

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 1

Registration, approval, record-keeping and registers

Section 2

Approval of certain types of aquaculture establishments

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;

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. (See end of Document for details) [View outstanding changes](#)

- 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:
- 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.

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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. \(t\)](#)