

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 I

GENERAL RULES

CHAPTER 2

Listed diseases and emerging diseases and listed species

Article 5

Listing of diseases

1 The disease-specific rules for the prevention and control of diseases provided for in this Regulation shall apply to:

- a the following listed diseases:
 - (i) foot and mouth disease;
 - (ii) classical swine fever;
 - (iii) African swine fever;
 - (iv) highly pathogenic avian influenza;
 - (v) African horse sickness; and
- b the listed diseases set out in the list in Annex II.

2 The Commission shall adopt delegated acts in accordance with Article 264 concerning amendments to the list referred to in point (b) of paragraph 1 of this Article.

3 A disease shall be included on the list referred to in point (b) of paragraph 1 of this Article if it has been assessed in accordance with Article 7 and it meets:

- a all of the following criteria:
 - (i) scientific evidence indicates that the disease is transmissible;
 - (ii) animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union;
 - (iii) the disease causes negative effects on animal health or poses a risk to public health due to its zoonotic character;
 - (iv) diagnostic tools are available for the disease; and
 - (v) risk-mitigating measures and, where relevant, surveillance of the disease are effective and proportionate to the risks posed by the disease in the Union; and
- b at least one of the following criteria:

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- (i) the disease causes or could cause significant negative effects in the Union on animal health, or poses or could pose a significant risk to public health due to its zoonotic character;
- (ii) the disease agent has developed resistance to treatments which poses a significant danger to public and/or animal health in the Union;
- (iii) the disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union;
- (iv) the disease has the potential to generate a crisis or the disease agent could be used for the purpose of bioterrorism; or
- (v) the disease has or could have a significant negative impact on the environment, including biodiversity, of the Union.

4 The Commission shall adopt delegated acts in accordance with Article 264 concerning the removal of a disease from the list referred to in point (b) of paragraph 1 of this Article when that disease no longer fulfils the criteria provided for in paragraph 3 of this Article.

5 The Commission shall review the listing of each disease in the light of newly available significant scientific data.

Article 6

Emerging diseases

1 The rules for the prevention and control of diseases shall apply to emerging diseases as provided for in this Regulation.

2 A disease other than a listed disease shall be considered to be an emerging disease ('emerging disease') provided it has the potential to meet the criteria for listing diseases provided for in Article 5(3) and:

- a results from the evolution or change of an existing disease agent;
- b is a known disease spreading to a new geographic area, species or population;
- c is diagnosed for the first time in the Union; or
- d is caused by an unrecognised or a previously unrecognised disease agent.

3 The Commission shall, by means of implementing acts, take the necessary measures regarding an emerging disease which fulfils the criteria set out in paragraph 2 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

4 On duly justified imperative grounds of urgency relating to a disease representing an emerging risk having a highly significant impact, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 266(3).

5 Any obligation on operators in respect of an emerging disease, as set out in this Regulation, shall only apply if the Commission has adopted an implementing act for that disease in accordance with paragraph 3 of this Article or if the disease is covered by a contingency plan in accordance with Article 43.

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Article 7

Assessment parameters for the listing of diseases

The Commission shall use the following assessment parameters in order to determine whether a disease meets the conditions requiring it to be listed in accordance with Article 5(2):

- (a) the disease profile, which shall comprise the following:
 - (i) the animal species concerned by the disease;
 - (ii) the morbidity and mortality rates of the disease in animal populations;
 - (iii) the zoonotic character of the disease;
 - (iv) the resistance to treatments, including antimicrobial resistance;
 - (v) the persistence of the disease in an animal population or in the environment;
 - (vi) the routes and speed of transmission of the disease between animals and, when relevant, between animals and humans;
 - (vii) the absence or presence and distribution of the disease in the Union, and, where the disease is not present in the Union, the risk of its introduction into the Union;
 - (viii) the existence of diagnostic and disease control tools;
- (b) the impact of the disease on:
 - (i) agricultural and aquaculture production and other parts of the economy, as regards:
 - the level of presence of the disease in the Union;
 - the loss of production due to the disease;
 - other losses;
 - (ii) human health, as regards:
 - transmissibility between animals and humans;
 - transmissibility between humans;
 - the severity of human forms of the disease;
 - the availability of effective prevention or medical treatment in humans;
 - (iii) animal welfare;
 - (iv) biodiversity and the environment;
- (c) its potential to generate a crisis situation and its potential use in bioterrorism;
- (d) the feasibility, availability and effectiveness of the following disease prevention and control measures:
 - (i) diagnostic tools and capacities;
 - (ii) vaccination;

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- (iii) medical treatments;
- (iv) biosecurity measures;
- (v) restrictions on the movement of animals and products;
- (vi) killing of animals;
- (vii) disposal of carcasses and other relevant animal by-products;
- (e) the impact of disease prevention and control measures, as regards:
 - (i) the direct and indirect costs for the affected sectors and the economy as a whole;
 - (ii) their societal acceptance;
 - (iii) the welfare of affected subpopulations of kept and wild animals;
 - (iv) the environment and biodiversity.

Article 8

Listing of species

1 The disease-specific rules for listed diseases provided for in this Regulation and the rules adopted pursuant to this Regulation shall apply to listed species.

2 The Commission shall, by means of implementing acts, establish a list of species as referred to in paragraph 1 of this Article that fulfil the criteria set out in paragraph 3 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

That list shall comprise those animal species, or groups of animal species which pose a considerable risk for the spread of specific listed diseases, based on the following criteria:

- a the susceptibility of the animal population at risk;
 - b the duration of the incubation period and infective period for the animals concerned;
 - c the capability of those animals to carry those specific diseases.
- 3 Animal species or groups of animal species shall be added to the list if they are affected or if they pose a risk for the spread of a specific listed disease because:
- a they are susceptible to a specific listed disease or scientific evidence indicates that such susceptibility is likely; or
 - b they are vector species or reservoirs for that disease, or scientific evidence indicates that such role is likely.
- 4 The Commission shall, by means of implementing acts, remove animal species or groups of animal species from the list when:
- a the relevant listed disease in relation to which the animal species or group of animal species concerned has been listed has been removed from the list of diseases; or
 - b scientific evidence indicates that the species or group of species concerned no longer fulfils the criteria set out in paragraph 3.

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

Article 9

Disease prevention and control rules to be applied to different categories of listed diseases

- 1 Disease prevention and control rules shall apply to listed diseases as follows:
- a As regards listed diseases that do not normally occur in the Union and for which immediate eradication measures must be taken as soon as they are detected, the following rules shall apply, as relevant:
- (i) the rules for disease awareness and preparedness provided for in Title I of Part III (Articles 43 to 52);
 - (ii) the disease control measures provided for in Chapter 1 of Title II of Part III (Articles 53 to 71); and
 - (iii) the rules for compartmentalisation provided for in Article 37(1).

For those listed diseases, the measures referred to in point (b), as appropriate, as well as points (d) and (e), shall also apply, as relevant.

- b As regards listed diseases which must be controlled in all Member States with the goal of eradicating them throughout the Union, the following rules shall apply, as relevant:
- (i) the rules for compulsory eradication programmes provided for in Article 31(1);
 - (ii) the rules for disease-free Member States and zones provided for in Article 36;
 - (iii) the rules for compartmentalisation provided for in Article 37(2); and
 - (iv) the disease control measures provided for in Articles 72 to 75, Articles 77 to 79 and Articles 81 and 83.

For those listed diseases, the measures referred to in points (d) and (e) shall also apply, as relevant.

- c As regards listed diseases which are of relevance to some Member States and for which measures are needed to prevent them from spreading to parts of the Union that are officially disease-free or that have eradication programmes for the listed disease concerned, the following rules shall apply, as relevant:
- (i) the rules for optional eradication provided for in Article 31(2);
 - (ii) the rules for disease-free Member States and zones provided for in Article 36;
 - (iii) the rules for compartmentalisation provided for in Article 37(2); and
 - (iv) the rules for disease control measures provided for in Articles 76, 77, 78, 80, 82 and 83.

For those listed diseases, the measures referred to in points (d) and (e) shall also apply, as relevant.

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- d As regards listed diseases for which measures are needed to prevent them from spreading on account of their entry into the Union or movements between Member States, the following rules shall apply, as relevant:
- (i) the rules for movement within the Union provided for in Chapters 3 to 6 of Title I (Articles 124 to 169), Chapters 2 and 3 of Title II of Part IV (Articles 191 to 225) and Chapters 2 and 3 of Part VI (Articles 247 to 251); and
 - (ii) the rules for entry into the Union and export from the Union provided for in Part V (Articles 229 to 243).

The listed diseases referred to in points (a), (b) and (c) shall also be considered as listed diseases under this point, as well as those referred to in point (e), where the risk posed by the disease in question can be effectively and proportionately mitigated by measures concerning movements of animals and products.

- e As regards listed diseases for which there is a need for surveillance within the Union, the following rules shall apply, as relevant:
- (i) the rules for notification and reporting provided for in Chapter 1 of Part II (Articles 18 to 23); and
 - (ii) the rules for surveillance provided for in Chapter 2 of Part II (Articles 24 to 30).

The listed diseases referred to in points (a), (b) and (c) shall also be considered as listed diseases under this point.

2 The Commission shall, by means of implementing acts, determine the application of the disease prevention and control rules referred to in paragraph 1 to the respective listed diseases on the basis of the criteria set out in Annex IV, also in the light of newly available significant scientific data.

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

3 The Commission shall, by means of implementing acts, modify the application of the disease prevention and control rules referred to in paragraph 2 to the respective listed diseases when the disease in question no longer fulfils the criteria laid down in the relevant Section of Annex IV, also in the light of newly available significant scientific data.

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

4 On duly justified imperative grounds of urgency relating to a listed disease representing an emerging risk having a highly significant impact, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 266(3).

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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. \(t\)](#)