

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 I

**TERRESTRIAL ANIMALS, GERMINAL PRODUCTS AND PRODUCTS OF ANIMAL ORIGIN FROM TERRESTRIAL ANIMALS**

CHAPTER 1

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

*Section 2*

***Approval of certain types of establishments***

*Article 94*

**Approval of certain establishments and delegated acts**

1 Operators of the following types of establishments shall apply to the competent authority for approval in accordance with Article 96(1) and shall not commence their activities until their establishment has been approved in accordance with Article 97(1):

- a establishments for assembly operations of ungulates and poultry from which those animals are moved to another Member State or which receive animals from another Member State;
- b germinal product establishments for bovine, porcine, ovine, caprine and equine animals from which germinal products of those animals are moved to another Member State;
- c hatcheries from which hatching eggs or poultry are moved to another Member State;
- d establishments keeping poultry from which poultry intended for purposes other than slaughter or hatching eggs are moved to another Member State;
- e any other type of establishment for kept terrestrial animals which poses a significant risk and is required to be approved in accordance with rules laid down in a delegated act adopted in accordance with point (b) of paragraph 3.

2 Operators shall cease activity at an establishment as referred to in paragraph 1 where:

- a the competent authority withdraws or suspends its approval in accordance with Article 100(2); or
- b in the event of conditional approval, granted in accordance with Article 99(3), the establishment in question fails to comply with the outstanding requirements referred to in Article 99(3) and does not obtain a final approval in accordance with Article 97(1).

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*Changes to legislation:* There are currently no known outstanding effects for the Regulation (EU) 2016/429 of the European Parliament and of the Council, Section 2. (See end of Document for details)

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

- a derogations from the requirement for operators of the types of establishments referred to in points (a) to (d) of paragraph 1 to apply to the competent authority for approval, where those establishments pose an insignificant risk;
- b the types of establishments which must be approved in accordance with point (e) of paragraph 1;
- c special rules for the cessation of activities for germinal product establishments as referred to in point (b) of paragraph 1.

4 When adopting delegated acts as provided for in paragraph 3, the Commission shall base those acts on the following criteria:

- a the species and categories of kept terrestrial animals or germinal products in an establishment;
- b the number of species and number of kept terrestrial animals or germinal products kept in an establishment;
- c the type of establishment and type of production; and
- d the movements of kept terrestrial animals or germinal products into and out of those types of establishments.

#### *Article 95*

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

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

- (a) apply to the competent authority for approval in accordance with Article 96(1);
- (b) move kept animals to or from their establishment in accordance with the requirements provided for in Article 137(1) and any delegated acts adopted in accordance with Article 137(2) only after their establishment has obtained an approval of that status from the competent authority in accordance with Articles 97 and 99.

#### *Article 96*

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

1 Operators shall, for the purposes of their application for approval of their establishment as provided for in Article 94(1) and point (a) of Article 95, 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 categories, species and number of kept terrestrial animals or germinal products relevant for the approval which are kept on the establishment;
- d the type of establishment;
- e other aspects of the establishment, related to its specificity, which are relevant in determining the risk, if any, posed by it.

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

- a any changes in the establishments concerning the matters referred to in points (a), (b) or (c) of 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, and the time-limits by which the information referred to in paragraph 1 and in point (b) of paragraph 2 is to be provided.

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

#### *Article 97*

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

1 Competent authorities shall only grant approval of establishments as provided for in Article 94(1) and point (a) of Article 95 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(2);
  - (ii) surveillance requirements as provided for in Article 24 and, where relevant for the type of establishment concerned and the risk involved, in Article 25;
  - (iii) record-keeping as provided for in Articles 102 and 103 and any rules adopted pursuant to Articles 106 and 107;
- 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 number of kept terrestrial animals or the volume of germinal products 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 adequately trained personnel for the activity of the establishment concerned;
- e have in place a system which enables the operator concerned to demonstrate to the competent authority compliance with points (a) to (d).

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;
- d responsibilities, competence and specialised training of personnel and veterinarians as provided for in point (d) of paragraph 1 for the activity of germinal products establishments and establishments for assembly operations of ungulates and poultry;

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- e the necessary supervision by the competent authority of germinal products establishments and establishments for assembly operations of ungulates and poultry.
- 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 kept terrestrial animals relevant for the approval;
  - c the type of production concerned;
  - d typical movement patterns of the type of establishment and species and categories of animals kept in those establishments.

### *Article 98*

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

The competent authority shall expressly specify in the approval of an establishment granted pursuant to Article 97(1), following an application made in accordance with Article 94(1) or point (a) of Article 95:

- (a) for which of the types of establishments referred to in Article 94(1) and Article 95, and in the rules adopted pursuant to point (b) of Article 94(3), the approval applies;
- (b) for which species and categories of kept terrestrial animals or germinal products of those species the approval applies.

### *Article 99*

#### **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 94(1), Article 95 or Article 96(1).

2 Upon receipt of an application for approval from an operator, the competent authority shall, in accordance with Article 94(1) or point (a) of Article 95, make an on-site visit.

3 Provided that the requirements referred to in Article 97 and paragraphs (1) and (2) of this Article 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 97, 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 as 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 of 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 97(1) and the rules adopted pursuant to Article 97(2).

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

#### *Article 100*

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

1 The competent authority shall keep approvals of establishments granted in accordance with Articles 97 and 99 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 97(1) and the rules adopted pursuant to Article 97(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.

**Changes to legislation:**

There are currently no known outstanding effects for the Regulation (EU) 2016/429 of the European Parliament and of the Council, Section 2.