

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 III

**DISEASE AWARENESS, PREPAREDNESS AND CONTROL**

TITLE II

**DISEASE CONTROL MEASURES**

*CHAPTER I*

***Disease control measures for listed diseases as referred to in point (a) of Article 9(1)***

*Section 1*

***Disease control measures in the event of suspicion of a listed disease in kept animals***

*Article 53*

**Obligations on operators and other relevant natural and legal persons concerned**

1 In the event of suspicion of a listed disease as referred to in point (a) of Article 9(1) in kept animals, in addition to complying with the notification obligation laid down in Article 18(1) and pending any disease control measures being taken by the competent authority in accordance with Articles 54(1) and 55(1), Member States shall take measures to ensure that operators and other relevant natural and legal persons concerned take the appropriate disease control measures provided for in points (c), (d) and (e) of Article 55(1), to prevent the spread of that listed disease from the affected animals, establishments and locations under their responsibility to other unaffected animals or to humans.

2 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning detailed rules for supplementing the disease control measures provided for in paragraph 1 of this Article.

*Article 54*

**Investigation by the competent authority in the event of suspicion of a listed disease**

1 In the event of suspicion of a listed disease as referred to in point (a) of Article 9(1) in kept animals, the competent authority shall conduct without delay an investigation to confirm or rule out the presence of that listed disease.

2 For the purpose of the investigation provided for in paragraph 1, the competent authority shall, when appropriate, ensure that:

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- a official veterinarians carry out a clinical examination of a representative sample of the kept animals of listed species for the listed disease in question;
  - b official veterinarians take appropriate samples from those kept animals of listed species and other samples for examination in laboratories designated for that purpose by the competent authority;
  - c such designated laboratories carry out examinations to confirm or rule out the presence of the listed disease in question.
- 3 The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed rules supplementing the rules for investigations by competent authorities as provided for in paragraph 1 of this Article.

#### *Article 55*

##### **Preliminary disease control measures by competent authorities**

- 1 The competent authority shall, in the event that it suspects the presence of a listed disease as referred to in point (a) of Article 9(1) in kept animals, carry out the following preliminary disease control measures, subject to national requirements for gaining access to private residences, pending the results of the investigation provided for in Article 54(1) and the carrying-out of the disease control measures provided for in Article 61(1):
- a place the establishment, food and feed business or animal by-products establishment concerned, or any other location where the disease is suspected of having occurred, including locations where the suspected disease may have originated, under official surveillance;
  - b compile an inventory of:
    - (i) the kept animals in the establishment, food and feed business, or animal by-products establishment concerned, or in any other location;
    - (ii) the products in that establishment, food and feed business, or animal by-products establishment, or in any other location, where relevant for the spread of that listed disease;
  - c ensure that appropriate biosecurity measures are applied to prevent the spreading of that listed disease agent to other animals or to humans;
  - d when appropriate to prevent the further spread of the disease agent, ensure that the kept animals of listed species for that listed disease are isolated, and that they are prevented from coming into contact with wildlife;
  - e restrict the movements of kept animals, products and, if appropriate, people, vehicles and any material or other means by which the disease agent could have spread to or from the establishment, food and feed business or animal by-products establishment, or from any other location where that listed disease is suspected, as far as necessary to prevent its spread;
  - f take any other necessary disease control measures, taking into account the disease control measures provided for in Section 4 of this Chapter, concerning:
    - (i) the application of the investigation by the competent authority provided for in Article 54(1) and disease control measures provided for in points (a) to (d) of this paragraph to other establishments, food and feed businesses, or animal by-products establishments, or to any other location;
    - (ii) the establishment of any temporary restricted zones which are appropriate, taking into account the disease profile;

g initiate the epidemiological enquiry provided for in Article 57(1).

2 The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed rules supplementing those laid down in paragraph 1 of this Article as regards the specific and detailed disease control measures to be taken depending on the listed disease referred to in point (a) of Article 9(1), based on the risks involved for:

- a the species or category of animals concerned;
- b the type of production concerned.

#### *Article 56*

#### **Review and extension of the preliminary disease control measures**

The disease control measures provided for in Article 55(1) shall be:

- (a) reviewed by the competent authority, as appropriate, following the findings of:
  - (i) the investigation provided for in Article 54(1);
  - (ii) the epidemiological enquiry provided for in Article 57(1);
- (b) further extended to other locations as referred to in point (a) of Article 55(1), where necessary.

#### *Section 2*

#### ***Epidemiological enquiry***

#### *Article 57*

#### **Epidemiological enquiry**

1 The competent authority shall carry out an epidemiological enquiry in the event of the confirmation of a listed disease as referred to in point (a) of Article 9(1) in animals.

- 2 The epidemiological enquiry provided for in paragraph 1 shall aim to:
- a identify the likely origin of the listed disease in question and the means of its spread;
  - b calculate the likely length of time that the listed disease has been present;
  - c identify establishments and epidemiological units therein, food and feed businesses or animal by-products establishments, or other locations, where animals of listed species for the suspected listed disease may have become infected, infested or contaminated;
  - d obtain information on the movements of kept animals, persons, products, vehicles, any material or other means by which the disease agent could have been spread during the relevant period preceding the notification of the suspicion or confirmation of the listed disease;
  - e obtain information on the likely spread of the listed disease in the surrounding environment, including the presence and distribution of disease vectors.

### *Section 3*

#### ***Disease confirmation in kept animals***

##### *Article 58*

#### **Official confirmation by the competent authority of a listed disease as referred to in point (a) of Article 9(1)**

1 The competent authority shall base an official confirmation of a listed disease as referred to in point (a) of Article 9(1) on the following information:

- a the results of the clinical and laboratory examinations provided for in Article 54(2);
- b the preliminary or final results of the epidemiological enquiry provided for in Article 57(1);
- c other available epidemiological data.

2 The Commission shall adopt delegated acts in accordance with Article 264 concerning the requirements to be fulfilled for the official confirmation referred to in paragraph 1 of this Article.

##### *Article 59*

#### **Lifting of preliminary disease control measures where the presence of the listed disease has been ruled out**

The competent authority shall continue to apply the preliminary disease control measures provided for in Article 55(1) and Article 56 until the presence of the listed disease in question, as referred to in point (a) of Article 9(1), has been ruled out on the basis of the information referred to in Article 58(1) or rules adopted pursuant to Article 58(2).

### *Section 4*

#### ***Disease control measures in the event of confirmation of disease in kept animals***

##### *Article 60*

#### **Immediate disease control measures to be taken by the competent authority**

In the event of an official confirmation in accordance with Article 58(1) of an outbreak of a listed disease as referred to in point (a) of Article 9(1) in kept animals, the competent authority shall immediately:

- (a) declare the affected establishment, food or feed business, animal by-products establishment or other location as officially infected with that listed disease;
- (b) establish a restricted zone appropriate for that listed disease;
- (c) implement the contingency plan provided for in Article 43(1) to ensure full coordination of the disease control measures.

## Article 61

### Affected establishments and other locations

1 In the event of an outbreak of a listed disease as referred to in point (a) of Article 9(1) in kept animals, the competent authority shall immediately take one or more of the following disease control measures, subject to national requirements for gaining access to private residences, in an establishment, food or feed business, animal by-products establishment, or any other location referred to in point (a) of Article 60, in order to prevent the further spread of that listed disease:

- a the imposition of restrictions on movements of persons, animals, products, vehicles or any other material or substance that may be contaminated and contribute to the spread of the listed disease;
- b the killing and disposal or slaughtering of animals that may be contaminated or contribute to the spread of the listed disease;
- c the destruction, processing, transformation or treatment of products, feed, or any other substances, or the treatment of equipment, means of transport, plants or plant products, or water which may be contaminated, as appropriate to ensure that any disease agent or vector of the disease agent is destroyed;
- d the vaccination or treatment with other veterinary medicinal products of kept animals in accordance with Article 46(1) and Article 69 and any delegated acts adopted pursuant to Article 47;
- e the isolation, quarantine or treatment of animals and products that are likely to be contaminated and contribute to the spread of the listed disease;
- f the cleaning, disinfection, control of insects and rodents, or other necessary biosecurity measures to be applied to the affected establishment, food or feed business, animal by-products establishment or other locations to minimise the risk of spread of the listed disease;
- g the taking of a sufficient number of appropriate samples needed to complete the epidemiological enquiry provided for in Article 57(1);
- h the laboratory examination of samples;
- i any other appropriate measures.

2 When determining which of the disease control measures provided for in paragraph 1 are appropriate to take, the competent authority shall take the following into account:

- a the disease profile;
- b the type of production, and epidemiological units within the affected establishment, food or feed business, animal by-products establishment or other location;

3 The competent authority shall only authorise the repopulation of the establishment concerned, or of any other location, when:

- a all appropriate disease control measures and laboratory examinations provided for in paragraph 1 have been successfully completed;
- b a sufficient period of time has elapsed to prevent re-contamination of the affected establishment, food or feed business, animal by-products establishment or other location with the listed disease that caused the outbreak referred to in paragraph 1.

### *Article 62*

#### **Epidemiologically linked establishments and locations**

1 The competent authority shall extend the disease control measures provided for in Article 61(1) to other establishments, epidemiological units therein, food or feed businesses, or animal by-products establishments, or any other location, or means of transport where the epidemiological enquiry provided for in Article 57(1) or the results of clinical or laboratory investigations or other epidemiological data, give reason to suspect the spread to, from or through them of the listed disease referred to in point (a) of Article 9(1) in respect of which such measures were taken.

2 If the epidemiological enquiry provided for in Article 57(1) shows that the likely origin of the listed disease referred to in point (a) of Article 9(1) is another Member State, or if it is likely that that listed disease has spread to another Member State, the competent authority shall inform that Member State and the Commission without delay.

3 Should any of the events referred to in paragraph 2 occur, the competent authorities of the different Member States shall cooperate in a further epidemiological enquiry and in the application of disease control measures.

### *Article 63*

#### **Delegation of powers in respect of disease control measures in affected and epidemiologically linked establishments and other locations**

The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed rules on the disease control measures to be taken by the competent authority in accordance with Articles 61 and 62 in affected and epidemiologically linked establishments, food or feed businesses, or animal by-products establishments, and other locations in respect of any listed disease referred to in point (a) of Article 9(1), including rules on which disease control measures referred to in Article 61(1) are to be applied in relation to each listed disease.

Those detailed rules shall cover the following matters:

- (a) the conditions and requirements for the disease control measures provided for in points (a) to (e) of Article 61(1);
- (b) the procedures for cleaning, disinfection, control of insects and rodents, or other necessary biosecurity measures as provided for in point (f) of Article 61(1), specifying, where appropriate, the use of biocidal products for those purposes;
- (c) the conditions and requirements for sampling and laboratory examination as provided for in points (g) and (h) of Article 61(1);
- (d) the detailed conditions and requirements in respect of repopulation as provided for in Article 61(3);
- (e) the carrying-out of the necessary disease control measures provided for in Article 62 in epidemiologically linked establishments, other locations and means of transport.

## Article 64

### **Establishment of restricted zones by the competent authority**

1 The competent authority shall establish a restricted zone as referred to in point (b) of Article 60 around the affected establishment, food or feed business, animal by-products establishment or other location where the outbreak of a listed disease as referred to in point (a) of Article 9(1) in kept animals has occurred, where appropriate taking into account:

- a the disease profile;
- b the geographical situation of the restricted zone;
- c the ecological and hydrological factors of the restricted zone;
- d the meteorological conditions;
- e the presence, distribution and type of vectors in the restricted zone;
- f the results of the epidemiological enquiry provided for in Article 57(1) and other studies carried out and epidemiological data;
- g the results of laboratory tests;
- h the disease control measures applied;
- i other relevant epidemiological factors.

The restricted zone shall include, when appropriate, a protection and surveillance zone of a defined size and configuration.

2 The competent authority shall continuously assess and review the situation and, when appropriate in order to prevent the spread of the listed disease referred to in point (a) of Article 9(1), shall:

- a adapt the boundaries of the restricted zone;
- b establish additional restricted zones.

3 Where restricted zones as provided for in paragraph 1 are situated in the territory of more than one Member State, the competent authorities of those Member States shall cooperate in establishing them.

4 The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed rules for the establishment and modification of restricted zones, including protection or surveillance zones.

## Article 65

### **Disease control measures in restricted zones**

1 The competent authority shall ensure that, subject to national requirements for gaining access to private residences, one or more of the following disease control measures are taken in the restricted zone concerned, in order to prevent the further spread of a listed disease as referred to in point (a) of Article 9(1):

- a the identification of establishments, food or feed businesses, animal by-products establishments or other locations with kept animals of listed species for that listed disease;
- b visits to establishments, food or feed businesses, animal by-products establishments or other locations with kept animals of listed species for that listed disease, and, where necessary, examinations, sampling and laboratory examination of the samples taken;

- c the imposition of conditions for the movement of persons, animals, products, feed, vehicles and any other material or substance that may be contaminated or contribute to the spread of that listed disease within and from the restricted zone and transport through the restricted zone;
  - d biosecurity requirements for:
    - (i) the production, processing and distribution of products of animal origin;
    - (ii) the collection and disposal of animal by-products;
    - (iii) the collection, storage and handling of germinal products;
  - e the vaccination and treatment with other veterinary medicinal products of kept animals in accordance with Article 46(1) and any delegated acts adopted pursuant to Article 47;
  - f cleaning, disinfection, control of insects and rodents, or other necessary biosecurity measures;
  - g the designation or where relevant, approval of a food business establishment for the purposes of the slaughtering of animals or the treatment of products of animal origin originating from the restricted zone;
  - h the identification and traceability requirements for the movement of animals, germinal products or products of animal origin;
  - i other necessary biosecurity and risk-mitigating measures to minimise the risk of the spread of that listed disease.
- 2 The competent authority shall:
- a take all necessary measures to fully inform persons in the restricted zone of the restrictions in force and the nature of the disease control measures;
  - b impose the necessary obligations on operators in order to prevent the further spread of the listed disease in question.
- 3 When determining which of the disease control measures provided for in paragraph 1 are to be taken, the competent authority shall take the following into account:
- a the disease profile;
  - b the types of production;
  - c the feasibility, availability and effectiveness of those disease control measures.

### *Article 66*

#### **Operators' obligations regarding movements in restricted zones**

1 In restricted zones as provided for in Article 64(1), operators shall only move the kept animals and products with the permission of the competent authority and in accordance with any instructions given by that authority.

2 Operators keeping animals and products in a restricted zone as provided for in Article 64(1) shall notify to the competent authority intended movements of kept animals and products within or out of the restricted zone in question. In so far as the competent authority has imposed notification obligations in accordance with point (b) of Article 65(2), the operators concerned shall notify in accordance with those obligations.



## Article 67

### **Delegation of powers concerning disease control measures in restricted zones**

The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed rules on the disease control measures to be taken in restricted zones as provided for in Article 65(1) for each listed disease referred to in point (a) of Article 9(1), including rules on which disease control measures referred to in Article 65(1) are to be applied in the case of each listed disease.

Those detailed rules shall cover the following matters:

- (a) the conditions and requirements for the disease control measures provided for in points (a), (c), (d), (e), (g), (h) and (i) of Article 65(1);
- (b) the procedures for cleaning, disinfection, control of insects and rodents, or other necessary biosecurity measures as provided for in point (f) of Article 65(1), specifying, where appropriate, the use of biocidal products for those purposes;
- (c) the necessary surveillance which is to be conducted following the application of the disease control measures and laboratory examinations provided for in point (b) of Article 65(1);
- (d) other specific disease control measures to limit the spread of specific listed diseases as referred to in point (a) of Article 9(1).

## Article 68

### **Maintaining disease control measures in restricted zones and delegated acts**

1 The competent authority shall continue to apply the disease control measures provided for in this Section until the following conditions are met:

- a the disease control measures appropriate to the listed disease referred to in point (a) of Article 9(1) for which they were applied have been carried out;
- b the final cleaning, disinfection, control of insects and rodents, or other necessary biosecurity measures has been carried out as appropriate for:
  - (i) the listed disease referred to in point (a) of Article 9(1) for which the disease control measures have been applied;
  - (ii) the affected species of kept animals;
  - (iii) the type of production;
- c adequate surveillance, as appropriate for the listed disease referred to in point (a) of Article 9(1) for which the disease control measures have been applied, and for the type of establishment or location concerned, has been carried out in the restricted zone substantiating the eradication of that listed disease.

2 The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed rules for the disease control measures to be taken by the competent authority, as provided for in paragraph 1, in relation to:

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- a the final procedures for cleaning, disinfection, control of insects and rodents, or other necessary biosecurity measures and, where appropriate, the use of biocidal products for those purposes;
  - b the design, means, methods, frequency, intensity, targeted animal population and sampling patterns of surveillance aimed at the restoration of disease-free status after the outbreak;
  - c repopulation of the restricted zone concerned after the completion of the disease control measures provided for in paragraph 1 of this Article, taking into account the conditions for repopulation provided for in Article 61(3).
- 3 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning detailed rules for the disease control measures to be taken by the competent authority, as provided for in paragraph 1, in relation to other disease control measures necessary for the restoration of disease-free status.

#### *Article 69*

### **Emergency vaccination**

- 1 Where relevant for the effective control of a listed disease as referred to in point (a) of Article 9(1) for which disease control measures apply, the competent authority may:
- a develop a vaccination plan;
  - b establish vaccination zones.
- 2 When deciding on the vaccination plan and the establishment of vaccination zones as provided for in paragraph 1, the competent authority shall take the following into account:
- a the requirements for emergency vaccination set out in the contingency plans provided for in Article 43;
  - b the requirements for the use of vaccines as provided for in Article 46(1) and any delegated acts adopted pursuant to Article 47.
- 3 Vaccination zones as provided for in point (b) of paragraph 1 of this Article shall meet the requirements in respect of risk-mitigating measures to prevent the spread of listed diseases and surveillance as laid down in any delegated acts adopted in accordance with points (c) and (d) of Article 47(1).

#### *Section 5*

### **Wild animals**

#### *Article 70*

### **Wild animals**

- 1 Where the competent authority of an affected Member State suspects or officially confirms the presence of a listed disease as referred to in point (a) of Article 9(1) in wild animals, it shall:
- a conduct, where relevant for that particular listed disease, surveillance in the wild animal population;
  - b take the necessary disease prevention and control measures.

2 The disease prevention and control measures provided for in point (b) of paragraph 1 of this Article may include one or more of the measures laid down in Article 53 to 69 and shall take into account the disease profile and the affected wild animals and the risk of transmission of diseases to animals and humans.

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

- a criteria and procedures for surveillance pursuant to point (a) of paragraph 1 of this Article in the case of official confirmation of a listed disease as referred to in point (a) of Article 9(1), in accordance with Article 27;
- b detailed rules supplementing the disease prevention and control measures to be taken pursuant to point (b) of paragraph 1 of this Article in the case of official confirmation of a listed disease as referred to in point (a) of Article 9(1).

When adopting those delegated acts, the Commission shall take into account the disease profile and the listed species for the listed disease referred to paragraph 1 of this Article.

#### *Section 6*

#### ***Additional disease control measures by the Member States, coordination by the Commission and temporary special disease control rules***

#### *Article 71*

#### **Additional disease control measures, coordination of measures and temporary special disease control rules concerning Sections 1 to 5 (Articles 53 to 70)**

1 Member States may take disease control measures additional to those provided for in Article 55, Article 61(1), Article 62, Article 65(1) and (2) and Article 68(1) and in any delegated acts adopted pursuant to Article 63, Article 67 and Article 68(2), provided that such measures respect the rules laid down in this Regulation and are necessary and proportionate to control the spread of a listed disease as referred to in point (a) of Article 9(1), taking into account:

- a the particular epidemiological circumstances;
- b the type of establishments, other locations and production concerned;
- c the species and categories of animals involved;
- d economic or social conditions.

2 Member States shall inform the Commission without delay of:

- a the disease control measures taken by their competent authority as provided for in Articles 58, 59, 61, 62, 64 and 65, Article 68(1), Article 69 and Article 70(1) and (2) and in any delegated acts adopted pursuant to Articles 63 and 67 and Articles 68(2) and 70(3);
- b any additional disease control measures taken by them as provided for in paragraph 1.

3 The Commission shall review the disease situation and the disease control measures taken by the competent authority and any additional disease control measures taken by the Member State concerned, in accordance with this Chapter, and may, by means of implementing acts, lay down special disease control measures for a limited period of time, under conditions appropriate to the epidemiological situation, where:

- a those disease control measures are found not to be suited to the epidemiological situation;

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- b the listed disease referred to in point (a) of Article 9(1) appears to be spreading despite the disease control measures taken in accordance with this Chapter.

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 of a highly significant impact, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 266(3).