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 1

Disease notification and reporting

Article 18

Notification within Member States

1 Member States shall ensure that operators and other relevant natural or legal persons:

a immediately notify the competent authority where there are any reasons to suspect the presence in animals of a listed disease as referred to in point (a) of Article 9(1), or where the presence of such a disease is detected in animals;

b as soon as practicable notify the competent authority where there are any reasons to suspect the presence in animals of a listed disease as referred to in point (e) of Article 9(1) other than those referred to in point (a) of Article 9(1), or where the presence of such a disease is detected in animals;

c notify a veterinarian of abnormal mortalities and other signs of serious disease or significant decreased production rates with an undetermined cause, for further investigation, including sampling for laboratory examination when the situation so requires.

2 Member States may decide that the notifications provided for in point (c) of paragraph 1 may be directed to the competent authority.

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

a criteria to determine whether the circumstances requiring notification described in point (c) of paragraph 1 occur;

b detailed rules for the further investigation provided for in point (c) of paragraph 1.

Article 19

Union notification

1 Member States shall immediately notify the Commission and the other Member States of any outbreaks of listed diseases as referred to in point (e) of Article 9(1) for which an immediate notification is required in order to ensure the timely implementation of necessary risk management measures, taking into account the disease profile.

2 The notification provided for in paragraph 1 shall contain the following information on the outbreak:

a the disease agent and, where relevant, the subtype;

b the relevant dates, in particular those of the suspicion and the confirmation of the outbreak;

c the type and location of the outbreak;

d any related outbreaks;

e the animals involved in the outbreak;

f any disease control measures taken in relation to the outbreak;

g the possible or known origin of the listed disease;

h the diagnostic methods used.

Article 20

Union reporting

1 Member States shall report to the Commission and to the other Member States the information on listed diseases referred to in in point (e) of Article 9(1) for which:

a immediate notification of an outbreak is not required under Article 19(1);

b immediate notification of an outbreak is required under Article 19(1), but additional information is required to be reported to the Commission and the other Member States on:

(i) surveillance in accordance with the rules laid down in an implementing act adopted in accordance with Article 30;

(ii) an eradication programme in accordance with the rules laid down in an implementing act adopted in accordance with Article 35.

2 The reports provided for in paragraph 1 shall include information on:

a the detection of the listed diseases referred to in paragraph 1;

b the results of surveillance when required in accordance with rules adopted in accordance with point (d)(ii) of Article 29 or point (b)(ii) of Article 30(1);

c the results of surveillance programmes when required in accordance with Article 28(3) and rules adopted in accordance with point (d)(ii) of Article 29 or point (b)(ii) of Article 30(1);

d eradication programmes when required in accordance with Article 34 and rules laid down in an implementing act adopted in accordance with Article 35.

3 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning provisions supplementing the requirements of paragraph 2 and reporting on other matters concerning surveillance and eradication programmes where necessary in order to ensure an efficient application of the disease prevention rules and control rules laid down in this Regulation.

Article 21

Notification and reporting regions

The Member States shall establish notification and reporting regions for the purpose of the notification and reporting provided for in Articles 19 and 20.

Article 22

Computerised information system for Union notification and Union reporting of diseases

The Commission shall set up and manage a computerised information system for the operation of the mechanisms and tools for the notification and reporting requirements provided for in Articles 19, 20 and 21.

Article 23

Implementing powers concerning Union notification and Union reporting and the computerised information system

The Commission shall, by means of implementing acts, lay down rules for the notification and reporting requirements and the computerised information system provided for in Articles 19 to 22 with respect to:

(a) those listed diseases referred to in point (e) of Article 9(1) which are to be subject to immediate notification by the Member States as well as the necessary measures relating to the notification, in accordance with Article 19;

(b) the information to be provided by the Member States in the reporting provided for in Article 20;

(c) procedures for the establishment and use of the computerised information system provided for in Article 22 and transitional measures for the migration of the data and the information from existing systems into the new system and its full operability;

(d) the format and structure of the data to be entered into the computerised information system provided for in Article 22;

(e) the deadlines and frequencies of the notification and reporting provided for in Articles 19 and 20, which shall be done at times and frequencies which ensure transparency and the timely application of the necessary risk management measures, based on the disease profile and the type of outbreak.

(f) the listing of notification and reporting regions provided for in Article 21.

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

CHAPTER 2

Surveillance

Article 24

Operators' surveillance obligation

For the purpose of detecting the presence of listed diseases and emerging diseases, operators shall:

(a) observe the health and behaviour of animals under their responsibility;

(b) observe any changes in the normal production parameters in the establishments, animals or germinal products under their responsibility that may give rise to a suspicion of being caused by a listed disease or emerging disease;

(c) look for abnormal mortalities and other signs of serious disease in animals under their responsibility.

Article 25

Animal health visits

1 Operators shall ensure that establishments under their responsibility receive animal health visits from a veterinarian when appropriate due to the risks posed by the establishment in question, taking into account:

a the type of establishment;

b the species and categories of kept animals on the establishment;

c the epidemiological situation in the zone or region as regards listed and emerging diseases to which the animals in the establishment are susceptible;

d any other relevant surveillance, or official controls to which the kept animals and type of establishment are subject.

Such animal health visits shall take place at frequencies that are proportionate to the risks posed by the establishment concerned.

They may be combined with visits for other purposes.

2 The animal health visits provided for in paragraph 1 shall be made for the purpose of disease prevention, in particular through:

a the provision of advice to the operator concerned on biosecurity and other animal health matters, as relevant for the type of establishment and the species and categories of kept animals on the establishment.

b the detection of, and information on, signs indicative of the occurrence of listed diseases or emerging diseases;

3 The Commission may, by means of implementing acts, lay down minimum requirements necessary for the uniform application of this Article.

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

Article 26

The competent authority's surveillance obligation

1 The competent authority shall conduct surveillance to detect the presence of listed diseases as referred to in point (e) of Article 9(1) and relevant emerging diseases.

2 The surveillance shall be designed in such a way as to ensure the timely detection of the presence of the listed diseases referred to in point (e) of Article 9(1) and emerging diseases by means of the collection, collation and analysis of relevant information relating to the disease situation.

3 The competent authority shall, whenever possible and appropriate, make use of the results of the surveillance conducted by operators and the information obtained through animal health visits in accordance with Articles 24 and 25, respectively.

4 The competent authority shall ensure that surveillance meets the requirements provided for in Article 27 and in any rules adopted pursuant to point (a) of Article 29.

5 The competent authority shall ensure that the information obtained through the surveillance provided for in paragraph 1 is collected and used in an effective and efficient manner.

Article 27

Methodology, frequency and intensity of surveillance

The design, means, diagnostic methods, frequency, intensity, targeted animal population, and sampling patterns of the surveillance provided for in Article 26 shall be appropriate and proportionate to the objectives of the surveillance, taking into account:

(a) the disease profile;

(b) the risk factors involved;

(c) the health status in:

  (i) the Member State, zone or compartment thereof subject to the surveillance;

  (ii) the Member States and third countries or territories which either border on, or from which animals and products enter into, that Member State, zone or compartment thereof;

(d) surveillance conducted by operators in accordance with Article 24, including animal health visits as referred to in Article 25, or by other public authorities.

Article 28

Union surveillance programmes

1 The competent authority shall undertake surveillance as provided for in Article 26(1) within the framework of a surveillance programme when a disease is relevant for the Union in accordance with point (c) of Article 29.

2 Member States establishing a surveillance programme in accordance with paragraph 1 shall submit it to the Commission.

3 Member States implementing a surveillance programme in accordance with paragraph 1 shall submit regular reports on the results of the implementation of that programme to the Commission.

Article 29

Delegation of powers

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

(a) the design, means, diagnostic methods, frequency, intensity, targeted animal population, and sampling patterns of the surveillance provided for in Article 27;

(b) the criteria for the official confirmation and case definitions of listed diseases as referred to in point (e) of Article 9(1), and, where relevant, of emerging diseases;

(c) the criteria used to establish the relevance of a disease which is to be subject to a surveillance programme relevant for the Union for the purposes of point (a) of Article 30(1), taking into account the disease profile and the risk factors involved;

(d) requirements for surveillance programmes as provided for in Article 28(1) regarding:

(i) the contents of surveillance programmes;

(ii) the information to be included in the submission of surveillance programmes in accordance with Article 28(2) and regular reports in accordance with Article 28(3);

(iii) the period of application of surveillance programmes.

Article 30

Implementing powers

1 The Commission shall, by means of implementing acts, lay down requirements concerning surveillance and surveillance programmes as provided for in Articles 26 and 28 and in the rules adopted pursuant to Article 29, as regards:

a establishing which of the listed diseases referred to in point (e) of Article 9(1) are to be subject to surveillance programmes in accordance with Article 28, including the geographical scope of such programmes;

b the format and procedure for:

(i) the submission of those surveillance programmes for information to the Commission and other Member States;

(ii) the reporting to the Commission on the results of the surveillance.

2 The Commission may, by means of implementing acts, lay down the criteria to be used for evaluating the surveillance programmes referred to in Article 28.

3 The implementing acts referred to in paragraphs 1 and 2 of this Article shall be adopted in accordance with the examination procedure referred to in Article 266(2).

CHAPTER 3

Eradication programmes

Article 31

Compulsory and optional eradication programmes

1 Member States which are not free, or not known to be free, from one or more of the listed diseases referred to in point (b) of Article 9(1) throughout their territory, or in zones or compartments thereof, shall:

a establish a programme for the eradication of, or demonstration of freedom from, that listed disease, to be carried out in the animal populations concerned by that disease and covering the relevant parts of their territory or the relevant zones or compartments thereof ('compulsory eradication programme'), to apply until the conditions for the grant of disease–free status in the territory of the Member State or zone concerned, as provided for in Article 36(1), or compartment, as provided for in Article 37(2), are fulfilled;

b submit the draft compulsory eradication programme to the Commission for approval.

2 Member States which are not free, or not known to be free, from one or more of the listed diseases referred to in point (c) of Article 9(1) and which decide to establish a programme for the eradication of that listed disease, to be carried out in the animal populations concerned by the disease in question and covering the relevant parts of their territory or zones or compartments thereof ('optional eradication programme'), shall submit a draft of that programme to the Commission for approval, where the Member State concerned asks for the recognition, within the Union, of animal health guarantees as regards the disease in question for movements of animals or products.

Such an optional eradication programme shall apply until:

a the conditions for the grant of disease–free status in the territory of the Member State or zone concerned, as provided for in Article 36(1), or compartment, as provided for in Article 37(2), are fulfilled; or

b it is established that the conditions for the grant of disease–free status cannot be achieved and that the programme no longer fulfils its purpose; or

c the Member State concerned withdraws the programme.

3 The Commission shall, by means of implementing acts, approve:

a draft compulsory eradication programmes submitted to it for approval in accordance with paragraph 1;

b draft optional eradication programmes submitted to it for approval in accordance with paragraph 2,

if the conditions set out in this Chapter are met.

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 a risk having a highly significant impact, the Commission shall adopt immediately applicable implementing acts provided for in point (a) of paragraph 3 of this Article in accordance with the procedure referred to in Article 266(3).

The Commission may, for duly justified reasons, by means of implementing acts, approve an amendment proposed by the Member State concerned or withdraw the approval of eradication programmes approved in accordance with points (a) and (b) of paragraph 3 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

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

a the disease control strategies, intermediate and final targets for specific diseases, and period of application of eradication programmes;

b derogations from the requirement for the submission of eradication programmes for approval, as provided for in point (b) of paragraph 1 of this Article and in paragraph

2 thereof, where such approval is not necessary due to the adoption of rules regarding those programmes in accordance with Articles 32(2) and 35;

c the information to be provided by Member States to the Commission and to the other Member States concerning derogations from the requirement for approval of eradication programmes as provided for in point (b) of this paragraph.

The Commission shall be empowered to adopt delegated acts in accordance with Article 264 amending or discontinuing rules adopted pursuant to point (b) of this paragraph.

Article 32

Measures under compulsory and optional eradication programmes

1 Eradication programmes shall consist of at least the following measures:

a disease control measures for the eradication of the disease agent from establishments, compartments and zones in which a disease occurs and to prevent re–infection;

b surveillance to be carried out in accordance with the rules laid down in Articles 26 to 30 to demonstrate:

(i) the effectiveness of the disease control measures provided for in point (a);

(ii) freedom from the listed disease;

c disease control measures to be taken in the event of positive surveillance results.

2 The Commission shall adopt delegated acts in accordance with Article 264 concerning the following elements to ensure the effectiveness of eradication programmes:

a disease control measures as provided for in point (a) of paragraph 1;

b disease control measures to be taken to avoid re–infection of the targeted animal population with the disease in question in establishments, zones and compartments;

c surveillance design, means, diagnostic methods, frequency, intensity, targeted animal population and sampling patterns;

d disease control measures to be taken in the event of positive surveillance results for the listed disease as provided for in point (c) of paragraph 1;

e criteria for vaccination, where relevant and appropriate for the disease or species in question.

Article 33

Content of compulsory and optional eradication programmes submitted for approval to the Commission

Member States shall include the following information in applications for approval of compulsory and optional eradication programmes submitted to the Commission in accordance with Article 31(1) and (2):

(a) a description of the epidemiological situation of the listed disease covered by the compulsory or optional eradication programme in question;

(b) a description and demarcation of the geographical and administrative area or the compartment covered by the eradication programme;

(c) a description of the disease control measures of the eradication programme as provided for in Article 32(1) and in the rules adopted pursuant to Article 32(2);

(d) a description of the organisation, supervision and roles of the parties involved in the eradication programme;

(e) the estimated duration of the eradication programme;

(f) the intermediate targets of, and the disease control strategies for implementing, the eradication programme.

Article 34

Reporting

Member States implementing eradication programmes shall submit to the Commission:

(a) reports enabling the Commission to monitor achievement of the intermediate targets of the on-going eradication programmes as referred to in point (f) of Article 33;

(b) a final report after completion of the eradication programme in question.

Article 35

Implementing powers

The Commission shall, by means of implementing acts, lay down rules concerning the information, format and procedural requirements provided for in Articles 31 to 34 as regards:

(a) the submission of draft compulsory and draft optional eradication programmes for approval;

(b) performance indicators;

(c) reporting to the Commission and other Member States on the results of the implementation of compulsory or optional eradication programmes.

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

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

(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

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.

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:

(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.

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.

Status:
Point in time view as at 09/03/2016.

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.