

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 V

**ENTRY INTO THE UNION AND EXPORT**

*CHAPTER 1*

***Entry into the Union of animals, germinal products and products of animal origin from third countries and territories***

*Section 1*

***Requirements for the entry into the Union***

*Article 229*

**Requirements for entry into the Union of animals, germinal products and products of animal origin**

1 Member States shall permit the entry into the Union of consignments of animals, germinal products and products of animal origin from third countries or territories only if those consignments fulfil the following requirements, unless such animals, germinal products or products of animal origin are covered by a derogation granted pursuant to Article 239(2):

- a without prejudice to Article 230(2), they come from a third country or territory listed in accordance with Article 230(1) for the particular species and category of animals, or germinal products or products of animal origin concerned, or from a zone or compartment thereof;
- b they come from establishments which are approved and listed, where such approval and listing is required by Article 233;
- c they fulfil the animal health requirements for entry into the Union laid down in Article 234(1) and in any delegated acts adopted pursuant to Article 234(2), where such requirements are laid down for the animal, germinal product or product of animal origin concerned;
- d they are accompanied by an animal health certificate and by declarations and other documents where required by Article 237(1) or by rules adopted pursuant to Article 237(4);

[<sup>F12</sup> The operators responsible for the consignment in question shall present consignments of animals, germinal products and products of animal origin from third countries or territories for the purposes of official control as provided for in Article 47 of Regulation [<sup>X1</sup>(EU) 2017/625].]

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**Changes to legislation:** There are outstanding changes not yet made to Regulation (EU) 2016/429 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

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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 \(Official Controls Regulation\) \(Official Journal of the European Union L 95 of 7 April 2017\).](#)

### 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 \(Official Controls Regulation\) \(Text with EEA relevance\).](#)

## Section 2

### *Listing of third countries and territories*

#### *Article 230*

#### **Lists of third countries and territories from which the entry into the Union of animals, germinal products and products of animal origin is permitted, and implementing and delegated acts**

1 The Commission may, by means of implementing acts, draw up lists of third countries and territories from which the entry into the Union of specific species and categories of animals, germinal products and products of animal origin is to be permitted, based on the following criteria:

- a the animal health legislation of the third country or territory concerned and the rules on the entry into that third country or territory of animals, germinal products and products of animal origin from other third countries and territories;
- b the assurances provided by the competent authority of the third country or territory concerned as regards the efficient implementation and control of the animal health legislation referred to in point (a);
- c the organisation, structure, resources and legal powers of the competent authority in the third country or territory concerned;

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- d the animal health certification procedures in the third country or territory concerned;
- e the animal health status of the third country or territory concerned, or of zones and compartments thereof, with regard to:
  - (i) listed diseases and emerging diseases;
  - (ii) any aspects of animal and public health or the environmental situation in the third country or territory concerned, or in a zone or compartment thereof, which may pose a risk to animal or public health or the environmental status of the Union;
- f the guarantees which the competent authority of the third country or territory concerned can provide regarding compliance or equivalence with the relevant animal health requirements applicable in the Union;
- g the regularity and speed with which the third country or territory concerned supplies information concerning infectious or contagious animal diseases in its territory to the World Organisation for Animal Health (OIE), in particular information concerning the diseases listed in the OIE Codes;
- h the results of controls carried out by the Commission in the third country or territory concerned;
- i any experience gathered from previous entries of animals, germinal products and products of animal origin from the third country or territory concerned and the results of official controls carried out at the point of entry into the Union on such animals, germinal products and products of animal origin.

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

2 Pending the adoption of the lists provided for in paragraph 1, and provided that such lists have not been drawn up pursuant to the Union legislation referred to in Article 270(2), Member States shall determine from which third countries and territories specific species and categories of animals, germinal products or products of animal origin may enter the Union.

For the purposes of the first subparagraph of this paragraph, Member States shall take into account the criteria for inclusion in the lists of third countries and territories provided for in points (a) to (i) of paragraph 1 of this Article.

3 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning derogations from paragraph 2 of this Article, limiting the possibility for Member States to decide from which third countries and territories a specific species and category of animal, germinal product or product of animal origin may enter the Union, where necessary due to the risk posed by that specific species and category of animal, germinal product or product of animal origin.

### *Article 231*

#### **Information to be included in the lists of third countries and territories**

The Commission shall specify the following information for each third country or territory in the lists provided for in Article 230(1):

- (a) the species and categories of animals, germinal products or products of animal origin that may enter the Union from that third country or territory;

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- (b) whether the animals, germinal products or products of animal origin specified in accordance with point (a) may enter the Union from the whole territory of that third country or territory or only from one or more zones or compartments thereof;
- (c) specific conditions and animal health guarantees concerning listed diseases.

### Article 232

#### **Suspension and withdrawal from the lists of third countries and territories and implementing acts**

1 The Commission shall, by means of implementing acts, withdraw a country or territory from the lists provided for in Article 230(1), or suspend the entry into the Union of animals, germinal products or products of animal origin from a third country or territory, or from a zone or compartment thereof, for any of the following reasons:

- a the third country or territory concerned, or one or more zones or compartments thereof, no longer complies with the criteria laid down in Article 230(1), where relevant for the entry into the Union of a particular species and category of animal, germinal product or product of animal origin;
- b the animal health situation in the third country or territory concerned, or in a zone or compartment thereof, is such that a suspension or withdrawal from the lists is necessary in order to protect the animal health status of the Union;
- c the Commission has requested the third country or territory concerned to supply up-to-date information on the animal health situation and other matters referred to in Article 230(1), and that third country or territory has not provided such information;
- d the third country or territory concerned has refused to agree to controls being carried out by the Commission on behalf of the Union in its territory.

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

2 On duly justified imperative grounds of urgency relating to a serious risk of the introduction into the Union of a listed disease as referred to in point (d) of Article 9(1), the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 266(3).

3 The Commission may, by means of implementing acts, reinstate in the lists provided for in Article 230(1) a third country or territory, or a zone or compartment thereof, that has been withdrawn from those lists, or may re-authorise the entry into the Union of animals, germinal products or products of animal origin from a third country or territory, or from a zone or compartment thereof, from which entry into the Union has been suspended, for one of the following reasons:

- a for the reasons referred to in point (a) or (c) of paragraph 1 of this Article, provided that the third country or territory concerned demonstrates that it complies with the listing criteria provided for in Article 230(1);
- b for the reason referred to in point (b) of paragraph 1 of this Article, provided that the third country or territory concerned provides appropriate guarantees that the animal health situation that gave rise to the suspension or withdrawal has been resolved or no longer represents a threat to animal or public health within the Union;
- c for the reason referred to in point (d) of paragraph 1 of this Article, provided that:
  - (i) the third country or territory concerned has agreed to controls being carried out by the Commission on behalf of the Union in its territory; and

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- (ii) the results of those controls by the Commission show that the third country or territory concerned, and the zones or compartments thereof, comply with the listing criteria provided for in Article 230(1).

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

### *Section 3*

#### ***Approval and listing of establishments in third countries and territories***

#### *Article 233*

#### **Approval and listing of establishments**

1 Member States shall only permit the entry into the Union of terrestrial animals and germinal products thereof originating from an establishment of a type for which approval is required in the Union in accordance with Article 94(2) and the rules adopted pursuant to Article 94(3) and Article 95, if the establishment in question in the third country or territory concerned:

- a complies with animal health requirements in that third country or territory which are equivalent to the rules for establishments of that type applicable in the Union;
- b is approved and listed by the competent authority of the third country or territory of dispatch, unless alternative risk-mitigation measures in place in that third country or territory provide equivalent guarantees for animal health within the Union.

2 The Commission shall collect the lists of approved establishments referred to in point (b) of paragraph 1 received from the competent authorities of the third countries or territories concerned.

3 The Commission shall provide to the Member States any new or updated lists of approved establishments received from the third countries or territories concerned, and shall make them publicly available.

4 The Commission shall, by means of implementing acts, adopt any rules necessary in order to ensure uniform application of point (b) of paragraph 1.

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

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#### Section 4

### **Entry into the Union of species and categories of animals, germinal products and products of animal origin**

#### Article 234

#### **Animal health requirements for the entry into the Union of species and categories of animals, germinal products and products of animal origin**

1 The animal health requirements for the entry into the Union of species and categories of animals, germinal products and products of animal origin from third countries or territories shall:

- a be as stringent as the animal health requirements laid down in this Regulation and in the rules adopted pursuant thereto applicable to movements of the species and categories of animals, germinal products or products of animal origin in question within the Union; or
- b offer equivalent guarantees to the animal health requirements applicable to the species and categories of animals, germinal products or products of animal origin provided for in Part IV (Articles 84 to 228) of this Regulation.

2 The Commission shall adopt delegated acts in accordance with Article 264 concerning the animal health requirements for:

- a the entry into the Union of species and categories of animals, germinal products and products of animal origin from third countries or territories;
- b the movement within the Union and handling of those animals, germinal products and products of animal origin after their entry into the Union, where this is necessary in order to mitigate the risk involved.

3 Pending the adoption of delegated acts laying down animal health requirements as regards a particular species and category of animal, germinal product or product of animal origin provided for in paragraph 1 of this Article, Member States may, following an evaluation of the risks involved, apply national rules, provided that those rules comply with the requirements laid down in that paragraph and provided that they take into account the matters referred to in Articles 235 and 236.

#### Article 235

#### **Matters to be taken into account in delegated acts provided for in Article 234 with regard to the entry into the Union of animals**

The Commission shall take the following matters into account when laying down, in delegated acts as provided for in Article 234(2), animal health requirements for the entry into the Union of particular species and categories of animals:

- (a) the listed diseases referred to in point (d) of Article 9(1) and emerging diseases;
- (b) the health status of the Union concerning the listed diseases referred to in point (d) of Article 9(1) and emerging diseases;
- (c) the listed species with regard to those listed diseases referred to in point (d) of Article 9(1) and emerging diseases;
- (d) the age and sex of the animals concerned;

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- (e) the origin of the animals concerned;
- (f) the type of establishment concerned and the type of production at the places of origin and of destination;
- (g) the intended place of destination;
- (h) the intended use of the animals concerned;
- (i) any risk-mitigation measures in place in the third countries or territories of origin or transit, or after the arrival of the animals concerned into the territory of the Union;
- (j) animal health requirements applicable to movements of those animals within the Union;
- (k) other epidemiological factors;
- (l) international animal health trade standards, relevant to the species and categories of those animals.

#### *Article 236*

#### **Matters to be taken into account in delegated acts as provided for in Article 234 with regard to the entry into the Union of germinal products and products of animal origin**

The Commission shall take the following matters into account when laying down, in delegated acts as provided for in Article 234(2), the animal health requirements for the entry into the Union of germinal products and products of animal origin:

- (a) the listed diseases referred to in point (d) of Article 9(1) and emerging diseases;
- (b) the health status of the animals from which the germinal products or products of animal origin originate and of the Union concerning the listed diseases referred to in point (d) of Article 9(1) and emerging diseases;
- (c) the type and nature of particular germinal products or products of animal origin, treatments, processing methods and other risk-mitigation measures that have been applied at the places of origin, dispatch of consignment or destination;
- (d) the type of establishment and the type of production at the places of origin and of destination;
- (e) the intended place of destination;
- (f) the intended use of the germinal products or products of animal origin concerned;
- (g) animal health requirements applicable to movements of the germinal products and products of animal origin concerned within the Union;
- (h) other epidemiological factors;
- (i) international animal health trade standards, relevant for the germinal products and products of animal origin in question.

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## Section 5

### ***Animal health certificates, declarations and other documents***

#### *Article 237*

#### **Animal health certificates, declarations and other documents for entry into the Union**

1 Member States shall only permit the entry into the Union of consignments of animals, germinal products and products of animal origin if such consignments are accompanied by one or both of the following:

- a an animal health certificate issued by the competent authority of the third country or territory of origin, unless a derogation is provided for in point (a) of paragraph 4;
- b declarations or other documents, where required by the rules adopted pursuant to point (b) of paragraph 4.

2 Member States shall not permit the entry into the Union of consignments of animals, germinal products and products of animal origin unless the animal health certificate referred to in point (a) of paragraph 1 has been verified and signed by an official veterinarian in a third country or territory in compliance with certification requirements equivalent to those laid down in Article 149(3) or 216(3) and any rules adopted pursuant to Article 149(4) or 216(4).

3 Member States shall permit electronic animal health certificates that are produced, handled and transmitted by means of Traces to replace the accompanying animal health certificates referred to in paragraph 1, where such electronic animal health certificates:

- a contain all the information that the animal health certificate referred to in point (a) of paragraph 1 of this Article is required to contain in accordance with Article 238(1) and any rules adopted pursuant to Article 238(3);
- b ensure the traceability of the consignments of animals, germinal products and products of animal origin concerned and link those consignments to the electronic animal health certificate.

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

- a derogations from the animal health certificate requirements provided for in point (a) of paragraph 1 and paragraph 2 of this Article, for consignments of animals, germinal products and products of animal origin, and in specific rules for the animal health certification of those consignments, where the consignments in question pose an insignificant risk to animal health or public health within the Union, due to one or more of the following factors:
  - (i) the species and categories of animals, germinal products or products of animal origin concerned;
  - (ii) the methods of keeping and types of production of the animals, germinal products and products of animal origin concerned;
  - (iii) their intended use;
  - (iv) alternative risk-mitigation measures which are in place in the third countries or territories of origin or transit, or after their arrival into the territory of the Union, affording equivalent protection of animal health and public health within the Union as provided for in this Regulation;



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- (v) the provision by the third country or territory concerned of guarantees of compliance with the requirements for entry into the Union, demonstrated by means other than an animal health certificate;
- b rules requiring consignments of animals, germinal products and products of animal origin entering into the Union to be accompanied by declarations or other documents needed to demonstrate that the animals, germinal products and products of animal origin in question meet the animal health requirements for entry into the Union laid down in rules adopted pursuant to Article 234(2).

### Article 238

#### Content of animal health certificates

1 The animal health certificate referred to in point (a) of Article 237(1) shall contain at least the following information:

- a the name and address of:
  - (i) the establishment or place of origin;
  - (ii) the establishment or place of destination;
  - (iii) where applicable, establishments for assembly operations or rest of the kept animals concerned;
- b a description of the animals, germinal products or products of animal origin concerned;
- c the number or volume of the animals, germinal products or products of animal origin concerned;
- d where applicable, the identification and registration of the animals, germinal products or products of animal origin concerned;
- e the information needed to demonstrate that the animals, germinal products and products of animal origin concerned fulfil the animal health requirements for entry into the Union provided for in Article 229 and Article 234(1) and in the rules adopted pursuant to Article 234(2) and Article 239.

2 The animal health certificate referred to in point (a) of Article 237(1) may include other information required under other Union legislation.

- 3 The Commission may, by means of implementing acts, lay down rules concerning:
- a information to be contained in the animal health certificate referred to in point (a) of Article 237(1) in addition to that referred to in paragraph 1 of this Article;
  - b information to be contained in declarations or other documents as referred to in point (b) of Article 237(1);
  - c model forms for the animal health certificates, declarations and other documents referred to in Article 237(1).

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

4 Pending the establishment of rules in implementing acts adopted pursuant to paragraph 3, as regards a particular species and category of animal, germinal product or product of animal origin, Member States may, following an evaluation of the risks involved, apply national rules, provided those national rules comply with the conditions laid down in paragraph 1.

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## Section 6

### ***Derogations and additional requirements in respect of certain categories of animals, germinal products and products of animal origin***

#### Article 239

### **Derogations and additional requirements in respect of certain categories of animals, germinal products and products of animal origin**

1 For certain specific types of entry of animals, germinal products and products of animal origin, the application of the rules set out in Article 229(1) and Articles 233 and 237 may not be adequate, and special rules may need to be adopted by the Commission through delegated acts which take into account the particular risks, the final destination, the type of final use and other circumstances.

2 The Commission shall adopt delegated acts in accordance with Article 264 concerning the special rules referred to in paragraph 1 of this Article regarding derogations from the requirements provided for in Article 229(1) and Articles 233 and 237 and imposing additional requirements for the entry into the Union of the following:

- a animals:
  - (i) intended for circuses, events, exhibitions, display, shows and confined establishments;
  - (ii) intended to be used for scientific or diagnostic purposes;
  - (iii) for which the Union is not the final destination;
  - (iv) which originate in the Union and which are moved to a third country or territory, and are then moved back to the Union from that third country or territory;
  - (v) which originate in the Union and which are transported through a third country or territory en route to another part of the Union;
  - (vi) which are intended for grazing purposes on a temporary basis, in the vicinity of the Union's borders;
  - (vii) which pose an insignificant risk to the animal health status within the Union;
- b products of animal origin:
  - (i) intended for personal use;
  - (ii) for consumption by the crew and passengers on means of transport arriving from third countries or territories;
- c germinal products and products of animal origin:
  - (i) intended to be used as trade samples;
  - (ii) intended to be used as research and diagnostic samples;
  - (iii) for which the Union is not the final destination;
  - (iv) which originate in the Union and are moved to a third country or territory, and are then moved back to the Union from that third country or territory;

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- (v) which originate in the Union and are transported through a third country or territory en route to another part of the Union;
- (vi) which pose an insignificant risk to the animal health status within the Union.

Those delegated acts shall take into account the matters referred to in Article 235 and 236.

- 3 The Commission may, by means of implementing acts, lay down rules:
- a concerning model forms for the animal health certificates, declarations and other documents for the categories of animals, germinal products and products of animal origin referred to in paragraph 2 of this Article;
  - b indicating, for the products referred to in paragraph 1 of this Article, the codes from the Combined Nomenclature, where such codes are not provided for by other relevant Union rules.

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

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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. \(t\)](#)