

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') (Text with EEA relevance)

PART IV

**REGISTRATION, APPROVAL, TRACEABILITY AND MOVEMENTS**

TITLE II

**AQUATIC ANIMALS AND PRODUCTS OF  
ANIMAL ORIGIN FROM AQUATIC ANIMALS**

CHAPTER I

***Registration, approval, record-keeping and registers***

*Section 1*

***Registration of aquaculture establishments***

*Article 172*

**Obligation of operators to register aquaculture establishments**

- 1 Operators of aquaculture establishments shall, in order for their establishments to be registered in accordance with Article 173, before they commence such activities:
- a inform the competent authority of any aquaculture establishment under their responsibility;
  - b provide the competent authority with the following information:
    - (i) the name and address of the operator concerned;
    - (ii) the location of the establishment and a description of its facilities;
    - (iii) the species, categories and quantities (numbers, volume or weight) of aquaculture animals which they intend to keep on the aquaculture establishment and the capacity of the aquaculture establishment;
    - (iv) the type of aquaculture establishment; and
    - (v) any other aspects of the establishment which are relevant for the purpose of determining the risk posed by it.
- 2 Operators of aquaculture establishments referred to in paragraph 1 shall inform the competent authority in advance of:
- a any significant changes in the aquaculture establishment in question concerning the matters referred to in point (b) of paragraph 1;

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b any cessation of activity by the operator or aquaculture establishment concerned.

3 Aquaculture establishments which are subject to approval in accordance with Article 176(1) and Article 177 shall not be required to provide the information referred to in paragraph 1 of this Article.

4 An operator may apply for registration as provided for in paragraph 1 to cover a group of aquaculture establishments, provided that they fulfil either of the following conditions:

- a they are located in an epidemiologically linked area and all operators in that area operate under a common biosecurity system;
- b they are under the responsibility of the same operator and operate under a common biosecurity system, and the aquaculture animals of the establishments concerned form part of a single epidemiological unit.

Where an application for registration covers a group of establishments, the rules laid down in paragraphs 1 to 3 of this Article and in point (b) of the first paragraph of Article 173, and the rules adopted pursuant to Article 175 which are applicable to a single aquaculture establishment, shall be applicable to the group of aquaculture establishments as a whole.

#### *Article 173*

##### **Obligations of the competent authority concerning the registration of aquaculture establishments**

A competent authority shall register:

- (a) aquaculture establishments in the register of aquaculture establishments provided for in Article 185(1), where the operator concerned has provided the information required in accordance with Article 172(1);
- (b) groups of aquaculture establishment in that register, provided that the criteria laid down in Article 172(4) are complied with.

The competent authority shall assign each establishment or group of establishments as referred to in this Article with a unique registration number.

#### *Article 174*

##### **Derogations from the obligation of operators to register aquaculture establishments**

By way of derogation from Article 172(1), Member States may exempt from the registration requirement certain aquaculture establishments posing an insignificant risk, as provided for in an implementing act adopted in accordance with Article 175.

#### *Article 175*

##### **Implementing powers concerning derogations from the obligation to register aquaculture establishments**

1 The Commission may, by means of implementing acts, lay down rules concerning the information to be provided by operators for the purpose of the registration of aquaculture

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establishments as provided for in Article 172(1), including the time-limits by which such information is to be provided.

2 The Commission shall, by means of implementing acts, lay down rules concerning the types of aquaculture establishments that may be exempted by Member States from the registration requirement in accordance with Article 174, based on:

- a the species, categories and quantity (number, volume or weight) of aquaculture animals on the aquaculture establishment in question and the capacity of that establishment;
- b the movements of aquaculture animals into and out of the aquaculture establishment.

3 The implementing acts referred to in this Article shall be adopted in accordance with the examination procedure referred to in Article 266(2).

## *Section 2*

### ***Approval of certain types of aquaculture establishments***

#### *Article 176*

### **Approval of certain aquaculture establishments and delegated acts**

1 Operators of the following types of aquaculture establishments shall apply to the competent authority for approval in accordance with Article 180(1):

- a aquaculture establishments where aquaculture animals are kept with a view to their being moved therefrom, either alive or as products of aquaculture animal origin;
- b other aquaculture establishments which pose a significant risk due to:
  - (i) the species, categories and number of aquaculture animals kept there;
  - (ii) the type of aquaculture establishment concerned;
  - (iii) movements of aquaculture animals into and out of the aquaculture establishment concerned.

2 By way of derogation from paragraph 1, Member States may exempt from the obligation to apply for approval operators of the following types of establishment:

- a aquaculture establishments producing a small quantity of aquaculture animals for supply for human consumption either:
  - (i) to the final consumer directly; or
  - (ii) to local retail establishments directly supplying the final consumer;
- b ponds and other installations where the population of aquatic animals is maintained only for recreational fishing purposes, by restocking with aquaculture animals which are confined and unable to escape;
- c aquaculture establishments keeping aquaculture animals for ornamental purposes in closed facilities,

provided that the establishment in question does not pose a significant risk.

3 Unless a derogation has been granted under paragraph 4 of this Article, operators shall not commence activity at an aquaculture establishment as referred to in paragraph 1 of this Article until that establishment has been approved in accordance with Article 181(1), and shall

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cease such activity at an aquaculture establishment referred to in paragraph 1 of this Article where:

- a the competent authority withdraws or suspends its approval in accordance with Article 184(2); or
- b in the event of conditional approval, granted in accordance with Article 183(3), the aquaculture establishment concerned fails to comply with the outstanding requirements referred to in Article 183(4) and does not obtain a final approval in accordance with Article 183(3).

4 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

- a derogations from the requirement for operators to apply to the competent authority for approval of the types of aquaculture establishments referred to in point (a) of paragraph 1, concerning types of establishments other than those specified in points (a)(i) and (ii) of paragraph 2, where those establishments do not pose a significant risk;
- b the types of aquaculture establishments which must be approved in accordance with point (b) of paragraph 1.

5 When adopting delegated acts as provided for in paragraph 4, the Commission shall base those acts on the following criteria:

- a the species and categories of aquaculture animals kept in an aquaculture establishment;
- b the type of aquaculture establishment and the type of production; and
- c typical movement patterns of the type of aquaculture establishment concerned and of the species or category of aquaculture animals concerned.

6 An operator may apply for approval of a group of aquaculture establishments, provided that the requirements provided for in points (a) and (b) of the first paragraph of Article 177 are complied with.

#### *Article 177*

#### **Approval by the competent authority of groups of aquaculture establishments**

The competent authority may grant approval as provided for in Article 181(1) covering a group of aquaculture establishments, provided that the aquaculture establishments in question comply with either of the following conditions:

- (a) they are located in an epidemiologically linked area and all operators in that area operate under a common biosecurity system; however, any on-shore or off-shore establishment for the reception, conditioning, washing, cleaning, grading, wrapping and packaging of live bivalve molluscs intended for human consumption (so-called 'dispatch centres'), establishment with tanks fed by clean seawater in which live bivalve molluscs are placed for the time necessary to reduce contamination to make them fit for human consumption (so-called 'purification centres') and similar establishments located inside such an epidemiologically linked area must be approved individually;
- (b) they are under the responsibility of the same operator; and
  - (i) operate under a common biosecurity system; and
  - (ii) the aquaculture animals of the establishments concerned form part of the same epidemiological unit.

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When a single approval is granted for a group of aquaculture establishments, the rules laid down in Article 178 and Articles 180 to 184 and the rules adopted pursuant to Articles 180(2) and 181(2), which are applicable to a single aquaculture establishment, shall be applicable to the whole group of aquaculture establishments.

#### *Article 178*

##### **Approval of status of confined aquaculture establishments**

Operators of aquaculture establishments wishing to obtain the status of a confined establishment shall:

- (a) apply to the competent authority for approval in accordance with Article 180(1);
- (b) move aquaculture animals to or from their establishment in accordance with the requirements provided for in Article 203(1) and any delegated acts adopted in accordance with Article 203(2) only after their establishment has obtained an approval of that status from the competent authority in accordance with Article 181 or 183.

#### *Article 179*

##### **Approval of disease control aquatic food establishments**

Operators of disease control aquatic food establishments shall:

- (a) ensure that the necessary approval in accordance with Article 4 of Regulation (EC) No 853/2004 of the European Parliament and of the Council<sup>(1)</sup> has been obtained; and
- (b) apply to the competent authority, in accordance with Article 180(1), for approval to slaughter or process aquatic animals for disease control purposes in accordance with point (b) of Article 61(1), Article 62 and Articles 68(1), 79 and 80 and the rules adopted pursuant to Article 63 and Articles 70(3) and 71(3).

#### *Article 180*

##### **Obligation of operators to provide information with a view to obtaining approval**

1 Operators shall, for the purposes of their application for approval of their establishment as provided for in Article 176(1), Article 177, point (a) of Article 178 and Article 179, provide the competent authority with the following information:

- a the name and address of the operator concerned;
- b the location of the establishment concerned and a description of its facilities;
- c the species, categories and quantities (numbers, volume or weight) of aquaculture animals relevant for the approval which are kept on the establishment;
- d the type of aquaculture establishment;
- e in cases of approval of a group of aquaculture establishments, details showing that the group in question complies with the conditions laid down in Article 177;
- f other aspects of the mode of operation of the aquaculture establishment in question which are relevant for determining the risk, posed by it;
- g the water supply to, and discharge of water from, the establishment;
- h the establishment's biosecurity measures.

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2 Operators of establishments as referred to in paragraph 1 shall inform the competent authority in advance of:

- a any changes in the establishments concerning the matters referred to in paragraph 1;
- b any cessation of activity by the operator or establishment concerned.

3 The Commission may, by means of implementing acts, lay down rules concerning the information to be provided by operators in their application for approval of their establishment, in accordance with paragraph 1, including the time-limits by which such information is to be provided.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

### Article 181

#### **Granting of, and conditions for, approval and delegated acts**

1 The competent authority shall only grant approvals of aquaculture establishments as referred to in Article 176(1) and point (a) of Article 178, groups of aquaculture establishments as referred to in Article 177 and disease control aquatic food establishments as referred to in Article 179, where such establishments:

- a comply with the following requirements, where appropriate, in relation to:
  - (i) quarantine, isolation and other biosecurity measures taking into account the requirements provided for in point (b) of Article 10(1) and any rules adopted pursuant to Article 10(6);
  - (ii) surveillance requirements as provided for in Article 24, where relevant for the type of establishment concerned and the risk involved, in Article 25;
  - (iii) record-keeping as provided for in Articles 186 to 188 and any rules adopted pursuant to Articles 189 and 190;
- b have facilities and equipment that are:
  - (i) adequate to reduce the risk of the introduction and spread of diseases to an acceptable level, taking into account the type of establishment concerned;
  - (ii) of a capacity adequate for the species, categories and quantity (numbers, volume or weight) of aquatic animals concerned;
- c do not pose an unacceptable risk as regards the spread of diseases, taking into account the risk-mitigation measures in place;
- d have in place a system which enables the operator concerned to demonstrate to the competent authority that the requirements laid down in points (a), (b) and (c) are fulfilled.

2 The Commission shall adopt delegated acts in accordance with Article 264 concerning:

- a quarantine, isolation and other biosecurity measures as referred to in point (a)(i) of paragraph 1;
- b surveillance as referred to in point (a)(ii) of paragraph 1;
- c facilities and equipment as referred to in point (b) of paragraph 1.

3 When establishing the rules to be laid down in the delegated acts to be adopted pursuant to paragraph 2, the Commission shall base those rules on the following matters:

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- a the risks posed by each type of establishment;
- b the species and categories of aquaculture or aquatic animals relevant for the approval;
- c the type of production concerned;
- d typical movement patterns of the type of aquaculture establishment and species and categories of animals kept in those establishments.

#### *Article 182*

### **Scope of the approval of establishments**

The competent authority shall expressly specify in the approval of an aquaculture establishment or a disease control aquatic food establishment granted pursuant to Article 181(1) following an application made in accordance with Article 176, Article 177, point (a) of Article 178 or Article 179:

- (a) for which of the types of aquaculture establishments referred to in Article 176(1) and point (a) of Article 178, groups of aquaculture establishments referred to in Article 177 and disease control aquatic food establishments referred to in Article 179, and in any rules adopted pursuant to point (b) of Article 176(4), the approval applies;
- (b) for which species and categories of aquaculture animals the approval applies.

#### *Article 183*

### **Procedures for the granting of approval by the competent authority**

1 The competent authority shall establish procedures for operators to follow when applying for approval of their establishments in accordance with Article 176(1) and Articles 178 and 179.

2 Upon receipt of an application for approval from an operator in accordance with Article 176(1), Article 178 or Article 179, the competent authority shall make an on-site visit.

3 Provided that the requirements referred to in Article 181 are fulfilled, the competent authority shall grant the approval.

4 Where an establishment does not fulfil all requirements for approval as referred to in Article 181, the competent authority may grant conditional approval of an establishment if it appears, on the basis of the application by the operator concerned and the subsequent on-site visit provided for in paragraph 2 of this Article, that the establishment meets all the main requirements that provide sufficient guarantees that the establishment does not pose a significant risk.

5 Where conditional approval has been granted by the competent authority in accordance with paragraph 4 of this Article, it shall grant full approval only where it appears from another on-site visit to the establishment, carried out within three months from the date of the grant of conditional approval, or from documentation provided by the operator within three months from that date, that the establishment meets all the requirements for approval provided for in Article 181(1) and the rules adopted pursuant to Article 181(2).

Where the on-site visit or the documentation referred to in the first subparagraph shows that clear progress has been made but that the establishment still does not meet all of those requirements, the competent authority may prolong the conditional approval.

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However, conditional approval shall not be granted for a period exceeding, in total, six months.

#### *Article 184*

##### **Review, suspension and withdrawal of approvals by the competent authority**

1 The competent authority shall keep approvals of establishments granted in accordance with Article 181(1) under review, at appropriate intervals based on the risk involved.

2 Where a competent authority identifies serious deficiencies in an establishment as regards compliance with the requirements laid down in Article 181(1) and the rules adopted pursuant to Article 181(2), and the operator of that establishment is not able to provide adequate guarantees that those deficiencies will be eliminated, the competent authority shall initiate procedures to withdraw the approval of the establishment.

However, the competent authority may merely suspend, rather than withdraw, approval of an establishment where the operator can guarantee that it will eliminate those deficiencies within a reasonable period of time.

3 Approval shall only be granted after withdrawal or restored after suspension in accordance with paragraph 2 when the competent authority is satisfied that the establishment fully complies with all the requirements of this Regulation appropriate for that type of establishment.

#### *Section 3*

##### ***Register of aquaculture establishments and disease control aquatic food establishments***

#### *Article 185*

##### **Register of aquaculture establishments and disease control aquatic food establishments**

1 Each competent authority shall establish and keep up to date a register of:

- a all aquaculture establishments registered in accordance with Article 173;
- b all aquaculture establishments approved in accordance with Article 181(1);
- c all disease control aquatic food establishments approved in accordance with Article 181(1).

2 The register of aquaculture establishments provided for in paragraph 1 shall contain the following information:

- a the name and address of the operator and the registration number of the establishment in question;
- b the location of the aquaculture establishment or, as the case may be, of the group of aquaculture establishments concerned;
- c the type of production at the establishment;
- d the water supply to, and discharge from, the establishment, when relevant;
- e the species of aquaculture animals kept at the establishment;
- f up-to-date information on the health status of the registered aquaculture establishment, or, as the case may be, of the group of establishments, as regards the listed diseases referred to in point (d) of Article 9(1).



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3 For establishments approved in accordance with Article 181(1), the competent authority shall make publicly available by electronic means at least the information referred to in points (a), (c), (e) and (f) of paragraph 2 of this Article, subject to data protection requirements.

4 Where appropriate and relevant, a competent authority may combine the registration provided for in paragraph 1 with registration for other purposes.

5 The Commission shall adopt delegated acts in accordance with Article 264 concerning:

- a the relevant detailed information to be included in the register of aquaculture establishments provided for in paragraph 1 of this Article;
- b the public availability of that register.

#### *Section 4*

#### ***Record-keeping and traceability***

#### *Article 186*

#### **Record-keeping obligations of operators of aquaculture establishments**

1 Operators of aquaculture establishments subject to the requirement of registration in accordance with Article 173, or approval in accordance with Article 181(1), shall keep and maintain records containing at least the following information:

- a the species, categories and quantities (numbers, volume or weight) of aquaculture animals on their establishment;
- b movements of aquaculture animals and products of animal origin obtained from those animals into and out of their establishment, stating as appropriate:
  - (i) their place of origin or destination;
  - (ii) the date of such movements;
- c the animal health certificates, in paper or electronic form, required to accompany movements of aquaculture animals arriving at the aquaculture establishment in accordance with Article 208 and the rules adopted pursuant to points (a) and (c) of Article 211(1) and Article 213(2);
- d mortality in each epidemiological unit and other disease problems at the aquaculture establishment as relevant for the type of production;
- e biosecurity measures, surveillance, treatments, test results and other relevant information as appropriate for:
  - (i) the species and categories of the aquaculture animals on the establishment;
  - (ii) the type of production at the aquaculture establishment;
  - (iii) the type and size of the aquaculture establishment;
- f the results of any animal health visits required in accordance with Article 25(1).

The records shall be kept and maintained in paper or electronic form.

2 Aquaculture establishments presenting a low risk of spreading listed or emerging diseases may be exempted by the Member State concerned from the requirement to keep records

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of all or some of the information listed in points (c), (d) and (e) of paragraph 1, provided that traceability is ensured.

3 Operators of aquaculture establishments shall keep the records provided for in paragraph 1 on their aquaculture establishment concerned and shall:

- a keep them in such a way that the tracing of the place of origin and destination of aquatic animals can be guaranteed;
- b make them available to the competent authority on request;
- c retain them for a minimum period to be prescribed by the competent authority, which may not be less than three years.

By way of derogation from the requirement that the records are to be kept on their establishment concerned, as set out in the first subparagraph, when it is physically not possible to keep the records on that establishment, they shall be kept in the office from which the business is administered.

#### *Article 187*

#### **Record-keeping obligations of disease control aquatic food establishments**

1 Operators of disease control aquatic food establishments subject to approval in accordance with Article 179 shall keep and maintain records of:

- a all movements into and from their establishment of aquaculture animals and products of animal origin obtained from such animals;
- b discharge of water and relevant biosecurity measures.

2 Operators of disease control aquatic food establishments shall:

- a keep the records provided for in paragraph 1 on their establishment and shall make them available to the competent authority on request;
- b retain those records for a minimum period to be prescribed by the competent authority, which may not be less than three years.

The records shall be kept and maintained in paper or electronic form.

#### *Article 188*

#### **Record-keeping obligations of transporters**

1 Transporters of aquatic animals intended for aquaculture establishments or to be released into the wild shall keep and maintain records in relation to:

- a the species, categories and quantities (numbers, volume or weight) of aquatic animals transported by them;
- b mortality rates of the aquaculture animals and wild aquatic animals in question during transport, in so far as is practicable for the type of transport and the species of aquaculture animals and wild aquatic animals transported;
- c aquaculture establishments and disease control aquatic food establishments visited by the means of transport;
- d any exchange of water that took place during transport, specifying the sources of new water and sites of release of water;
- e the cleaning and disinfection of the means of transport.

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The records shall be kept and maintained in paper or electronic form.

2 Transporters presenting a low risk of spreading listed or emerging diseases may be exempted by the Member State concerned from the requirement to keep records of all or some of the information listed in paragraph 1, provided that traceability is ensured.

3 Transporters shall keep the records provided for in paragraph 1:

- a in such a manner that they can be made immediately available to the competent authority on request;
- b for a minimum period to be prescribed by the competent authority, which may not be less than three years.

#### *Article 189*

### **Delegation of powers concerning record-keeping**

1 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning rules supplementing the record-keeping requirements provided for in Articles 186, 187 and 188, as regards information to be recorded by operators in addition to that provided for in Articles 186(1), 187(1) and 188(1).

2 The Commission shall take the following matters into account when adopting the delegated acts provided for in paragraph 1:

- a the risks posed by each type of aquaculture establishment or transport;
- b the species and categories of aquatic animals kept on the aquaculture establishment concerned, or transported to or from that establishment;
- c the type of production of the establishment;
- d typical movement patterns for the type of aquaculture establishment or disease control aquatic food establishment;
- e the numbers, volume or weight of aquatic animals kept on the establishment or transported to or from it.

#### *Article 190*

### **Implementing powers concerning exemptions from the record-keeping requirements**

The Commission may, by means of implementing acts, lay down rules concerning the types of aquaculture establishments and operators that may be exempted by Member States from the record-keeping requirements provided for in Articles 186 and 188, as regards:

- (a) operators of certain categories of aquaculture establishments and transporters;
- (b) aquaculture establishments keeping, or transporters transporting, respectively, a small number of aquaculture animals or a small number of aquatic animals;
- (c) certain species and categories of aquatic animals.

When adopting those implementing acts, the Commission shall base those acts on the criteria provided for in Article 189(2).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

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## CHAPTER 2

### *Movements within the Union of aquatic animals*

#### *Section 1*

#### **General requirements for movements**

#### *Article 191*

#### **General requirements for movements of aquatic animals**

1 Operators shall take appropriate measures to ensure that the movement of aquatic animals does not jeopardise the health status at the place of destination with regard to:

- a the listed diseases referred to in point (d) of Article 9(1);
- b emerging diseases.

2 Operators shall only move aquatic animals into an aquaculture establishment or for human consumption purposes, or release them into the wild, if the animals in question fulfil the following conditions:

- a they come, except in the case of wild aquatic animals, from establishments that have been:
  - (i) registered by the competent authority in accordance with Article 173,
  - (ii) approved by that competent authority in accordance with Articles 181 and 182, when required by Article 176(1), Article 177 or Article 178, or
  - (iii) granted a derogation from the registration requirement laid down in Article 173.
- b they are not subject to:
  - (i) movement restrictions affecting the species and categories concerned in accordance with the rules laid down in Article 55(1), Article 56, Article 61(1), Articles 62, 64 and 65, point (b) of Article 70(1), Article 74(1), Article 79 and Article 81 and the rules adopted pursuant to Article 55(2), Articles 63 and 67 and Articles 70(3), 71(3), 74(4) and 83(2); or
  - (ii) the emergency measures laid down in Articles 257 and 258 and the rules adopted pursuant to Article 259.

However, operators may move those aquatic animals where derogations from the movement restrictions for such movements or release are provided for in Title II of Part III (Articles 53–83) or derogations from emergency measures are provided for in rules adopted pursuant to Article 259.

3 Operators shall take all necessary measures to ensure that aquatic animals, after leaving their place of origin, are consigned directly to the final place of destination.

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## Article 192

### Disease prevention measures in relation to transport

1 Operators shall take the appropriate and necessary disease prevention measures to ensure that:

- a the health status of aquatic animals is not jeopardised during transport;
- b transport operations of aquatic animals do not cause the potential spread of listed diseases as referred to in point (d) of Article 9(1) to humans or animals en route, and at places of destination;
- c cleaning and disinfection of equipment and means of transport and other adequate biosecurity measures are taken, as appropriate to the risks involved with the transport operations concerned;
- d any exchanges of water and discharges of water during the transport of aquatic animals intended for aquaculture or release into the wild are carried out at places and under conditions which do not jeopardise the health status with regard to the listed diseases referred to in point (d) of Article 9(1) of:
  - (i) the aquatic animals being transported;
  - (ii) any aquatic animals en route to the place of destination;
  - (iii) aquatic animals at the place of destination.

2 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

- a the conditions and requirements for cleaning and disinfection of equipment and means of transport in accordance with point (c) of paragraph 1 of this Article and the use of biocidal products for such purposes;
- b other appropriate biosecurity measures during transport as provided for in point (c) of paragraph 1 of this Article;
- c water exchanges and discharges of water during transport as provided for in point (d) of paragraph 1 of this Article.

## Article 193

### Change of intended use

1 Aquatic animals which are moved for destruction or slaughter in accordance with the following measures shall not be used for any other purpose:

- a any of the disease control measures provided for in point (c) of Article 32(1) and Article 55(1), Articles 56, 61, 62, 64, 65 and 70, Articles 74(1) and (2) and Articles 79, 80, 81 and 82 and in the rules adopted pursuant to Article 55(2), Articles 63 and 67, Articles 70(3), 71(3) and 74(4), and Article 83(2);
- b emergency measures as provided for in Articles 257 and 258 and in rules adopted pursuant to Article 259.

2 Aquatic animals moved for human consumption, aquaculture, release into the wild or any other purpose, shall not be used for any purpose other than the intended one.

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3 By way of derogation from paragraph 2, the competent authority of the place of destination may authorise a change of use of aquatic animals for a purpose other than that originally intended, provided that the new use does not pose a higher risk to the health status of the aquatic animals at the place of destination than the originally intended use.

#### *Article 194*

### **Obligations of operators at the place of destination**

1 Operators of aquaculture establishments and disease control aquatic food establishments receiving aquatic animals and operators receiving aquatic animals for release into the wild shall, before the aquatic animals are unloaded:

- a check that, where required, one of the following documents is present:
  - (i) the animal health certificates provided for in Article 208(1), Article 209 and Article 223(1) and in the rules adopted pursuant to Articles 189, 211 and 213;
  - (ii) the self-declaration documents provided for in Article 218(1) and in the rules adopted pursuant to Article 218(3) and (4);
- b inform the competent authority of the place of destination, after checking the aquatic animals received, of any irregularity with regard to:
  - (i) the aquatic animals received;
  - (ii) the documents referred to in point (a)(i) and (ii).

2 In the event of any irregularity as referred to in point (b) of paragraph 1, the operator shall isolate the aquatic animals concerned by that irregularity until the competent authority of the place of destination has taken a decision regarding them.

#### *Article 195*

### **General requirements in respect of movements of aquaculture animals passing through Member States but intended for export from the Union to third countries or territories**

Operators shall ensure that aquaculture animals intended for export to a third country or territory and passing through the territory of another Member State fulfil the requirements laid down in Articles 191, 192 and 193.

#### *Section 2*

### ***Aquatic animals intended for aquaculture establishments or release into the wild***

#### *Article 196*

### **Abnormal mortalities or other serious disease symptoms**

1 Operators shall only move aquatic animals from an aquaculture establishment or from the wild to another aquaculture establishment, or release them into the wild, if the animals in question:

- a show no disease symptoms; and

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- b originate from an aquaculture establishment or environment where there are no abnormal mortalities with an undetermined cause.

2 By way of derogation from paragraph 1, the competent authority may, on the basis of an evaluation of the risks involved, authorise the movement or release of aquatic animals as referred to in that paragraph, provided that the animals in question originate from a part of the aquaculture establishment or from the wild that is independent of the epidemiological unit where the abnormal mortalities or other disease symptoms have occurred.

If the movement or release referred to in this paragraph is to be made to another Member State, it shall only be authorised by the competent authority if the competent authorities of the Member State of destination and, where relevant, of the Member States of passage have given their consent to such movement or release.

#### *Article 197*

#### **Movements of aquaculture animals intended for Member States, zones or compartments which have been declared disease-free or which are subject to an eradication programme, and delegated acts**

1 Operators shall only move aquaculture animals of listed species relevant for one or more of the listed diseases referred to in points (b) or (c) of Article 9(1) to an aquaculture establishment, or for release into the wild, in a Member State, zone or compartment which has been declared free of those listed diseases in accordance with Article 36(4) or 37(4), if the animals in question originate from a Member State, or a zone or compartment thereof, which has been declared free of those diseases.

2 Operators shall only move aquaculture animals of listed species relevant for one or more of the listed diseases referred to in points (b) or (c) of Article 9(1) to an aquaculture establishment, or for release into the wild, in a Member State, zone or compartment subject to an eradication programme for one or more of those listed diseases as provided for in Article 31(1) or (2), if the animals in question originate from a Member State, or a zone or compartment thereof, which has been declared free of those listed diseases.

3 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning derogations from the movement or release requirements laid down in paragraphs 1 and 2 of this Article which do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1) on account of:

- a the species, categories, and life stage of the aquaculture animals concerned;
- b the type of establishment of origin and of destination;
- c the intended use of the aquaculture animals;
- d the place of destination of the aquaculture animals;
- e treatments, processing methods and other special risk-mitigation measures applied at the place of origin or destination.

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#### Article 198

### **Derogations by Member States concerning the obligation of operators for movement of aquaculture animals between Member States, zones or compartments which are subject to an eradication programme**

By way of derogation from Article 197(1) and (2), Member States may authorise operators to move aquaculture animals into a zone or compartment for which an eradication programme has been established in accordance with Article 31(1) and (2) as regards the listed diseases referred to in points (b) and (c) of Article 9(1), from another zone or compartment for which such a programme has also been established for the same listed diseases, provided that such movement will not jeopardise the health status of the Member State, zone or compartment of destination.

If such movements are to be made to another Member State, the competent authority shall only authorise them if the competent authorities of the Member State of destination and, where relevant, of the Member States of passage, have given their consent to them.

#### Article 199

### **Member States' measures concerning the release of aquatic animals into the wild**

Member States may require that aquatic animals may be released into the wild only if they originate from a Member State, or a zone or compartment thereof, which has been declared disease-free in accordance with Article 36(1) or Article 37(1) as regards one or more of the listed diseases referred to in points (b) and (c) of Article 9(1) for which the species of aquatic animals to be moved is a listed species, regardless of the health status of the area where those aquatic animals are to be released.

#### Article 200

### **Movements of wild aquatic animals intended for Member States, or zones or compartments thereof, which have been declared disease-free or which are subject to an eradication programme, and delegated acts**

1 Articles 196, 197 and 198 shall apply to movements of wild aquatic animals intended for an aquaculture establishment or for release into the wild.

2 Operators shall take the appropriate and necessary disease prevention measures when moving wild aquatic animals between habitats to ensure that:

- a such movements do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1) to aquatic animals at the place of destination; and
- b risk-mitigation or other adequate biosecurity measures are in place where necessary to ensure compliance with point (a).

3 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the disease prevention and risk-mitigation measures to be taken by operators as provided for in paragraph 2 of this Article. Pending the adoption of such delegated acts, the competent authority of the place of destination may decide on such measures.



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### Section 3

#### ***Aquatic animals intended for human consumption***

##### *Article 201*

#### **Movements of live aquaculture animals intended for human consumption in Member States, or in zones or compartments thereof, which have been declared disease-free or which are subject to an eradication programme, and delegated acts**

1 Operators shall only move live aquaculture animals of listed species relevant for listed diseases as referred to in points (b) or (c) of Article 9(1) intended for human consumption to a Member State, or to a zone or compartment thereof, which has been declared disease-free in accordance with Article 36(4) or Article 37(4) or for which an eradication programme has been established in accordance with Article 31(1) or (2), as regards one or more of the listed diseases referred to in points (b) and (c) of Article 9(1), if the animals in question originate from a Member State, or a zone or compartment thereof, which has been declared disease-free in accordance with Article 36(4) or Article 37(4).

2 By way of derogation from paragraph 1 of this Article, Member States may authorise operators to introduce live aquaculture animals into a zone or compartment for which an eradication programme has been established in accordance with Article 31(1) or (2) as regards the listed diseases referred to in points (b) and (c) of Article 9(1), from another zone or compartment for which such a programme has also been established as regards the same diseases within that Member State, provided that such movement will not jeopardise the health status of the Member State or of the zone or compartment thereof.

3 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the derogations provided for in paragraph 2 of this Article in respect of movements of live aquaculture animals which do not pose a significant risk of spreading of diseases on account of:

- a the species, categories, and live stage of the aquaculture animals concerned;
- b the methods of keeping the aquaculture animals and the type of production in the aquaculture establishments of origin and of destination;
- c the intended use of the aquaculture animals;
- d the place of destination of the aquaculture animals;
- e treatments, processing methods and other special risk-mitigation measures applied at the place of origin or the place of destination.

##### *Article 202*

#### **Movements of live wild aquatic animals intended for Member States, or zones or compartments thereof, which have been declared disease-free or which are subject to an eradication programme, and delegated acts**

1 Article 201(1) and (2) and the rules adopted pursuant to Article 201(3) shall apply to movements of live wild aquatic animals intended for human consumption and which are intended for Member States, or zones or compartments thereof, which have been declared disease-free in accordance with Articles 36(4) or 37(4) or which are subject to an eradication programme in accordance with Article 31(1) or (2), where the measures adopted pursuant thereto are necessary in order to ensure that the animals in question do not pose a significant

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risk for the spread of listed diseases as referred to in point (d) of Article 9(1) to aquatic animals at the place of destination.

2 Paragraph 1 of this Article shall also apply to live aquatic animals not covered by the definition of aquaculture animals contained in Article 4(7).

3 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning movement requirements for wild aquatic animals intended for human consumption, supplementing paragraphs 1 and 2 of this Article.

#### *Section 4*

### ***Derogations from Sections 1 to 3 (Articles 191 to 202) and additional risk-mitigation measures***

#### *Article 203*

### **Aquatic animals intended for confined establishments for aquaculture and delegated acts**

1 Operators shall only move aquatic animals to a confined establishment for aquaculture if the animals in question fulfil the following conditions:

- a they originate from another confined establishment for aquaculture;
- b they do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1) to listed species of animals at the confined establishment for aquaculture of destination, except where the movement in question is authorised for scientific purposes.

2 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

- a detailed rules for movements of aquaculture animals to confined establishments for aquaculture in addition to those provided for in paragraph 1 of this Article;
- b specific rules for movements of aquaculture animals to confined establishments for aquaculture where the risk-mitigation measures in place guarantee that such movements do not pose a significant risk for the health of aquaculture animals within that confined establishment for aquaculture and the surrounding establishments.

#### *Article 204*

### **Movements of aquatic animals for scientific purposes and delegated acts**

1 The competent authority of the place of destination may, subject to the agreement of the competent authority of the place of origin, authorise movements of aquatic animals into the territory of the Member State of destination, for scientific purposes, where those movements do not fulfil the requirements of Sections 1 to 3 (Articles 191 to 202), with the exception of Article 191(1) and (3) and Articles 192, 193 and 194.

2 The competent authority referred to in paragraph 1 shall only grant derogations as provided for in that paragraph under the following conditions:

- a the competent authorities of the places of destination and origin:
  - (i) have agreed on the conditions for such movements;

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- (ii) ensure that the necessary risk-mitigation measures are in place so that movements of the aquatic animals in question do not jeopardise the health status in places en route and in the places of destination with regard to the listed diseases referred to in point (d) of Article 9(1);
  - (iii) have notified, where relevant, the competent authorities of the Member States of passage of the derogation granted and of the conditions under which it is granted;
- b those movements take place under the supervision of the competent authorities of the places of origin and destination, and where relevant, the competent authorities of the Member States of passage.
- 3 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning rules for the granting of derogations by competent authorities, supplementing those provided for in paragraphs 1 and 2 of this Article.

#### *Article 205*

#### **Other specific uses of aquatic animals, specific requirements and derogations and delegation of powers**

- 1 Operators shall take the necessary preventive measures to ensure that movements of aquatic animals intended for the specific purposes or uses listed in point (a)(i) to (vi) of paragraph 2 of this Article do not pose a risk for the spread of listed diseases as referred to in point (d) of Article 9(1) to aquatic animals at the place of destination.
- 2 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:
- a specific requirement supplementing the rules laid down in Sections 1 to 3 (Articles 191 to 202) and for movements of aquatic animals for the following purposes:
    - (i) zoos, pet shops, wholesalers and garden ponds;
    - (ii) exhibitions;
    - (iii) sports fishing, including fishing baits;
    - (iv) cultural and similar events;
    - (v) commercial aquaria; or
    - (vi) health care and other similar uses.
  - b derogations from Sections 1 to 3 (Articles 191 to 202) with the exception of Article 191(1) and (3) and Articles 192, 193 and 194 for the movements of aquatic animals referred to in point (a) of this paragraph, provided that adequate biosecurity provisions are in place to ensure that those movements do not pose a significant risk to the health status of the place of destination.

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### Article 206

#### **Implementing power to adopt temporary rules for movements of specific species or categories of aquatic animals**

1 The Commission may, by means of implementing acts, lay down temporary rules, by way of addition or alternative to those laid down in this Chapter, for movements of specific species or categories of aquatic animals where:

- a the movement requirements provided for in Article 196, Article 197(1), Articles 198 and 199, Article 200(1) and (2), Article 201 and Articles 202(1), 203(1), 204(1) and (2) and the rules adopted pursuant to Articles 197(3), 200(3), 202(3), 203(2) and 204(3) and Article 205 do not efficiently mitigate the risks posed by the movement of those aquatic animals; or
- b a listed disease as referred to in point (d) of Article 9(1) appears to be spreading despite the movement requirements laid down in accordance with Sections 1 to 4 (Articles 191 to 207).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

2 On duly justified imperative grounds of urgency relating to a listed disease representing a risk of a highly significant impact and taking into account the matters referred to in Article 205, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure provided for in Article 266(3).

### Article 207

#### **Matters to be taken into account in the adoption of delegated and implementing acts as provided for in this Section**

When establishing the rules to be laid down in the delegated and implementing acts provided for in Article 203(2), Article 204(3) and Articles 205 and 206, the Commission shall base those rules on:

- (a) the risks involved with the movements referred to in those provisions;
- (b) the health status as regards the listed diseases referred to in point (d) of Article 9(1) at the places of origin, passage and destination;
- (c) listed aquatic animal species for the listed diseases referred to in point (d) of Article 9(1);
- (d) biosecurity measures in place at the places of origin, passage and destination;
- (e) any specific conditions under which the aquaculture animals are kept;
- (f) specific movement patterns of the type of aquaculture establishment and the species or category of aquatic animals concerned;
- (g) other epidemiological factors.

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## Section 5

### **Animal health certification**

#### Article 208

#### **Obligation of operators to ensure that aquaculture animals are accompanied by an animal health certificate**

1 Operators shall only move aquaculture animals if they are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Article 216(1), where the animals in question are of listed species for the listed diseases referred to in points (b) and (c) of Article 9(1) and are intended for introduction into a Member State, or a zone or compartment thereof, which has been declared disease-free in accordance with Articles 36(4) and 37(4) or for which an eradication programme has been established as provided for in Article 31(1) or (2) as regards one or more of the listed diseases referred to in points (b) and (c) of Article 9(1).

2 Operators shall only move aquaculture animals if they are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Article 216(1), where the animals in question are of listed species for the relevant disease(s) referred to in points (a) and (b) of Article 9(1) and are allowed to leave a restricted zone subject to disease control measures as provided for in point (f)(ii) of Article 55(1), Articles 56 and 64 or Articles 65(1), 74(1), 79 and rules adopted pursuant to Article 55(2), Articles 67 and 68, Articles 71(3), 74(4) and 83(2) and Article 259 for one or more of the listed diseases referred to in points (a) and (b) of Article 9(1).

3 Operators shall take all necessary measures to ensure that the animal health certificate accompanies the aquaculture animals from their place of origin to their final place of destination, unless specific measures are provided for in rules adopted pursuant to Article 214.

#### Article 209

#### **[<sup>XI</sup>Obligation of operators to ensure that other aquatic animals are accompanied by an animal health certificate]**

1 In cases where, due to the risk involved with the movement of aquatic animals other than aquaculture animals, animal health certification is required in accordance with the rules provided for in point (a) of Article 211(1), operators shall only move those aquatic animals if the animals in question are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Article 216(1).

2 Article 208 shall also apply to aquatic animals other than aquaculture animals intended for an aquaculture establishment or release into the wild. Where the competent authority of the Member State of origin concludes that certification is not feasible due to the nature of the place of origin of the aquatic animals in question, it may authorise their movement without an animal health certificate subject to the consent of the competent authority of the place of destination.

3 This Article shall not apply to wild aquatic animals harvested or caught for direct human consumption.

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#### Editorial Information

- X1** Substituted by [Corrigendum 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 \('Animal Health Law'\) \(Official Journal of the European Union L 84 of 31 March 2016\)](#).

#### Article 210

### Grant of derogations by Member States in respect of national animal health certification

By way of derogation from the animal health certification requirements laid down in Articles 208 and 209, Member States may grant derogations for movements of certain consignments of aquatic animals without an animal health certificate within their territories provided that they have in place an alternative system to ensure that consignments of such animals are traceable and those consignments comply with the animal health requirements for such movements provided for in Sections 1 to 4 (Articles 191 to 207).

#### Article 211

### Delegation of powers and implementing acts concerning animal health certification in respect of aquatic animals

1 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

- a the requirement for animal health certification for movements of aquatic animals other than aquaculture animals as referred to in Article 209(1), in cases where animal health certification is imperative in order to ensure that the movement in question complies with the following animal health requirements for the listed species of animals concerned:
  - (i) the requirements provided for in Sections 1 to 4 (Articles 191 to 207) and the rules adopted pursuant to those Sections;
  - (ii) disease control measures as provided for in Article 55(1), Article 56, Article 61(1), Articles 62 and 64, and Article 65(1), Article 74(1), and Articles 79 and 80 or the rules adopted pursuant to Article 55(2), Articles 63, 67 and 68, and Articles 71(3), 74(4) and 83(2);
  - (iii) emergency measures as provided for in the rules adopted pursuant to Article 259;
- b special rules for animal health certification as provided for in Articles 208 and 209 where specific risk-mitigation measures are taken by the competent authority to ensure:
  - (i) the traceability of the aquatic animals being moved;
  - (ii) that the aquatic animals being moved fulfil the animal health requirements for movements provided for in Sections 1 to 4 (Articles 191 to 207);
- c derogations from the animal health certificate requirements provided for in Articles 208 and 209 and the conditions for such derogations for movements of aquatic animals which do not pose a significant risk of the spread of diseases, on account of:

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- (i) species, the categories or live stage of the aquatic animals concerned;
- (ii) the methods of keeping and the type of production of those species and categories of aquaculture animals;
- (iii) the intended use of the aquatic animals; or
- (iv) the place of destination of the aquatic animals.

2 The Commission shall, by means of implementing acts, lay down rules concerning the obligation of operators, as provided for in Article 209(2), to ensure that wild aquatic animals intended for an aquaculture establishment are accompanied by an animal health certificate.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

#### *Article 212*

##### **Contents of animal health certificates**

1 The animal health certificate referred to in Articles 208, 209 and 210 shall contain at least the following information:

- a the establishment or place of origin, the establishment or place of destination and, where relevant for the spread of diseases, any establishment or place visited en route;
- b a description, including the species and category, of the aquatic animals concerned;
- c the quantity (number, volume or weight) of aquatic animals;
- d the information needed to demonstrate that the aquatic animals fulfil the relevant animal health requirements in respect of movements provided for in Sections 1 to 4 (Articles 191 to 207).

2 The animal health certificate may include other information required under other Union legislation.

#### *Article 213*

##### **Delegation of powers and implementing acts concerning the content of animal health certificates**

1 The Commission shall adopt delegated acts in accordance with Article 264 concerning the content of animal health certificates as provided for in Article 212(1):

- a detailed rules on the content of those animal health certificates provided for in Article 212(1) for different species and categories of aquatic animals;
- b additional information to be contained in the animal health certificate provided for in Article 212(1).

2 The Commission may, by means of implementing acts, lay down rules concerning the model forms for the animal health certificates.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

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#### Article 214

##### **Delegation of powers concerning specific types of movements of aquatic animals to the place of destination**

The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning specific measures supplementing the requirements for animal health certification provided for in Article 208 and 209 for the following types of movements of aquatic animals:

- (a) movements of aquatic animals which are required to return to their place of origin or to be moved to a different destination, for one or more of the following reasons:
  - (i) their intended journey was unexpectedly interrupted for animal welfare reasons;
  - (ii) unforeseen accidents or events during the journey;
  - (iii) they were rejected at the place of the destination in another Member State or at the external border of the Union;
  - (iv) they were rejected in a third country or territory;
- (b) movements of aquaculture animals intended for exhibitions and for sporting, cultural and similar events, and their subsequent return to their place of origin.

#### Article 215

##### **Operators' obligations to cooperate with the competent authorities for the purposes of animal health certification**

Operators shall:

- (a) provide the competent authority with all the information necessary to complete the animal health certificate provided for in Articles 208 and 209 and in the rules adopted pursuant to Articles 211, 213 and 214, in advance of the intended movement;
- (b) where necessary, ensure that the aquatic animals in question are subjected to documentary, identity and physical checks as provided for in Article 216(3) and in the rules adopted pursuant to Article 216(4).

#### Article 216

##### **Responsibility of the competent authority for animal health certification and delegated acts**

1 The competent authority shall, upon request by an operator, issue an animal health certificate for the movement of aquatic animals, where required by Articles 208 and 209, or by rules adopted pursuant to Articles 211 and Article 214, provided that the following animal health requirements have been complied with, as relevant:

- a those provided for in Article 191, Article 192(1), Articles 193, 195 and 196, Article 197(1), Articles 198 and 199, Article 200(1) and (2), Article 201, Article 203(1) and Article 204(1) and (2);



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- b those provided for in delegated acts adopted pursuant to Articles 192(2), 197(3), 200(3), 201(3), 202(3), 203(2) and 204(3) and Article 205;
  - c those provided for in implementing acts adopted pursuant to Article 206.
- 2 Animal health certificates shall:
- a be verified, stamped and signed by an official veterinarian;
  - b remain valid for the period of time, provided for in the rules adopted pursuant to point (c) of paragraph 4, during which the aquatic animals covered by it must continue to fulfil the animal health guarantees contained in it.
- 3 Before signing an animal health certificate, the official veterinarian concerned shall verify, by means of documentary, identity and physical checks as provided for by delegated acts adopted pursuant to paragraph 4 where appropriate, that the aquatic animals covered by it fulfil the requirements of this Chapter, taking into account the species and categories of aquatic animals concerned and the animal health requirements.
- 4 The Commission shall adopt delegated acts in accordance with Article 264 laying down rules concerning:
- a the types of documentary, identity and physical checks and examinations in relation to different species and categories of aquatic animals that must be carried out by the official veterinarian in accordance with paragraph 3 in order to verify compliance with the requirements of this Chapter;
  - b the timeframes for the carrying-out of such documentary, identity and physical checks and examinations, and the issuing of animal health certificates by the official veterinarian prior to the movement of consignments of aquatic animals;
  - c the duration of the validity of animal health certificates.

#### *Article 217*

### **Electronic animal health certificates**

Electronic animal health certificates, produced, handled and transmitted by means of Traces, may replace accompanying animal health certificates as provided for in Article 216(1) where such electronic animal health certificates:

- (a) contain all the information that the model form of animal health certificate is required to contain in accordance with Article 212(1) and the rules adopted pursuant to Article 213;
- (b) ensure the traceability of the aquatic animals in question and the link between those animals and the electronic animal health certificate;
- (c) ensure that the competent authorities of the Member States of origin, passage and destination are able to have access to the electronic documents at all times during the transport.

#### *Article 218*

### **Self-declaration by operators for movements of aquaculture animals to other Member States and delegated acts**

1 Operators at the place of origin shall issue a self-declaration document for movements of aquaculture animals from their place of origin in one Member State to their place of

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destination in another Member State, and shall ensure that it accompanies such aquaculture animals, where they are not required to be accompanied by an animal health certificate as provided for in Articles 208 and 209 or in any rules adopted pursuant to Articles 211 and Article 214.

2 The self-declaration document provided for in paragraph 1 shall contain at least the following information concerning the aquaculture animals in question:

- a their places of origin and destination, and, when relevant, any places en route;
- b the means of transport
- c a description of the aquaculture animals, and their categories, species and quantity (numbers, volume or weight), as relevant for the animals concerned;
- d the information needed to demonstrate that the aquaculture animals fulfil the movement requirements provided for in Sections 1 to 4 (Articles 191 to 207).

3 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:

- a detailed rules on the content of the self-declaration document provided for in paragraph 2 of this Article for different species and categories of aquaculture animals;
- b additional information to be contained in the self-declaration document to the one provided for in paragraph 2 of this Article.

4 The Commission may, by means of implementing acts, lay down rules for a model form of the self-declaration document provided for in paragraph 1.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

## *Section 6*

### ***Notification of movements of aquatic animals to other Member States***

#### *Article 219*

#### **Obligation of operators concerning the notification of movements of aquatic animals to other Member States**

1 Operators other than transporters shall notify the competent authority in their Member State of origin in advance of intended movements of aquatic animals from one Member State to another Member State where:

- a the aquatic animals are required to be accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Articles 208 and 209 [<sup>XI</sup>and any rules adopted pursuant to Articles 211 and 214;]
- b the aquatic animals are required to be accompanied by an animal health certificate for aquatic animals [<sup>XI</sup>when they are being moved from a restricted zone as referred to in Article 208(2);]
- c the aquaculture animals and wild aquatic animals being moved are intended for:
  - (i) an establishment subject to registration in accordance with Article 173 or approval in accordance with Articles 176 to 179;
  - (ii) release into the wild;

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d notification is required in accordance with delegated acts adopted pursuant to Article 221.

2 For the purposes of the notification provided for in paragraph 1 of this Article, operators shall provide the competent authority of their Member State of origin with all the necessary information to enable it to notify the movement to the competent authority of the Member State of destination in accordance with Article 220(1).

#### **Editorial Information**

**X1** Substituted by [Corrigendum 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 \('Animal Health Law'\) \(Official Journal of the European Union L 84 of 31 March 2016\)](#).

### *Article 220*

#### **Responsibility of the competent authority to notify movements of aquatic animals to other Member States**

1 The competent authority of the Member State of origin shall notify the competent authority of the Member State of destination of movements of aquatic animals as referred to in Article 219, unless a derogation has been granted in accordance with point (c) of Article 221(1) as regards such notification.

2 The notification referred to in paragraph 1 shall be carried out prior to the movement in question and, whenever possible, through Traces.

3 Member States shall designate regions for the management of notifications of movements as provided for in paragraph 1.

4 By way of derogation from paragraph 1, the competent authority of Member State of origin may authorise the operator concerned to notify, partially or completely, movements of aquatic animals through Traces to the competent authority of the Member State of destination.

### *Article 221*

#### **Delegation of powers and implementing acts for the notification of movements of aquatic animals by operators and by the competent authority**

1 The Commission shall adopt delegated acts in accordance with Article 264 concerning:

- a the requirement for advance notification by operators, in accordance with Article 219, of movements between Member States of aquatic animals of species or categories other than those referred to in points (a), (b) and (c) of Article 219(1), where traceability of such movements is necessary in order to ensure compliance with the animal health requirements laid down in this Chapter;
- b the information needed in order to notify movements of aquatic animals as provided for in Articles 219 and 220(1);
- c derogations from the notification requirements provided for in point (c) of Article 219(1) for species and categories of aquatic animals or types of movements which pose an insignificant risk;

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- d the emergency procedures for notification of movements of aquatic animals in the event of power cuts or other disturbances of Traces;
  - e the requirements for the designation of regions by Member States as provided for in Article 220(3).
- 2 The Commission may, by means of implementing acts, lay down rules concerning:
- a the details of notifications by:
    - (i) operators to the competent authority of the Member State of origin of movements of aquatic animals in accordance with Article 219;
    - (ii) the competent authority of the Member State of origin to the Member State of destination of movements of aquatic animals in accordance with Article 220(1);
  - b the deadlines for:
    - (i) the provision by operators of the necessary information referred to in Article 219(2) to the competent authority of the Member State of origin;
    - (ii) the notification of movements by the competent authority of the Member State of origin as referred to in Article 220(1).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

### CHAPTER 3

#### ***Production, processing and distribution within the Union of products of animal origin from aquatic animals, other than live aquatic animals***

##### *Article 222*

#### **General animal health obligations for operators and delegated acts**

- 1 Operators shall take appropriate preventive measures to ensure that, during all stages of the production, processing and distribution of products of animal origin from aquatic animals, other than live aquatic animals, those products do not cause the spread of:
- a listed diseases as referred to in point (d) of Article 9(1), taking into account the health status of the place of production, processing and destination;
  - b emerging diseases.
- 2 Operators shall ensure that products of animal origin from aquatic animals, other than live aquatic animals, do not come from establishments or food businesses, or are not obtained from animals which come from such establishments or food businesses, that are subject to:
- a emergency measures as provided for in Articles 257 and 258 and any rules adopted pursuant to Article 259, unless derogations have been provided for in respect of those rules in Part VII (Articles 257 to 262);
  - b movement restrictions applicable to aquatic animals and products of animal origin from aquatic animals, as provided for in point (c) of Article 32(1), point (e) of Article 55(1), Article 56, point (a) of Article 61(1), Article 62(1), point (c) of Article 65(1), point (b) of Article 70(1), point (a) of Article 74(1), point (b) of Article 76(2), Article 76(3), Article 79, Article 81 and Article 82(2) and (3) and the rules adopted pursuant to Article 55(2),

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Articles 63 and 67, and Articles 70(3), 71(3), 74(4), 76(5) and 83(2), unless derogation from those movement restrictions have been provided for in those rules.

3 The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed requirements supplementing those referred to in paragraph 2 of this Article in relation to movements of products of animal origin from aquatic animals other than live aquatic animals, as regards:

- a the diseases, and species of aquatic animals concerned by the diseases, for which emergency measures or movement restrictions as referred to in paragraph 2 of this Article apply;
- b the types of products of animal origin from aquatic animals;
- c the risk-mitigation measures applied to the products of animal origin from aquatic animals at the places of origin and destination;
- d the intended use of the products of animal origin from aquatic animals;
- e the place of destination of the products of animal origin from aquatic animals.

4 This Article shall not apply to products of animal origin from wild aquatic animals harvested or caught for direct human consumption.

#### *Article 223*

#### **Animal health certificates and delegated acts**

1 Operators shall only move the following products of animal origin from aquatic animals other than live aquatic animals where those products are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with paragraph 3:

- a products of animal origin from aquatic animals that:
  - (i) are allowed to leave a restricted zone subject to emergency measures as provided for in rules adopted pursuant to Article 259; and
  - (ii) originate from aquatic animals of species subject to those emergency measures;
- b products of animal origin from aquatic animals that:
  - (i) are allowed to leave a restricted zone subject to disease control measures in accordance with point (c) of Article 32(1), point (c) of Article 55(1), Article 56, [X<sup>1</sup> point (a) of Article 61(1), Article 62(1), point (c) of Article 65(1),] point (b) of Article 70(1), point (a) of Article 74(1) and Article 79 and the rules adopted pursuant to Article 55(2), Articles 63 and 67 and Articles 71(3), 74(4) and 83(2); and
  - (ii) originate from aquatic animals of species subject to those disease control measures.

2 By way of derogation from paragraph 1, such a certificate shall not be required for movements of products of animal origin from wild aquatic animals, provided that:

- a alternative risk-mitigation measures authorised by the competent authority are in place to ensure that those movements do not pose a risk of the spread of listed diseases;
- b consignments of such products are traceable.

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3 Operators shall take all necessary measures to ensure that the animal health certificate referred to in paragraph 1 accompanies the products of animal origin from their place of origin to their place of destination.

4 The competent authority shall, upon request by the operator concerned, issue an animal health certificate for movements of products of animal origin other than live aquatic animals as referred to in paragraph 1, provided that the relevant requirements referred to in this Article have been complied with.

5 Article 212 and Articles 214 to 217 and the rules adopted pursuant to Article 213 and Article 216(4) shall apply to the animal health certification of movements of products of animal origin other than live aquatic animals as referred to in paragraph 1 of this Article.

6 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning requirements and detailed rules on the animal health certificate to accompany products of animal origin other than live aquatic animals, as referred to in paragraph 1 of this Article, taking into account:

- a the types of products of animal origin concerned;
- b the risk-mitigation measures applied to the products concerned which reduce the risks of the spread of diseases;
- c the intended use of those products;
- d the place of destination of those products.

#### **Editorial Information**

- X1** Substituted by [Corrigendum 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 \('Animal Health Law'\) \(Official Journal of the European Union L 84 of 31 March 2016\)](#).

### *Article 224*

#### **Content of animal health certificates and delegated and implementing acts**

1 The animal health certificate for products of animal origin from aquatic animals, other than live aquatic animals, shall contain at least the following information:

- a the establishment or place of origin and the establishment or place of destination;
- b a description of the products of animal origin concerned;
- c the quantity (numbers, volume or weight) of the products of animal origin;
- d the identification of the products of animal origin, when required by point (h) of Article 65(1) or by any rules adopted pursuant to Article 67;
- e the information needed to demonstrate that the products concerned fulfil the movement restriction requirements provided for in Article 222(2) and in any rules adopted pursuant to Article 222(3).

2 The animal health certificate referred to in paragraph 1 may include other information required under other Union legislation.

3 The Commission shall adopt delegated acts in accordance with Article 264 concerning amending and supplementing the information to be contained in the animal health certificate as provided for in paragraph 1 of this Article.

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4 The Commission may, by means of implementing acts, lay down rules concerning model forms of animal health certificates as provided for in paragraph 1 of this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

#### *Article 225*

### **Notification of movements of products of animal origin to other Member States**

1 Operators shall:

- a inform the competent authority in the Member State of origin in advance of intended movements of products of animal origin from aquatic animals, other than live aquatic animals, when the consignments in question are required to be accompanied by an animal health certificate in accordance with Article 223(1);
- b provide all necessary information to enable the competent authority of the Member State of origin to notify the movement in question to the Member State of destination in accordance with paragraph 2 of this Article.

2 The competent authority of the Member State of origin shall notify the competent authority of the Member State of destination of movements of products of animal origin from aquatic animals, other than live aquatic animals, in accordance with Article 220(1).

3 Articles 219 and 220 and any rules adopted pursuant to Article 221 shall be applicable to the notification of products of animal origin from aquatic animals, other than live aquatic animals.

## *CHAPTER 4*

### ***National measures***

#### *Article 226*

### **National measures designed to limit the impact of diseases other than listed disease**

1 Where a disease other than a listed disease as referred to in point (d) of Article 9(1) constitutes a significant risk for the health of aquatic animals in a Member State, the Member State concerned may take national measures to prevent the introduction, or to control the spread, of that disease.

Member States shall ensure that those national measures do not exceed the limits of what is appropriate and necessary in order to prevent the introduction, or to control the spread, of the disease in question within the Member State concerned.

2 Member States shall notify the Commission in advance of any proposed national measures as referred to in paragraph 1 that may affect movements of aquatic animals and products of animal origin from aquatic animals between Member States.

3 The Commission shall approve and, if necessary, amend the national measures referred to in paragraph 2 of this Article by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

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4 The approval referred to in paragraph 3 shall only be granted where the establishment of movement restrictions between Member States is necessary in order to prevent the introduction, or to control the spread, of the disease referred to in paragraph 1, taking into account the overall impact on the Union of the disease in question and of the measures taken.



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- (1) 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](#)).

**Changes to legislation:**

There are outstanding changes not yet made to Regulation (EU) 2016/429 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.

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**Changes and effects yet to be applied to the whole legislation item and associated provisions**

- Art. 17(1A) words substituted by [S.I. 2021/1273 reg. 8Sch. 2 para. \(t\)](#)