



EUROPEAN  
COMMISSION

Brussels, **XXX**  
SANTE/7162/2020  
(POOL/G2/2020/7162/7162-EN.docx)  
[...] (2021) **XXX** draft

**COMMISSION IMPLEMENTING REGULATION (EU) .../...**

**of XXX**

**laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to exemptions from the obligations for the registration of aquaculture establishments and record-keeping of operators**

(Text with EEA relevance)

*This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.*

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

**laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to exemptions from the obligations for the registration of aquaculture establishments and record-keeping of operators**

(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 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 Article 175(2), and Article 190 thereof,

Whereas:

- (1) Regulation (EU) 2016/429 lays down rules concerning the obligation of operators to register aquaculture establishments, and record-keeping obligations of operators of aquaculture establishments and transporters of aquatic animals. In addition, that Regulation provides that the Commission may lay down implementing rules concerning the types of aquaculture establishments, which may be exempted by Member States from the requirement to be registered, because they pose an insignificant risk of spreading listed or emerging diseases, as well as implementing rules concerning the types of aquaculture establishments and transporters of aquatic animals that may be exempted by the Member States, from the requirement to keep certain types of records. Accordingly, it is appropriate to lay down such rules in this Regulation. Furthermore, as Commission Delegated Regulation (EU) 2020/691<sup>2</sup> was adopted within the framework of Regulation (EU) 2016/429, and it lays down rules concerning aquatic animals, the definitions laid down in that Delegated Regulation should also apply for the purposes of this Regulation.
- (2) The definition of 'establishment' set out in Article 4, point (27) of Regulation (EU) 2016/429 is broad. It is therefore appropriate, that the empowerment provided to the Commission by Article 175(2) of that Regulation, should be used to allow Member States to exempt certain types of establishments that pose an insignificant risk, from the requirement to be registered by the competent authority.
- (3) In general terms, aquaculture establishments that are closed facilities, present a lower risk of contaminating open waters, than aquaculture establishments that are open facilities. To be considered as suitable for an exemption from the requirement to be registered, an aquaculture establishment should be a closed facility. Additional factors

---

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

<sup>2</sup> Commission Delegated Regulation (EU) 2020/691 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for aquaculture establishments and transporters of aquatic animals (OJ L 174, 3.6.2020, p.345)

such as movements of aquatic animals to and from the establishment and the species, categories, and quantity of animals kept there should also be taken into consideration.

- (4) Ornamental aquatic animals are often kept as pet animals in premises that are not households. Such premises are covered by the definition of ‘establishment’ as set out in Article 4, point (27) of Regulation (EU) 2016/429. Likewise, premises where aquaculture animals are kept for health care and other similar purposes, are covered by the definition of ‘establishment’. Aquaculture animals are also often kept on display in restaurants awaiting purchase for human consumption. If such establishments are closed facilities from which the aquaculture animals are not moved, they pose an insignificant risk, and Member States should therefore, be permitted to exempt them from the requirement to be registered.
- (5) In certain cases, depending on the type of aquaculture facility in question, additional requirements should also be fulfilled in order to mitigate disease risks and make the exemption from registration possible. For example, retail stores that sell ornamental species to a large number of individual pet-keepers, or recreational facilities or households where aquaculture animals are kept outdoors in ponds or tanks as their final destination, should be supplied directly from an aquaculture establishment approved in accordance with Regulation (EU) 2016/429, in order to be exempted by Member States, from the requirement to be registered.
- (6) Record-keeping is important for the traceability of aquaculture animals. In certain circumstances however, exemptions from the requirement for operators to keep such records may be granted when the risk associated with a particular type of aquaculture establishment is low. Establishments registered in accordance with Article 173 of Regulation (EU) 2016/429, which do not move aquaculture animals to other aquaculture establishments or release them into the wild, present a lower level of risk than those which must be approved in accordance with Articles 176 or 177 of that Regulation. Such registered establishments may therefore, be exempted by Member States from the requirement to keep certain records.
- (7) Transporters of certain categories of aquatic animals, that are transported in a biosecure manner may also be exempted by Member States from the requirement to keep certain records. The categories of aquatic animals and the details of the conditions under which they must be transported, as well as the records from which they are exempted, should be laid down in this Regulation.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

*Article 1*  
*Subject matter and scope*

This Regulation lays down rules concerning:

- (a) the types of aquaculture establishments posing an insignificant risk that may be exempted by Member States from the registration requirement in accordance with Article 174 of Regulation (EU) 2016/429;
- (b) the types of aquaculture establishments and transporters posing a low risk for the spread of listed or emerging diseases that may be exempted by Member States from

the record-keeping requirements provided for in Articles 186 and 188 of Regulation (EU) 2016/429.

## *Article 2* *Definitions*

For the purposes of this Regulation, the definitions laid down in Article 2 of Delegated Regulation (EU) 2020/691 apply.

## *Article 3* *Types of aquaculture establishments that may be exempted by Member States from the requirement to be registered*

The types of aquaculture establishments that may be exempted by Member States from the registration requirement, in accordance with Article 174 of Regulation (EU) 2016/429, shall be the aquaculture establishments that are closed facilities, that do not move aquaculture animals to other aquaculture establishments or release them into the wild, and are one of the following types of aquaculture establishments:

- (a) premises where ornamental animals are kept on display in aquaria or in ponds as pet animals;
- (b) restaurants where aquaculture animals are kept on display in aquaria or in ponds awaiting human consumption;
- (c) establishments where aquaculture animals are kept for health care and other similar uses;
- (d) retail stores keeping aquaculture animals intended for ornamental purposes which:
  - (i) are supplied directly by an aquaculture establishment or groups thereof, approved in accordance with Article 176 or Article 177 of Regulation (EU) 2016/429 ('approved aquaculture establishment(s)'); and
  - (ii) are sold directly to the final pet keeper;
- (e) outdoor recreational facilities where aquaculture animals are kept in ponds for aesthetic or water quality purposes, which are supplied directly by an approved aquaculture establishment or approved aquaculture establishments;
- (f) households where aquaculture animals are kept outdoors in ponds or tanks solely for personal consumption or personal recreational use, and which are supplied directly by an approved aquaculture establishment or approved aquaculture establishments.

## *Article 4* *Types of aquaculture establishments and transporters that may be exempted by Member States from certain record-keeping requirements*

1. The types of aquaculture establishments that, in accordance with Article 186(2) of Regulation (EU) 2016/429, may be exempted by Member States from the requirement to keep records of all or some of the information listed in Article 186(1), points (c), (d) and (e) of that Regulation shall be the aquaculture establishments or groups thereof, which comply with the following conditions:
  - (a) they have been registered by the competent authority in accordance with Article 173 of Regulation (EU) 2016/429; and

- (b) they do not move aquaculture animals to other aquaculture establishments or release them into the wild.
2. The transporters that, in accordance with Article 188(2) of Regulation (EU) 2016/429, may be exempted by Member States from the requirement to keep records of all or some of the information listed in Article 188(1) of that Regulation shall be transporters of the following categories of aquatic animals, provided that the aquatic animals are moved in sealed, leak-proof containers which remain unopened and intact from the time they are loaded to the time they are unloaded at their final destination:
- (a) aquaculture animals which are intended for ornamental purposes;
  - (b) eggs and gametes of aquatic animals which are intended for aquaculture purposes or for release into the wild.

*Article 5*  
*Entry into force*

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

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

Done at Brussels,

*For the Commission*  
*The President*  
*Ursula VON DER LEYEN*