adequate health monitoring to be carried out;
  - (c) as far as possible, equipment and facilities must be made from materials which can be appropriately cleaned and disinfected;
  - (d) appropriate predator control measures must be put in place, taking into account the risk these predators pose and the environmental constraints of the aquaculture establishment;
  - (e) appropriate equipment must be available for the cleaning and disinfection of facilities, equipment and means of transport;
  - (f) an appropriate system is in place to ensure the collection and appropriate disposal of animal by-products in compliance with Article 13 of Regulation (EC) No 1069/2009.

#### PART 12

#### **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 as referred to in Article 19**

1. The requirements in relation to biosecurity measures of vessels or other mobile premises where aquaculture animals are kept temporarily to be treated or to undergo another husbandry related procedure as referred to in point (a) of Article 19, shall be the following:
- (a) the operator shall implement the biosecurity plan in accordance with Article 5, which must take the following elements into consideration:
    - (i) the vessel or mobile premises and all equipment used during the treatment process must be cleaned and disinfected when a treatment has been completed and before it moves to another aquaculture establishment;
    - (ii) work clothing and footwear for personnel must be kept at the aquaculture establishment and cleaned and disinfected regularly;
    - (iii) equipment must not be shared with other aquaculture establishments but in cases where this is unavoidable, an appropriate protocol for cleaning and disinfection of the equipment must be put in place and evidence of its implementation kept;
    - (iv) visitors to the aquaculture establishment must be controlled in cases where they cause a disease risk; these visitors must either:
      - wear protective clothing and footwear provided at the aquaculture establishment, or
      - clean and disinfect any protective clothing and footwear they bring onto the aquaculture establishment on arrival and in the case of non-disposable clothing and footwear, on departure;

- (v) the cause of any mortality which occurs during a treatment must be recorded and dead animals must be removed from the aquaculture establishment at a frequency that minimises infective pressure and which is practicable given the treatment schedule for the aquaculture animals concerned;
  - (vi) dead animals are removed at a frequency that ensures infective pressure is kept to a minimum and disposed of in compliance with Article 13 of Regulation (EC) No 1069/2009.
  - (b) operators shall ensure that a named person is charged with implementing the biosecurity plan for the establishment, with other personnel reporting to that individual in relation to biosecurity matters, where necessary.
2. The requirements in relation to facilities and equipment of vessels or other mobile premises where aquaculture animals are kept temporarily to be treated or to undergo another husbandry-related procedure as referred to in point (b) of Article 19, shall be the following:
- (a) suitable equipment and facilities must be available for the purpose of maintaining appropriate husbandry conditions for the aquaculture animals kept in the establishment;
  - (b) as far as possible, equipment and facilities must be made from materials which can be readily cleaned and disinfected;
  - (c) appropriate equipment must be available for cleaning and disinfection of facilities and equipment;
  - (d) where automated cleaning and disinfection systems are used, their efficacy must be validated before their initial use and at appropriate frequencies thereafter;
  - (e) an appropriate system is in place to ensure the collection and appropriate disposal of animal by-products in compliance with Article 13 of Regulation (EC) No 1069/2009.
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## ANNEX II

**RISK-BASED SURVEILLANCE TO BE CARRIED OUT IN CERTAIN APPROVED ESTABLISHMENTS**

## PART 1

**Risk-based surveillance in aquaculture establishments and groups thereof referred to in Articles 7, 8, 17 and 18**

Risk-based surveillance shall be implemented as follows in the aquaculture establishments, and groups thereof, which are referred to in Articles 7, 8, 17 and 18:

- (a) aquaculture establishments keeping listed species of aquaculture animals other than the species referred to in point (b)(ii) of this Part, shall implement risk-based surveillance according to their ranking as 'high', 'medium' or 'low' risk as a result of a risk assessment carried out in accordance with Part I of Annex VI to Delegated Regulation (EU) 2020/689;
- (b) aquaculture establishments keeping the species of aquaculture animals referred to in points (i) and (ii) shall implement risk-based surveillance if they have been ranked as 'high' risk as a result of a risk assessment carried out in accordance with Part I of Annex VI to Delegated Regulation (EU) 2020/689:
  - (i) non-listed species;
  - (ii) listed species referred to in the fourth column of the table set out in the Annex to Implementing Regulation (EU) 2018/1882; but those listed species must be in contact with the listed species referred to in the third column of that table in order to be classified as vectors species, and that contact has not occurred.

## PART 2

**Content of risk-based surveillance at aquaculture establishments or groups thereof conducted in accordance with Article 26 of Regulation (EU) 2016/429**

1. Record checks, clinical inspections and laboratory examinations at the approved aquaculture establishments referred to in Articles 7, 17 and 18 shall be carried out as follows:
  - (a) the relevant records kept in accordance with the record-keeping obligations of Article 186 of Regulation (EU) 2016/429 and with Articles 23, 32 and 33 of this Regulation must be examined to assess if there are any indications of increased mortality or the presence of a listed or emerging disease in the aquaculture establishment which must be taken into account during the visit by a veterinarian;
  - (b) all parts of the aquaculture establishment must be examined with particular attention being paid to those production units where increased mortalities have been indicated in the records referred to in point (a);
  - (c) where there are no indications of the presence of a listed or emerging disease either from an examination of the records or from the clinical inspection of all production units, there shall be no requirement to take samples for laboratory examination;
  - (d) where recently dead or moribund aquaculture animals are identified, a representative selection of these aquaculture animals must be examined clinically, both externally and internally, to determine if pathological changes are present; that examination must in particular, aim at detecting listed or emerging diseases;
  - (e) if the outcome of the clinical examination provided for in point (d) leads to a suspicion of the presence of such a listed or emerging disease in an aquaculture establishment in a Member State, zone or compartment in which an eradication programme is being implemented, or which has been declared free from that particular disease, a sample of aquaculture animals from that aquaculture establishment shall be collected and subjected to a laboratory examination in accordance with the relevant Chapter of Part II of Annex VI to Delegated Regulation (EU) 2020/689;
  - (f) if the outcome of the clinical examination provided for in point (d) leads to a suspicion of the presence of a listed disease in an aquaculture establishment in which a surveillance programme is being implemented for that particular category C disease, a sample of aquaculture animals from the aquaculture establishment shall be collected and subjected to a laboratory examination in accordance with the relevant Chapter of Part III of Annex VI to Delegated Regulation (EU) 2020/689;

- (g) if the outcome of the clinical examination provided for in point (d) leads to the suspicion of an emerging disease, a sample of aquaculture animals from the aquaculture establishment shall be collected and subjected to a laboratory examination with the objective of identifying the emerging disease in question.
2. Record checks and clinical and laboratory examinations at the approved groups of aquaculture establishments referred to in Article 8 shall be carried out as follows:
- (a) the relevant records kept by or on behalf of each aquaculture establishment in the group of aquaculture establishments in accordance with Article 186 of Regulation (EU) 2016/429 and with Article 24 of this Regulation, must be examined to assess if there are indications of increased mortality or of the presence of a listed or emerging disease which must be taken into account when deciding which aquaculture establishment in the group is required to be visited for the purpose of risk-based surveillance;
  - (b) when the examination of records referred to in point (a) indicates increased mortality or the presence of a listed or emerging disease in a particular aquaculture establishment within the group, that establishment must be visited for the purpose of risk based surveillance; the steps outlined in point 1(b) to (g) must be followed during that visit;
  - (c) when the examination of records referred to in point (a) does not indicate increased mortality or the presence of a listed or emerging disease in any aquaculture establishment within the group, the risk-based surveillance visit or visits shall be carried out either:
    - (i) after risk assessment, in the aquaculture establishment or aquaculture establishments within the group which pose the highest risk of disease introduction; or
    - (ii) to the establishment which has had the greatest number of movements of aquaculture animals for further farming, since the last risk-based surveillance visit was carried out.

In either case, the steps outlined in point 1 (c) to (g) must be followed during the risk-based surveillance visit.

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