

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 IV

REGISTRATION, APPROVAL, TRACEABILITY AND MOVEMENTS

TITLE I

TERRESTRIAL ANIMALS, GERMINAL PRODUCTS AND PRODUCTS OF ANIMAL ORIGIN FROM TERRESTRIAL ANIMALS

CHAPTER 5

Movements within the Union of germinal products

Section 1

General requirements

Article 157

General requirements for movements of germinal products

- 1 Operators shall take appropriate preventive measures to ensure that movements of germinal products do not jeopardise the health status of kept terrestrial animals at the place of destination with regard to:
 - a the listed diseases referred to in point (d) of Article 9(1);
 - b emerging diseases.
- 2 Operators shall only move germinal products from their establishments, and receive such germinal products, if the products in question fulfil the following conditions:
 - a they come from establishments that have been:
 - (i) entered in the register of establishments by the competent authority in accordance with point (a) of the first paragraph of Article 93 and no derogation has been granted by the Member State of origin in accordance with Article 85;
 - (ii) approved by the competent authority in accordance with Article 97(1), when such approval is required by Article 94(1) or Article 95;
 - b they fulfil the traceability requirements of Article 121(1) and any rules adopted pursuant to Article 122(1).
- 3 Operators shall comply with the requirements of Article 125 for the transport of germinal products of kept terrestrial animals.

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Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/429 of the European Parliament and of the Council, CHAPTER 5. (See end of Document for details)

4 Operators shall not move germinal products from an establishment in one Member State to an establishment in another Member State unless the competent authority of the Member State of destination gives its express authorisation for such movement, where those germinal products are required to be destroyed for disease eradication purposes as part of an eradication programme as provided for in Article 31(1) or (2).

Article 158

Obligations for operators at the place of destination

1 Operators of establishments at the place of destination receiving germinal products from an establishment in another Member State shall:

- a check for the presence of:
 - (i) marks in accordance with Article 121 and with rules adopted pursuant to Article 122;
 - (ii) animal health certificates as provided for in Article 161;
- b after checking the germinal products received, inform the competent authority of the place of destination of any irregularity with regard to:
 - (i) the germinal products received;
 - (ii) the marks referred to in point (a)(i);
 - (iii) the animal health certificates referred to in point (a)(ii).

2 In the event of an irregularity as referred to in point (b) of paragraph 1, the operator concerned shall keep the germinal products stored separately until the competent authority has taken a decision regarding them.

Section 2

Movements to other Member States of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry

Article 159

Operators' obligations in respect of movements to other Member States of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry

1 Operators shall only move germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry to another Member State if those germinal products fulfil the following conditions:

- a they are collected, produced, processed and stored in germinal product establishments approved for that purpose in accordance with Article 97(1) and Article 99;
- b they have been collected from donor animals which fulfil the necessary animal health requirements, in order to ensure that the germinal products do not spread listed diseases;
- c they have been collected, produced, processed, stored and transported in such a way as to ensure that they do not spread listed diseases as referred to in point (d) of Article 9(1).

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2 Operators shall not move germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry from a germinal product establishment which is subject to movement restrictions affecting the listed species in question in accordance with:

- a points (a), (c) and (e) of Article 55(1), point (f)(ii) of Article 55(1), Article 56, point (a) of Article 61(1), Article 62(1), point (c) of Article 65(1), Article 74(1), and Articles 79 and 80;
- b rules adopted pursuant to Article 55(2), Articles 63 and 67, and Articles 71(3), 74(4) and 83(2); and
- c emergency measures as provided for in Articles 257 and 258 and rules adopted pursuant to Article 259, unless derogations have been provided for in rules adopted pursuant to Article 258.

The restrictions provided for in this paragraph shall not apply to cases where the germinal products were collected before the outbreak in question occurred and those products have been stored separately from other germinal products.

Article 160

Delegation of power in respect of movements to other Member States of germinal products of kept animals of the bovine, porcine, ovine, caprine and equine species and germinal products of poultry

1 The Commission shall adopt delegated acts in accordance with Article 264 concerning the animal health requirements for movements of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry to other Member States as provided for in Article 159, specifying:

- a rules for the collection, production, processing and storage of germinal products of those kept animals in approved establishments as referred to in point (a) of Article 159(1);
- b animal health requirements as provided for in point (b) of Article 159(1) for kept donor animals from which germinal products were collected, and concerning isolation or quarantine for those animals;
- c laboratory and other tests to be carried out on kept donor animals and germinal products;
- d animal health requirements for the collection, production, processing, storage or other procedures and transport provided for in point (c) of Article 159(1).

2 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the animal health requirements for movements of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry to other Member States as provided for in Article 159, specifying derogations for operators from the rules provided for in Article 159, taking into account the risks attached to such germinal products and any risk-mitigation measures in place.

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Section 3

Animal health certification and notification of movements

Article 161

Operators' obligations concerning animal health certification for movements of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry and delegated acts

1 Operators shall only move germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry to another Member State where such products are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with paragraph 3;

2 In cases where germinal products of kept animals are allowed to leave a restricted zone subject to:

- a disease control measures as provided for in point (f)(ii) of Article 55(1), Articles 56, 64 and 65, Article 74(1) and Article 79, and the rules adopted pursuant to Article 55(2), Article 67, Articles 71(3) and 74(4), Article 83(2), or
- b emergency measures as provided for in Articles 257 and 258 and the rules adopted pursuant to Article 259,

and those germinal products are of species subject to those disease control or emergency measures, operators shall only move such germinal products within a Member State or from one Member State to another Member State when they are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Article 149(1), unless derogations have been granted from the animal health certification requirement in accordance with the rules referred in this subparagraph.

The competent authority may decide that such a certificate does not have to be issued for movements of germinal products within the Member State concerned when that authority considers that an alternative system is in place ensuring that the consignment of such germinal products is traceable and that those germinal products comply with the animal health requirements for such movement.

3 Operators shall take all necessary measures to ensure that the animal health certificate referred to in paragraph 1 accompanies the germinal products from their place of origin to their place of destination.

4 The competent authority shall, upon request by an operator, issue an animal health certificate for the movements of germinal products referred to in paragraph 1, provided that the relevant requirements referred to in Chapter 5 of Title I of Part IV have been complied with.

5 Articles 148, 149 and 150, and the rules adopted pursuant to Articles 146 and 147 and Article 149(4), shall apply to the animal health certification of the germinal products referred to in paragraph 1 of this Article. Article 151(1) and the rules adopted pursuant to Article 151(3) shall apply to the self-declaration of movements of germinal products.

6 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning derogations from the animal health certificate requirements provided for in paragraph 1 of this Article as regards movements of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry which do not pose a significant risk for the spread of listed diseases due to:

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- a the nature of the germinal products concerned or the species of animal that those products come from;
- b the methods of production and processing at the germinal product establishment;
- c the intended use of the germinal products;
- d alternative risk-mitigation measures in place for the type and category of germinal products and the germinal product establishment;
- e the place of destination of the germinal products, when the place of destination is in the same Member State as the place of origin but the germinal products pass through another Member State in order to reach the place of destination.

Article 162

Content of animal health certificates

- 1 The animal health certificate for the germinal products provided for in Article 161 shall contain at least the following information:
 - a the germinal product establishment of origin and the establishment or place of destination;
 - b the type of the germinal products and the species of kept donor animals;
 - c the volume or number of the germinal products;
 - d the marking of the germinal products, when required by Articles 121(1) and by any rules adopted pursuant to Article 122(1);
 - e the information needed to demonstrate that the germinal products of the consignment fulfil the movement requirements for the relevant species as provided for in Articles 157 and 159 and in any rules adopted pursuant to Article 160.
- 2 The animal health certificate for germinal products as provided for in Article 161 may include other information required under other Union legislation.
- 3 The Commission shall adopt delegated acts in accordance with Article 264 concerning the information to be contained in the animal health certificate pursuant to paragraph 1 of this Article;
- 4 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning animal health certification for different types of germinal products and of different animal species.
- 5 The Commission may, by means of implementing acts, lay down rules concerning model forms of animal health certificates for germinal products. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 163

Notification of movements of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry to other Member States

- 1 Operators shall:
 - a inform the competent authority in their Member State of origin in advance of the intended movement of germinal products of kept animals of the bovine, ovine, caprine,

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porcine and equine species and germinal products of poultry to another Member State when:

- (i) the germinal products in question are required to be accompanied by an animal health certificate in accordance with Article 161(1) or (2);
 - (ii) notification of movement is required in accordance with delegated acts adopted pursuant to point (a) of paragraph 5 of this Article for germinal products, taking into account paragraph 3 of this Article;
- b provide all the necessary information to enable the competent authority of the Member State of origin to notify the movement of the germinal products to the competent authority of the Member State of destination in accordance with paragraph 2.

2 The competent authority of the Member State of origin shall notify, prior to the movement in question and whenever possible through Traces, the competent authority of the Member State of destination of any movement of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry in accordance with the rules adopted pursuant to paragraphs 5 and 6.

3 Member States shall use, for the management of notifications, regions designated in accordance with Article 153(3).

4 Article 153(4) shall apply to the notification of germinal products by operators.

5 The Commission shall adopt delegated acts in accordance with Article 264 concerning:

- a the requirement for advance notification by operators of movements of germinal products between Member States in accordance with point (a)(ii) of paragraph 1 of this Article, where traceability of such movements is necessary in order to ensure compliance with the animal health requirements for movements laid down in Sections 1 and 2 (Articles 157 to 160);
- b information necessary to notify movements of germinal products as provided for in paragraph 1 of this Article;
- c the emergency procedures for the notification of movements of germinal products in the event of power cuts and other disturbances of Traces.

6 The Commission may, by means of implementing acts, lay down rules concerning:

- a the provision of information on movements of germinal products by operators to the competent authority of their Member State of origin in accordance with paragraph 1;
- b notification by the competent authority of the Member State of origin to the Member State of destination of movements of germinal products in accordance with paragraph 2;
- c the deadlines for:
 - (i) the provision of the information referred to in paragraph 1 by the operator to the competent authority of the Member State of origin;
 - (ii) notification by the competent authority of the Member State of origin of movements of germinal products as referred to in paragraph 2.

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

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Section 4

Movements to other Member States of germinal products of kept terrestrial animals of species other than bovine, ovine, caprine, porcine and equine species and germinal products of poultry

Article 164

Germinal products of kept terrestrial animals other than those of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry

- 1 Operators shall only move germinal products of kept terrestrial animals of species other than those of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry to another Member State if those products do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1) to listed species at the place of destination, taking into account the health status at the place of destination.
- 2 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning animal health requirements, animal health certification and notification requirements for movements of germinal products of kept terrestrial animals of species other than those of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry, taking into account the following matters:
 - a listed diseases as referred to in point (d) of Article 9(1) for the listed species concerned;
 - b the species of animals from which the germinal products have been collected and the type of germinal product;
 - c the health status at the places of origin and of destination;
 - d the type of collection, production, processing and storage;
 - e other epidemiological factors.
- 3 Where animal health certification and notification of movements of germinal products are required in accordance with paragraph 2:
 - a the rules provided for in Articles 161(1) to (5), 162 (1) and (2) and the rules adopted pursuant to Articles 161(6) and 162(3) to (5) shall apply for such certification;
 - b the rules provided for in Article 163(1), (2) and (4) and the rules adopted pursuant to Article 163(5) shall apply for notification of movements.

Section 5

Derogations

Article 165

Germinal products intended for scientific purposes and delegated acts

- 1 The competent authority of the place of destination may, subject to the agreement of the competent authority of the place of origin, authorise movements of germinal products into the territory of the Member State of destination, for scientific purposes, where those movements do not fulfil the requirements of Articles 159 to 164.
- 2 The competent authority shall only grant derogations provided for in paragraph 1 under the following conditions:

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- a the competent authorities of the places of destination and origin:
 - (i) have agreed on the conditions for the movements proposed;
 - (ii) ensure that necessary risk-mitigation measures are in place so that those movements do not jeopardise the health status en route and in the place of destination with regard to the listed diseases referred to in point (d) of Article 9(1);
 - (iii) have notified, where relevant, the competent authorities of Member States of passage of the derogation granted and of the conditions under which it is granted;
 - b those movements take place under the supervision of the competent authorities of the places of origin and destination, and where relevant, of the competent authorities of any Member States of passage.
- 3 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the rules for the granting of derogations by competent authorities, supplementing those provided for in paragraphs 1 and 2 of this Article.

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