

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 1

##### *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).

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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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- 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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