

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 II

DISEASE NOTIFICATION AND REPORTING, SURVEILLANCE, ERADICATION PROGRAMMES, DISEASE-FREE STATUS

CHAPTER 4

Disease-free status

Article 36

Disease-free Member States and zones

1 A Member State may apply to the Commission for approval of disease-free status for one or more of the listed diseases referred to in points (b) and (c) of Article 9(1), for one or more of the relevant animal species, for its entire territory or for one or more zones thereof, provided that one or more of the following conditions are fulfilled:

- a none of the listed species for the disease covered by the application for disease-free status is present anywhere in the territory of the Member State concerned or in the relevant zone or zones covered by the application;
- b the disease agent is known not to be able to survive in the entire territory of the Member State, or in the relevant zone or zones covered by the application, according to the criteria referred to in point (a)(ii) of Article 39;
- c in the case of listed diseases only transmitted by vectors, none of the vectors are present, or they are known not to be able to survive in the entire territory of the Member State, or in the relevant zone or zones covered by the application, according to the criteria referred to in point (a)(ii) of Article 39;
- d freedom from the listed disease has been demonstrated by:
 - (i) an eradication programme complying with the rules laid down in Article 32(1) and rules adopted pursuant to paragraph 2 of that Article; or
 - (ii) historical and surveillance data.

2 Applications by Member States for disease-free status shall include evidence demonstrating that the conditions for disease-free status laid down in paragraph 1 are fulfilled.

3 A Member State may in certain specific cases apply to the Commission for approval of disease-free status for one or more of the listed diseases referred to in point (a) of Article 9(1), and in particular for approval of non-vaccination status for the entire territory, or for one or more zones thereof, provided that the following conditions are fulfilled:

- a freedom from the listed disease has been demonstrated by:
 - (i) an eradication programme complying with the rules laid down in Article 32(1) and rules adopted pursuant to paragraph 2 of that Article; or

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- (ii) historical and surveillance data;
 - b it has been demonstrated that vaccination against the disease would lead to costs which would exceed those resulting from maintaining freedom from disease without vaccination.
- 4 The Commission shall, by means of implementing acts, approve, subject to amendments where necessary, applications by Member States for disease-free status or non-vaccination status when the conditions referred to in paragraphs 1 and 2 and, as relevant, paragraph 3 are fulfilled.

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

Article 37

Compartments

1 A Member State may apply to the Commission for recognition of the disease-free status of compartments for listed diseases referred to in point (a) of Article 9(1), and for the protection of the disease-free status of such a compartment in the event of an outbreak of one or more of those listed diseases in its territory, provided that:

- a the introduction of the listed disease or listed diseases covered by the application can be effectively prevented at compartment level, taking into account the disease profile;
- b the compartment covered by the application is subject to a single common biosecurity management system designed to ensure the disease-free status of all establishments forming part of it; and
- c the compartment covered by the application has been approved by the competent authority for the purposes of movements of animals and products thereof in accordance with:
 - (i) Articles 99 and 100 for compartments keeping terrestrial animals and products thereof;
 - (ii) Articles 183 and 184 for compartments keeping aquaculture animals and products thereof.

2 A Member State may apply to the Commission for recognition of the disease-free status of compartments for one or more of the listed diseases referred to in points (b) and (c) of Article 9(1), provided that:

- a the introduction of the listed disease or listed diseases covered by the application can be effectively prevented at compartment level, taking into account the disease profile;
- b one or more of the following conditions are complied with:
 - (i) the conditions laid down in Article 36(1) are fulfilled;
 - (ii) the establishments of the compartment covered by the application have started or resumed their activities and have established a common biosecurity management system designed to ensure the freedom from disease of that compartment;
- c the compartment covered by the application is subject to a single common biosecurity management system designed to ensure the disease-free status of all establishments forming part of it; and

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- d the compartment covered by the application has been approved by the competent authority for the purposes of movements of animals and products thereof in accordance with:
 - (i) Articles 99 and 100 for compartments keeping terrestrial animals and products thereof;
 - (ii) Articles 183 and 184 for compartments keeping aquaculture animals and products thereof.

3 Applications by Member States for recognition of the disease-free status of compartments in accordance with paragraphs 1 and 2 shall include evidence demonstrating that the conditions laid down in those paragraphs are fulfilled.

4 The Commission shall, by means of implementing acts:

- a recognise, subject to amendments where necessary, the disease-free status of compartments, when the conditions laid down in paragraph 1 or paragraph 2 and in paragraph 3 are fulfilled;
- b determine for which of the listed diseases referred to in points (a), (b) and (c) of Article 9(1) the disease-free compartments may be established.

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

5 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning provisions supplementing those contained in this Article, on:

- a the requirements for recognition of the disease-free status of compartments as provided for in paragraphs 1 and 2 of this Article, based on the profile of the listed diseases referred to in points (a), (b) and (c) of Article 9(1), concerning at least:
 - (i) surveillance results and other evidence needed to substantiate freedom from disease;
 - (ii) biosecurity measures;
- b the detailed rules for the approval by the competent authority of the disease-free status of compartments as provided for in paragraphs 1 and 2; and
- c rules concerning compartments which are located in the territory of more than one Member State.

Article 38

Lists of disease-free Member States, zones or compartments

Each Member State shall establish and maintain an up-to-date list of its territory or zones with disease-free status as provided for in Article 36(1) and (3), and of its compartments with disease-free status, as provided for in Article 37(1) and (2), when applicable.

Member States shall make those lists publicly available. The Commission shall assist the Member States in making the information contained in those lists available to the public by providing on its internet page the links to the internet-based information pages of the Member States.

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Article 39

Delegation of powers concerning the disease-free status of Member States and zones

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

- (a) detailed rules for the disease-free status of Member States and zones thereof, based on the different disease profiles, concerning:
 - (i) the criteria to be used to substantiate claims by Member States that no listed species are present or able to survive in their territory and the evidence required to substantiate such claims, as provided for in point (a) of Article 36(1);
 - (ii) the criteria to be used, and the evidence required, to substantiate claims that a disease agent or vector is not able to survive, as provided for in points (b) and (c) of Article 36(1);
 - (iii) the criteria to be used, and the conditions to be applied, to determine freedom from the disease in question, as referred to in point (d) of Article 36(1);
 - (iv) surveillance results and other evidence needed to substantiate freedom from disease;
 - (v) biosecurity measures;
 - (vi) restrictions and conditions for vaccination in disease-free Member States and zones thereof;
 - (vii) the establishment of zones separating disease-free zones or zones under the eradication programme from restricted zones ('buffer zones');
 - (viii) zones which are located in the territory of more than one Member State;
- (b) derogations from the requirement for approval by the Commission of disease-free status for one or more listed diseases referred to in points (b) and (c) of Article 9(1), as laid down in Article 36(1), where such approval is not necessary on account of detailed rules for freedom from disease having been laid down in rules adopted pursuant to point (a) of this Article;
- (c) the information to be provided by Member States to the Commission and the other Member States to substantiate declarations of disease-free status, without the adoption of an implementing act in accordance with Article 36(4), as provided for in point (b) of this Article.

Article 40

Implementing powers

The Commission shall, by means of implementing acts, lay down detailed requirements concerning the information to be provided by Member States to the Commission and the other Member States to substantiate declarations of disease-free status of territories, zones and compartments in accordance with Articles 36 to 39, and the format and procedures for:

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- (a) applications for recognition of disease-free status of the entire territory of the Member State concerned, or zones and compartments thereof;
- (b) exchanges of information between the Member States and the Commission on disease-free Member States, or zones and compartments thereof.

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

Article 41

Maintenance of disease-free status

1 Member States shall only maintain disease-free status for their territories, or zones or compartments thereof, as long as:

- a the conditions for disease-free status laid down in Article 36(1) and Article 37(1) and (2), and rules laid down pursuant to paragraph 3 of this Article and Article 39, continue to be fulfilled;
- b surveillance, taking into account the requirements provided for in Article 27, is undertaken to verify that the territory, zone or compartment concerned continues to be free of the listed disease for which it was approved or recognised as having disease-free status;
- c restrictions are applied on movements of animals, and where relevant products derived therefrom, of listed species for the listed disease for which the disease-free status was approved or recognised, into the territory, zone or compartment concerned, in accordance with the rules laid down in Parts IV and V;
- d other biosecurity measures are applied to prevent the introduction of the listed disease for which it was approved or recognised as having disease-free status.

2 A Member State shall immediately inform the Commission if the conditions referred to in paragraph 1 for maintaining disease-free status are no longer met.

3 The Commission shall adopt delegated acts in accordance with Article 264 concerning the following conditions for maintaining disease-free status:

- a surveillance as provided for in point (b) of paragraph 1;
- b biosecurity measures as provided for in point (d) of paragraph 1.

Article 42

Suspension, withdrawal and restoration of disease-free status

1 Where a Member State becomes aware, or has reason to suspect, that any of the conditions for maintaining its status as a disease-free Member State or zone or compartment thereof, have been breached, it shall immediately:

- a where relevant, depending on the risk, suspend or restrict movements of the listed species, for the listed disease for which it was approved or recognised as having disease-free status, to other Member States, zones or compartments with a higher health status for that listed disease;
- b where relevant for the prevention of the spread of a listed disease for which disease-free status has been approved or recognised, apply the disease control measures provided for in Title II of Part III.

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2 The measures provided for in paragraph 1 shall be lifted where further investigation confirms that:

- a the suspected breach has not taken place; or
- b the suspected breach has not had a significant impact and the Member State concerned can provide assurances that the conditions for maintaining its disease-free status are again fulfilled.

3 Where further investigation by the Member State concerned confirms that there has been an outbreak of the listed disease for which it obtained disease-free status, or that other significant breaches of the conditions for maintaining disease-free status as referred to in Article 41(1) have occurred, or where there is a significant likelihood of this having occurred, the Member State shall immediately inform the Commission thereof.

4 The Commission shall, by means of implementing acts, withdraw without undue delay the approval of the disease-free status of a Member State or zone granted in accordance with Article 36(4) or the recognition of the disease-free status of a compartment granted in accordance with Article 37(4) after obtaining the information from the Member State concerned that the conditions for maintaining the disease-free status are no longer met.

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

5 On duly justified imperative grounds of extreme urgency, where the listed disease referred to in paragraph 3 of this Article spreads in a rapid manner, carrying with it the risk of a highly significant impact on animal or public health, the economy or society, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure provided for in Article 266(3).

6 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning provisions supplementing the rules for the suspension, withdrawal and restoration of disease-free status set out in paragraphs 1 and 2 of this Article.

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