

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 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;
 - (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:

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- 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.

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;

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- 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:

- 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.

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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.

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, [X¹as regards activities listed in Article 61, points (a), (b), (e), (f) and (i) of Article 65(1), Article

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- 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.

Editorial Information

- X1** 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.

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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.

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);

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- 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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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. \(t\)](#)