

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 I

*Subject matter, aim, scope and definitions*

*Article 1*

**Subject matter and aim**

1 This Regulation lays down rules for the prevention and control of animal diseases which are transmissible to animals or to humans.

Those rules provide for:

- a the prioritisation and categorisation of diseases of Union concern and for the establishment of responsibilities for animal health (Part I: Articles 1 to 17);
- b the early detection, notification and reporting of diseases, surveillance, eradication programmes and disease-free status (Part II: Articles 18 to 42);
- c disease awareness, preparedness and control (Part III: Articles 43 to 83);
- d the registration and approval of establishments and transporters, movements and traceability of animals, germinal products and products of animal origin within the Union (Part IV: Articles 84 to 228; and Part VI: Articles 244 to 248 and 252 to 256);
- e the entry of animals, germinal products, and products of animal origin into the Union and the export of such consignments from the Union (Part V: Articles 229 to 243; and Part VI: Articles 244 to 246 and 252 to 256);
- f non-commercial movements of pet animals into a Member State from another Member State or from a third country or territory, (Part VI: Articles 244 to 256);
- g the emergency measures to be taken in the event of a disease emergency situation (Part VII: Articles 257 to 262).

2 The rules referred to in paragraph 1:

- a aim to ensure:
  - (i) improved animal health to support sustainable agricultural and aquaculture production in the Union;
  - (ii) the effective functioning of the internal market;
  - (iii) a reduction in the adverse effects on animal health, public health and the environment of:
    - certain diseases;
    - the measures taken to prevent and control diseases;
- b take into account:

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- (i) the relationship between animal health and:
  - public health;
  - the environment, including biodiversity and valuable genetic resources, as well as the impact of climate change;
  - food and feed safety;
  - animal welfare, including the sparing of any avoidable pain, distress or suffering;
  - antimicrobial resistance;
  - food security;
- (ii) the economic, social, cultural and environmental consequences arising from the application of disease control and prevention measures;
- (iii) relevant international standards.

### *Article 2*

#### **Scope**

- 1 This Regulation shall apply to:
  - a kept and wild animals;
  - b germinal products;
  - c products of animal origin;
  - d animal by-products and derived products, without prejudice to the rules laid down in Regulation (EC) No 1069/2009;
  - e facilities, means of transport, equipment and all other paths of infection and material involved or potentially involved in the spread of transmissible animal diseases.
- 2 This Regulation shall apply to transmissible diseases, including zoonoses, without prejudice to the rules laid down in:
  - a Decision No 1082/2013/EU;
  - b Regulation (EC) No 999/2001;
  - c Directive 2003/99/EC;
  - d Regulation (EC) No 2160/2003.

### *Article 3*

#### **Scope of Parts IV, V and VI**

- 1 Title I of Part IV (Articles 84 to 171) shall apply to:
  - a terrestrial animals, and animals which are not terrestrial animals but which may transmit diseases affecting terrestrial animals;
  - b germinal products from terrestrial animals;
  - c products of animal origin from terrestrial animals.
- 2 Title II of Part IV (Articles 172 to 226) shall apply to:
  - a aquatic animals, and animals which are not aquatic animals but which may transmit diseases affecting aquatic animals;
  - b products of animal origin from aquatic animals.

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- 3 Title III of Part IV (Articles 227 and 228) shall apply to:
- a other animals;
  - b germinal products and products of animal origin from the other animals referred to in point (a).

4 Parts IV and V shall not apply to non-commercial movements of pet animals as referred to in paragraph 6 of this Article or to non-commercial movements of pet animals within a Member State.

5 Movements of pet animals, other than non-commercial movements, shall comply with the animal health requirements laid down in Parts IV and V.

The Commission shall adopt delegated acts in accordance with Article 264 concerning the adaptations which are necessary in order to ensure that Parts IV and V are correctly applied to pet animals, in particular to take account of the fact that pet animals are kept in households by pet keepers.

6 Part VI shall only apply to non-commercial movements of pet animals that comply with the requirements laid down in Articles 245 and 246 as regards the maximum number of animals that may accompany their owner and the maximum number of days elapsing between the movement of the owner and the movement of the animal.

#### Article 4

#### Definitions

For the purposes of this Regulation, the following definitions apply:

- (1) ‘animals’ means vertebrate and invertebrate animals;
- (2) ‘terrestrial animals’ means birds, terrestrial mammals, bees and bumble bees;
- (3) ‘aquatic animals’ means animals of the following species, at all life stages, including eggs, sperm and gametes:
  - (a) fish belonging to the superclass *Agnatha* and to the classes *Chondrichthyes*, *Sarcopterygii* and *Actinopterygii*;
  - (b) aquatic molluscs belonging to the phylum *Mollusca*;
  - (c) aquatic crustaceans belonging to the subphylum *Crustacea*;
- (4) ‘other animals’ means animals of species other than those falling within the definition of terrestrial or aquatic animals;
- (5) ‘kept animals’ means animals which are kept by humans, including, in the case of aquatic animals, aquaculture animals;
- (6) ‘aquaculture’ means the keeping of aquatic animals where the animals remain the property of one or more natural or legal persons throughout the rearing or culture stages, up to and including harvesting, excluding the harvesting or catching for the purposes of human consumption of wild aquatic animals which are subsequently temporarily kept while awaiting slaughter without being fed;
- (7) ‘aquaculture animals’ means any aquatic animals subject to aquaculture,
- (8) ‘wild animals’ means animals which are not kept animals;

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- (9) ‘poultry’ means birds that are reared or kept in captivity for:
- (a) the production of:
    - (i) meat;
    - (ii) eggs for consumption;
    - (iii) other products;
  - (b) restocking supplies of game birds;
  - (c) the purpose of breeding of birds used for the types of production referred to in points (a) and (b);
- (10) ‘captive birds’ means any birds other than poultry that are kept in captivity for any reason other than those referred to in point (9), including those that are kept for shows, races, exhibitions, competitions, breeding or selling;
- (11) ‘pet animal’ means a kept animal of the species listed in Annex I which is kept for private non-commercial purposes;
- (12) ‘pet keeper’ means a natural person, and may include a pet owner, keeping a pet animal;
- (13) ‘pet owner’ means a natural person indicated as the owner in the identification document referred to in point (c) of Article 247, point (c) of Article 248(2), point (c) of Article 249(1) and point (c) of Article 250(2);
- (14) ‘non-commercial movement’ means any movement of a pet animal accompanying its owner and which
- (a) does not have as its aim either the sale of or another form of transfer of ownership of the pet animal concerned; and
  - (b) is part of the movement of the pet owner:
    - (i) either under his direct responsibility; or
    - (ii) under the responsibility of an authorised person, in cases where the pet animal is physically separated from the pet owner;
- (15) ‘authorised person’ means any natural person who has authorisation in writing from the pet owner to carry out the non-commercial movement of the pet animal on behalf of the pet owner;
- (16) ‘disease’ means the occurrence of infections and infestations in animals, with or without clinical or pathological manifestations, caused by one or more disease agents;
- (17) ‘disease agent’ means a pathogen transmissible to animals or to humans which is capable of causing a disease in animals;
- (18) ‘listed diseases’ means diseases listed in accordance with Article 5(1);
- (19) ‘disease profile’ means the criteria of a disease referred to in point (a) of Article 7;
- (20) ‘listed species’ means an animal species or group of animal species listed in accordance with Article 8(2), or, in the case of emerging diseases, an animal species or group of animal species which meets the criteria for listed species laid down in Article 8(2);

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- (21) ‘hazard’ means a disease agent in, or a condition of, an animal or product with the potential to have an adverse effect on the health of humans or animals;
- (22) ‘risk’ means the likelihood of the occurrence and the likely magnitude of the biological and economic consequences of an adverse effect on animal or public health;
- (23) ‘biosecurity’ means the sum of management and physical measures designed to reduce the risk of the introduction, development and spread of diseases to, from and within:
- (a) an animal population, or
  - (b) an establishment, zone, compartment, means of transport or any other facilities, premises or location;
- (24) ‘operator’ means any natural or legal person having animals or products under his responsibility, including for a limited duration of time, but excluding pet keepers and veterinarians;
- (25) ‘transporter’ means an operator transporting animals on his own account or on account of a third party;
- (26) ‘animal professional’ means a natural or legal person having an occupational relationship with animals or products, other than operators or veterinarians;
- (27) ‘establishment’ means any premises, structure, or, in the case of open-air farming, any environment or place, where animals or germinal products are kept, on a temporary or permanent basis, except for:
- (a) households where pet animals are kept;
  - (b) veterinary practices or clinics;
- (28) ‘germinal products’ means:
- (a) semen, oocytes and embryos intended for artificial reproduction;
  - (b) hatching eggs;
- (29) ‘products of animal origin’ means:
- (a) food of animal origin, including honey and blood;
  - (b) live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods, intended for human consumption; and
  - (c) animals other than those referred to in point (b) intended to be prepared with a view to being supplied live to the final consumer;
- (30) ‘animal by-products’ means entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, excluding germinal products;
- (31) ‘derived products’ means products obtained from one or more treatments, transformations or steps in the processing of animal by-products;
- (32) ‘products’ means:
- (a) germinal products;
  - (b) products of animal origin;

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- (c) animal by-products and derived products;
- (33) ‘[<sup>F1</sup>official control’ means any form of control performed in accordance with Regulation [<sup>X1</sup>(EU) 2017/625] of the European Parliament and of the Council<sup>(1)</sup>];
- (34) ‘health status’ means the disease status as regards the listed diseases relevant for a particular listed species with respect to:
  - (a) an animal;
  - (b) animals within:
    - (i) an epidemiological unit;
    - (ii) an establishment;
    - (iii) a zone;
    - (iv) a compartment;
    - (v) a Member State;
    - (vi) a third country or territory;
- (35) ‘zone’ means:
  - (a) for terrestrial animals, an area of a Member State, third country or territory with a precise geographical delimitation, containing an animal subpopulation with a distinct health status with respect to a specific disease or specific diseases subject to appropriate surveillance, disease control and biosecurity measures;
  - (b) for aquatic animals, a contiguous hydrological system with a distinct health status with respect to a specific disease or specific diseases that forms an area that is referred to in one of the following:
    - (i) an entire water catchment from the source of a waterway to the estuary or lake;
    - (ii) more than one water catchment;
    - (iii) part of a water catchment from the source of a waterway to a barrier that prevents the introduction of a specific disease or diseases;
    - (iv) part of a coastal area with a precise geographical delimitation;
    - (v) an estuary with a precise geographical delimitation;
- (36) ‘water catchment’ means an area or basin of land bounded by natural features such as hills or mountains, into which all run-off water flows;
- (37) ‘compartment’ means an animal subpopulation contained in one or more establishments and, in the case of aquatic animals, in one or more aquaculture establishments, under a common biosecurity management system with a distinct health status with respect to a specific disease or specific diseases subject to appropriate surveillance, disease control and biosecurity measures;
- (38) ‘quarantine’ means the keeping of animals in isolation with no direct or indirect contact with animals outside the epidemiological unit, for the purpose of ensuring that

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- there is no spread of one or more specified diseases while the animals in isolation are undergoing observation for a specified length of time and, if appropriate, testing and treatment;
- (39) ‘epidemiological unit’ means a group of animals with the same likelihood of exposure to a disease agent;
- (40) ‘outbreak’ means the officially confirmed occurrence of a listed disease or an emerging disease in one or more animals in an establishment or other place where animals are kept or located;
- (41) ‘restricted zone’ means a zone in which restrictions on the movements of certain animals or products and other disease control measures are applied, with a view to preventing the spread of a particular disease into areas where no restrictions are applied; a restricted zone may, when relevant, include protection and surveillance zones;
- (42) ‘protection zone’ means a zone around and including the location of an outbreak, where disease control measures are applied in order to prevent the spread of the disease from that zone;
- (43) ‘surveillance zone’ means a zone which is established around the protection zone, and where disease control measures are applied in order to prevent the spread of the disease from the protection zone;
- (44) ‘hatching eggs’ means eggs, laid by poultry or captive birds, intended for incubation;
- (45) ‘ungulates’ means the animals listed in Annex III;
- (46) ‘germinal product establishment’ means:
- (a) in relation to semen, an establishment where semen is collected, produced, processed or stored;
  - (b) in relation to oocytes and embryos, a group of professionals or structure supervised by a team veterinarian competent to perform the collection, production, processing and storage of oocytes and embryos;
  - (c) in relation to hatching eggs, a hatchery;
- (47) ‘hatchery’ means an establishment which collects, stores, incubates and hatches eggs for the supply of:
- (a) hatching eggs;
  - (b) day-old chicks or hatchlings of other species;
- (48) ‘confined establishment’ means any permanent, geographically limited establishment, created on a voluntary basis and approved for the purpose of movements, where the animals are:
- (a) kept or bred for the purposes of exhibitions, education, the conservation of species or research;
  - (b) confined and separated from the surrounding environment; and
  - (c) subject to animal health surveillance and biosecurity measures;

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- (49) ‘assembly operation’ means the assembling of kept terrestrial animals from more than one establishment for a period shorter than the required residency period for the species of animals concerned;
- (50) ‘residency period’ means the minimum period necessary in order to ensure that an animal which has been introduced into an establishment is not of a lower health status than that of the animals in that establishment;
- (51) ‘<sup>F1</sup>traces’ means a system component integrated into the IMSOC as referred to in Articles 131 to 136 of Regulation [<sup>X1</sup>(EU) 2017/625];]
- (52) ‘disease control aquatic food establishment’ means a food business approved in accordance with Article 179;
- (53) ‘<sup>F1</sup>official veterinarian’ means an official veterinarian as defined in Article 3(32) of Regulation [<sup>X1</sup>(EU) 2017/625];]
- (54) ‘official veterinarian in a third country or territory’ means a veterinarian in a third country or territory corresponding to an official veterinarian as referred to in point (53);
- (55) ‘<sup>F1</sup>competent authority’ means the central veterinary authority of a Member State responsible for the organisation of official controls and any other official activities in accordance with this Regulation and Regulation [<sup>X1</sup>(EU) 2017/625], or any other authority to which that responsibility has been delegated;]
- (56) ‘competent authority of a third country or territory’ means the authority in a third country or territory corresponding to the competent authorities referred to in point (55).

#### Editorial Information

- X1** Substituted by Corrigendum to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (Official Journal of the European Union L 95 of 7 April 2017).

#### Textual Amendments

- F1** Substituted by Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC



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and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (Text with EEA relevance).

## 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:
  - (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;

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- (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.

### *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):

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- (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;
  - (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;

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- (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.

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:

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- 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.

- 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

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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).

### CHAPTER 3

#### **Responsibilities for animal health**

##### *Section 1*

#### **Operators, animal professionals and pet keepers**

##### *Article 10*

#### **Responsibilities for animal health and biosecurity measures**

- 1 Operators shall:
- a as regards kept animals and products under their responsibility, be responsible for:
- (i) the health of kept animals;

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- (ii) prudent and responsible use of veterinary medicines, without prejudice to the role and responsibility of veterinarians,
    - (iii) minimising the risk of the spread of diseases;
    - (iv) good animal husbandry;
  - b where appropriate, take such biosecurity measures regarding kept animals, and products under their responsibility, as are appropriate for:
    - (i) the species and categories of kept animals and products;
    - (ii) the type of production; and
    - (iii) the risks involved, taking into account:
      - geographical location and climatic conditions; and
      - local circumstances and practices;
  - c where appropriate, take biosecurity measures regarding wild animals.
- 2 Animal professionals shall take action to minimise the risk of the spread of diseases in the context of their occupational relationship with animals and products.
- 3 Point (a) of paragraph 1 shall also apply to pet keepers.
- 4 The biosecurity measures referred to in point (b) of paragraph 1 shall be implemented, as appropriate, through:
  - a physical protection measures, which may include:
    - (i) enclosing, fencing, roofing, netting, as appropriate;
    - (ii) cleaning, disinfection and control of insects and rodents;
    - (iii) in the case of aquatic animals, where appropriate:
      - measures concerning the water supply and discharge;
      - natural or artificial barriers to surrounding water courses that prevent aquatic animals from entering or leaving the establishment concerned, including measures against flooding or infiltration of water from surrounding water courses;
  - b management measures, which may include:
    - (i) procedures for entering and exiting the establishment for animals, products, vehicles and persons;
    - (ii) procedures for using equipment;
    - (iii) conditions for movement based on the risks involved;
    - (iv) conditions for introducing animals or products into the establishment;
    - (v) quarantine, isolation or separation of newly introduced or sick animals;
    - (vi) a system for safe disposal of dead animals and other animal by-products.
- 5 Operators, animal professionals and pet keepers shall cooperate with the competent authority and veterinarians in the application of the disease prevention and control measures provided for in this Regulation.

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

Such implementing acts shall reflect the matters referred to in point (b) of paragraph 1.

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

### *Article 11*

#### **Knowledge of animal health**

- 1 Operators and animal professionals shall have adequate knowledge of:
  - a animal diseases, including those that are transmissible to humans;
  - b biosecurity principles;
  - c the interaction between animal health, animal welfare and human health;
  - d good practice of animal husbandry for the animal species under their care;
  - e resistance to treatments, including antimicrobial resistance, and its implications.
- 2 The content and the level of knowledge required in accordance with paragraph 1 shall depend on:
  - a the species and categories of kept animals or products under the responsibility of the operators and animal professionals concerned and the nature of their occupational relationship with those animals or products;
  - b the type of production;
  - c the tasks performed.
- 3 The knowledge provided for in paragraph 1 shall be acquired in one of the following ways:
  - a professional experience or training;
  - b existing programmes in agricultural or aquaculture sectors that are relevant for animal health;
  - c formal education;
  - d other experience or other training which results in the same level of knowledge as that covered by points (a), (b) or (c).
- 4 Operators selling or otherwise transferring the ownership of future pet animals shall provide basic information to the future pet keeper, regarding the matters referred to in paragraph 1, as relevant for the pet animal in question.

### *Section 2*

#### ***Veterinarians and aquatic animal health professionals***

### *Article 12*

#### **Responsibilities of veterinarians and aquatic animal health professionals**

- 1 Veterinarians shall in the course of their activities which fall within the scope of this Regulation:



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- a take all appropriate measures to prevent the introduction, development and spread of diseases;
- b take action to ensure the early detection of diseases by carrying out proper diagnosis and differential diagnosis to rule out or confirm a disease;
- c play an active role in:
  - (i) raising animal health awareness, and awareness of the interaction between animal health, animal welfare and human health;
  - (ii) disease prevention;
  - (iii) the early detection of, and rapid response to, diseases.
  - (iv) raising awareness of resistance to treatments, including antimicrobial resistance, and its implications;
- d cooperate with the competent authority, operators, animal professionals and pet keepers in the application of the disease prevention and control measures provided for in this Regulation.

2 Aquatic animal health professionals may undertake activities assigned to veterinarians under this Regulation in relation to aquatic animals provided that they are authorised to do so by the Member State concerned under national law. In that event, paragraph 1 shall apply to those aquatic animal health professionals.

3 Veterinarians and aquatic animal health professionals shall maintain and develop their professional capacities related to their areas of activities which fall within the scope of this Regulation.

### *Section 3*

#### **Member States**

#### *Article 13*

#### **Member States' responsibilities**

1 In order to ensure that the competent authority for animal health has the capability to take the necessary and appropriate measures, and to carry out the activities, required by this Regulation, each Member State shall, at the appropriate administrative level, ensure that competent authority has:

- a qualified personnel, facilities, equipment, financial resources and an effective organisation covering the whole territory of the Member State;
- b access to laboratories with the qualified personnel, facilities, equipment and financial resources needed to ensure the rapid and accurate diagnosis and differential diagnosis of listed diseases and emerging diseases;
- c sufficiently trained veterinarians involved in performing the activities referred to in Article 12.

2 Member States shall encourage operators and animal professionals to acquire, maintain and develop the adequate knowledge of animal health provided for in Article 11 through relevant programmes in agricultural or aquaculture sectors or formal education.

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## Article 14

### Delegation by a competent authority of official activities

1 The competent authority may delegate one or more of the following activities to veterinarians other than official veterinarians:

- a practical application of measures under the eradication programmes provided for in Article 32;
- b supporting the competent authority in carrying out surveillance as provided for in Article 26 or in relation to surveillance programmes as provided for in Article 28;
- c activities related to:
  - (i) disease awareness, preparedness and control as provided for in Part III, concerning:
    - sampling activities and implementation of investigations and epidemiological enquiries within the framework of Article 54, points (b) to (g) of Article 55(1), and Articles 57, 73, 74, 79 and 80 in the event of the suspected presence of a disease, and any implementing and delegated acts adopted pursuant to those Articles;
    - carrying out activities relating to disease control measures in the event of an outbreak of disease, [<sup>x2</sup>as regards activities listed in Article 61, points (a), (b), (e), (f) and (i) of Article 65(1), Article 70(1), Articles 79, 80, 81 and 82, and] any implementing and delegated acts adopted pursuant to those Articles;
    - carrying out emergency vaccination in accordance with Article 69;
  - (ii) registration, approval, traceability and movements as provided for in Part IV;
  - (iii) issuing and completing the identification documents for pet animals as provided for in point (c) of Article 247, point (c) of Article 248(2), point (c) of Article 249(1) and point (c) of Article 250(2);
  - (iv) the application and use of means of identification as referred to in point (a) (ii) of Article 252(1).

2 Member States may provide for natural or legal persons to be authorised to perform activities referred to in points (a), (b) and (c)(i), (ii) and (iv) of paragraph 1 for specifically identified tasks for which those persons have sufficient specific knowledge. In that event, paragraph 1 of this Article and the responsibilities laid down in Article 12 shall apply to those persons.

3 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning other activities which may be delegated to veterinarians in addition to those provided for in paragraph 1, and, as appropriate, to prescribe the necessary circumstances and conditions for such delegation.

The Commission shall take account of the nature of those activities and of relevant international standards when adopting those delegated acts.

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#### **Editorial Information**

- X2** Substituted by [Corrigendum to 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 \('Animal Health Law'\) \(Official Journal of the European Union L 84 of 31 March 2016\)](#).

### *Article 15*

#### **Public information**

Where there are reasonable grounds to suspect that animals or products originating from within the Union or entering from outside the Union may present a risk, the competent authority shall take appropriate steps to inform the public of the nature of the risk and the measures which are taken or about to be taken to prevent or control that risk, taking into account the nature, seriousness and extent of that risk and the public interest in being informed.

### *Section 4*

#### ***Laboratories, facilities and other natural and legal persons handling disease agents, vaccines and other biological products***

### *Article 16*

#### **Obligations of laboratories, facilities and others handling disease agents, vaccines and other biological products**

1 Laboratories, facilities and other natural or legal persons handling disease agents for the purpose of research, education, diagnosis or the production of vaccines and other biological products shall, whilst taking into account any relevant international standards:

- a take appropriate biosecurity, biosafety and bio-containment measures to prevent the escape of the disease agents and their subsequent contact with animals outside the laboratory or other facility handling disease agents for those purposes;
- b ensure that the movement of disease agents, vaccines and other biological products between laboratories or other facilities does not give rise to a risk of the spread of listed and emerging diseases.

2 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the safety measures for the prevention and control of listed and emerging diseases as regards laboratories, facilities and other natural or legal persons handling the disease agents, vaccines and other biological products in relation to:

- a biosecurity, biosafety and bio-containment measures;
- b movement requirements for disease agents, vaccines and other biological products.

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## Article 17

### Animal health laboratories

1 Official laboratories for animal health, consisting of Union reference laboratories, national reference laboratories and official animal health laboratories, shall, in fulfilling their tasks and responsibilities, cooperate within a network of Union animal health laboratories.

2 The laboratories referred to in paragraph 1 shall cooperate under the coordination of the Union reference laboratories, to ensure that the surveillance, notification and reporting of diseases, eradication programmes, the definition of disease-free status, and the movements of animals and products within the Union, their entry into the Union and exports to third countries or territories provided for in this Regulation, are based on state-of-the-art, solid and reliable laboratory analyses, tests and diagnoses.

3 The results and reports provided by the official laboratories shall be subject to the principles of professional secrecy and confidentiality and the duty of notification to the competent authority which designated them, irrespective of the natural or legal person who requested the laboratory analyses, tests or diagnoses.

4 In the event that an official laboratory in one Member State conducts diagnostic analyses on samples from animals originating in another Member State, that official laboratory shall notify the competent authority of the Member State from which the samples originated:

- a immediately of any results indicating the suspicion or detection of a listed disease as referred to in point (a) of Article 9(1);
- b without undue delay of any results indicating the suspicion or detection 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).

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- (1) [<sup>F1</sup>Regulation [<sup>X1</sup>(EU) 2017/625] of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) ([<sup>X1</sup>OJ L 95, 7.4.2017, p. 1]).]

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#### Editorial Information

- X1** Substituted by [Corrigendum to Regulation \(EU\) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations \(EC\) No 999/2001, \(EC\) No 396/2005, \(EC\) No 1069/2009, \(EC\) No 1107/2009, \(EU\) No 1151/2012, \(EU\) No 652/2014, \(EU\) 2016/429 and \(EU\) 2016/2031 of the European Parliament and of the Council, Council Regulations \(EC\) No 1/2005 and \(EC\) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations \(EC\) No 854/2004 and \(EC\) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC \(Official Controls Regulation\) \(Official Journal of the European Union L 95 of 7 April 2017\).](#)

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#### Textual Amendments

- F1** Substituted by [Regulation \(EU\) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations \(EC\) No 999/2001, \(EC\) No 396/2005, \(EC\) No 1069/2009, \(EC\) No 1107/2009, \(EU\) No 1151/2012, \(EU\) No 652/2014, \(EU\) 2016/429 and \(EU\) 2016/2031 of the European Parliament and of the Council, Council Regulations \(EC\) No 1/2005 and \(EC\) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations \(EC\) No 854/2004 and \(EC\) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC \(Official Controls Regulation\) \(Text with EEA relevance\).](#)

**Changes to legislation:**

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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. \(t\)](#)