

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 2

Traceability requirements for kept terrestrial animals and germinal products

Section 1

Kept terrestrial animals

Article 108

Member States' responsibility for establishing a system for the identification and registration of kept terrestrial animals

- 1 Member States shall have in place a system for the identification and registration of those species of kept terrestrial animals for which such a system is required by this Regulation and by any rules adopted pursuant to it. Such a system shall, when appropriate, provide for the recording of the movements of such animals.
- 2 When establishing the system referred to in paragraph 1, Member States shall take into account:
 - a the species or categories of kept terrestrial animals concerned;
 - b the risk posed by that species or category.
- 3 The system provided for in paragraph 1 shall include the following elements:
 - a the means to identify kept terrestrial animals individually or in groups;
 - b identification documents, movement documents and other documents for identifying and tracing kept terrestrial animals as referred to in Article 110;
 - c up-to-date records in establishments as provided for in points (a) and (b) of Article 102(1);
 - d a computer database of kept terrestrial animals as provided for in Article 109(1).
- 4 The system provided for in paragraph 1 shall be designed in such a manner that it:
 - a ensures the efficient application of the disease prevention and control measures provided for in this Regulation;

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- b facilitates the traceability of kept terrestrial animals and their movements within and between Member States and their entry into the Union;
 - c ensures the efficient interoperability, integration and compatibility of the elements of that system;
 - d ensures that the system, to the extent appropriate, is adapted to:
 - (i) the computerised information system for Union notification and reporting provided for in Article 22;
 - (ii) TRACES;
 - e ensures a coherent approach in respect of the different animal species covered by the system.
- 5 Member States may when appropriate:
- a use the whole or part of the system provided for in paragraph 1 for purposes other than those referred to in points (a) and (b) of paragraph 4;
 - b integrate the identification documents, movement documents and other documents referred to in Article 110 with the animal health certificates or self-declaration document provided for in Article 143(1) and (2) and Article 151(1) and in any rules adopted pursuant to points (b) and (c) of Article 144(1) and Article 151(3) and (4);
 - c designate another authority or authorise another body or a natural person to ensure the practical application of the identification and registration system provided for in paragraph 1 of this Article, including the issuing of identification documents and the drawing-up of models as provided for in points (a), (b) and (c) of Article 110(1).

Article 109

Member States' obligation to establish and maintain a computer database of kept terrestrial animals

- 1 The Member States shall establish and maintain a computer database for the recording of at least:
- a the following information related to kept animals of the bovine species:
 - (i) their individual identification as provided for in point (a) of Article 112;
 - (ii) the establishments keeping them;
 - (iii) their movements into and from those establishments;
 - b the following information related to kept animals of the ovine and caprine species:
 - (i) information on their identification as provided for in point (a) of Article 113(1) and the number of animals at the establishments keeping them;
 - (ii) the establishments keeping them;
 - (iii) their movements into and from those establishments;
 - c the following information related to kept animals of the porcine species:
 - (i) information on their identification as provided for in Article 115 and the number of animals at the establishments keeping them;
 - (ii) the establishments keeping them;
 - (iii) their movements into and from those establishments;

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- d the following information related to kept animals of the equine species:
 - (i) their unique code as provided for in Article 114;
 - (ii) the method of identification provided for in point (b) of Article 114(1) linking the animal concerned with the identification document referred to in point (iii) where relevant;
 - (iii) the relevant identification details from the identification document provided for in point (c) of Article 114(1), as determined in the rules adopted pursuant to Articles 118 and 120;
 - (iv) the establishments where those animals are habitually kept;
- e information related to kept terrestrial animals of species other than those referred to in points (a), (b), (c) and (d) of this paragraph, when this is provided for in the rules adopted pursuant to paragraph 2.

2 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the recording of information related to animal species other than those referred to in points (a), (b), (c) and (d) of paragraph 1 of this Article in the computer database provided for in that paragraph where necessary, due to the specific and significant risks posed by those species, in order to:

- a ensure the efficient application of the disease prevention measures and control measures provided for in this Regulation;
- b facilitate the traceability of kept terrestrial animals, their movements between Member States and their entry into the Union.

Article 110

Obligation of the competent authority in respect of identification documents, movement documents and other documents for the identification and tracing of kept terrestrial animals

- 1 Each competent authority shall:
 - a issue identification documents in respect of kept terrestrial animals where those documents are required by point (c) of Article 114(1) and point (b) of Article 117 and by rules adopted pursuant to Articles 118 and 120;
 - b issue identification documents in respect of bovine animals as required by point (b) of Article 112, unless Member States exchange electronic data with other Member States within the framework of an electronic exchange system from the date when the Commission recognises the full operability of that system;
 - c draw up models of movement documents and other documents for the identification and tracing of kept terrestrial animals, when required by point (b) of Article 113(1), point (b) of Article 115, point (b) of Article 117 and any rules adopted pursuant to Articles 118 and 120.
- 2 Point (b) of paragraph (1) is without prejudice to the right of Member States to adopt national rules on the issuing of passports for animals not intended for movement between Member States.

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Article 111

Public availability of information on means of identification

Each competent authority shall inform the Commission of, and make publicly available, information on:

- (a) contact points for the computer databases established by the Member States in accordance with Article 109(1);
- (b) the authorities or bodies responsible for issuing identification documents, movement documents and other documents in accordance with Article 110, taking into account point (c) of Article 108(5);
- (c) the means of identification that are to be used for each species and category of kept terrestrial animals in accordance with point (a) of Article 112, point (a) of Article 113(1), Article 114(1), point (a) of Article 115, point (a) of Article 117 and any rules adopted pursuant to Articles 118 and 120;
- (d) the prescribed format for the issuing of the identification documents and other documents referred to in Article 110.

Article 112

Operators' obligations in respect of the identification of kept animals of the bovine species

Operators keeping animals of the bovine species shall:

- (a) ensure that those kept animals are identified individually by a physical means of identification;
- (b) ensure that those kept animals, when they are moved between Member States, are issued with an identification document from the competent authority or designated authority or authorised body of origin, unless the conditions laid down in point (b) of Article 110(1) are met;
- (c) ensure that that identification document:
 - (i) is kept, correctly completed and updated by the operator concerned; and
 - (ii) accompanies those kept terrestrial animals at the time of movement, when such document is required by point (b);
- (d) transmit the information on movements of those kept animals from and to the establishment concerned, and all births and deaths in that establishment, to the computer database provided for in Article 109(1).

Article 113

Operators' obligations in respect of the identification of kept animals of the ovine and caprine species

- 1 Operators keeping kept animals of the ovine and caprine species shall:

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- a ensure that those kept animals are each identified by a physical means of identification;
 - b ensure that those kept animals are accompanied by a correctly completed movement document based on the model drawn up by the competent authority in accordance with Article 110 when they are moved from the establishment keeping those animals within the Member State concerned;
 - c transmit the information on movements of those kept animals from and to the establishment to the computer database provided for in Article 109(1).
- 2 Member States may exempt operators from the requirement to ensure that kept animals of the ovine and caprine species are accompanied by movement documents during movements within their territory, provided that:
- a the information contained in the relevant movement document is included in the computer database provided for in Article 109(1);
 - b the system for the identification and registration of kept animals of the ovine and caprine species provides level of traceability equivalent to that provided by movement documents.

Article 114

Operators' obligations in respect of the identification and registration of kept animals of the equine species

- 1 Operators keeping kept animals of the equine species shall ensure that those animals are individually identified by:
- a a unique code which is recorded in the computer database provided for in Article 109(1);
 - b a physical means of identification or other method which unequivocally links the kept animal with the identification document provided for in point (c) of this paragraph and issued by the competent authority in accordance with Article 110;
 - c a correctly completed single lifetime identification document.
- 2 Operators of kept animals of the equine species shall ensure that the information on those animals is transmitted to the computer database provided for in Article 109(1).

Article 115

Operators' obligations in respect of the identification and registration of kept animals of the porcine species

Operators keeping kept animals of the porcine species shall:

- (a) ensure that those kept animals are each identified by a physical means of identification;
- (b) ensure that those kept animals are accompanied by a correctly completed movement document based on the model drawn up by the competent authority in accordance with point (b) of Article 110(1) when they are moved from the establishment keeping those animals within the Member State concerned;
- (c) transmit the information relating to the establishment keeping those animals to the computer database provided for in Article 109(1).

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Article 116

Derogations concerning movements of kept animals of the porcine species

By way of derogation from point (b) of Article 115, Member States may exempt operators from the requirement to ensure that kept animals of the porcine species are accompanied by correctly completed movement documents based on the model drawn up by the competent authority for movements within the Member State concerned, provided that:

- (a) the information contained in such movement documents is included in the computer database established by that Member State in accordance with Article 109(1);
- (b) the system for the identification and registration of kept terrestrial animals of the porcine species provides a level of traceability equivalent to that provided by such movement documents.

Article 117

Operators' obligation in respect of the identification of kept terrestrial animals other than animals of the bovine, ovine, caprine, porcine and equine species

Operators shall ensure that kept terrestrial animals of species other than those of the bovine, ovine, caprine, porcine and equine species fulfil the following requirements, when required by the rules adopted pursuant to Articles 118 and 120:

- (a) they are identified, either individually or in groups;
- (b) they are accompanied by correctly completed and updated identification documents, movement documents or other documents for the identification and tracing of animals, as appropriate for the animal species concerned.

Article 118

Delegation of powers concerning identification and registration

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

- a detailed requirements for the means and methods of identification of kept terrestrial animals provided for in point (a) of Article 112, point (a) of Article 113(1), Article 114(1), point (a) of Article 115 and point (a) of Article 117, including their application and use;
- b rules on the information to be included in:
 - (i) the computer databases provided for in points (a) to (d) of Article 109(1);
 - (ii) the identification and movement documents provided for in point (b) of Article 112, point (b) of Article 113(1), point (c) of Article 114(1), and point (b) of Article 115;
- c rules on the exchange of electronic data between computer databases of Member States as referred to in point (b) of Article 110(1).

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

- a detailed requirements for alternative means and methods of identification to those referred to in point (a) of paragraph 1 of this Article, as well as exemptions and special provisions for certain categories of animals or circumstances and conditions for such exemptions;
- b specific provisions for the identification or movement documents provided for in point (b) of Article 112, point (b) of Article 113(1), point (c) of Article 114(1), point (b) of Article 115 and point (b) of Article 117 that have to accompany animals when they are moved;
- c detailed requirements for the identification and registration of kept terrestrial animals of species other than the bovine, ovine, caprine, porcine and equine species where necessary, taking into account the risks posed by the species concerned, in order to:
 - (i) ensure the efficient application of the disease prevention and control measures provided for in this Regulation;
 - (ii) facilitate the traceability of kept terrestrial animals, and their movements within and between Member States and their entry into the Union;
- d rules on the information to be included in:
 - (i) the computer databases provided for in point (e) of Article 109(1);
 - (ii) the identification and movement documents provided for in point (b) of Article 117;
- e rules on the identification and registration of kept terrestrial animals as referred to in Articles 112 to 117 after their entry into the Union.

3 When establishing the rules to be laid down in the delegated acts provided for in this Article, the Commission shall base those rules on the considerations provided for in Article 119(2).

Article 119

Delegation of powers concerning derogations from the traceability requirements

1 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning derogations for operators from the identification and registration requirements provided for in Articles 112, 113, 114 and 115:

- a in cases where one or more of the elements listed in Article 108(3) are not necessary in order to meet the requirements provided for in points (a) and (b) of Article 108(4); and
- b when other traceability measures in place in the Member States guarantee that the level of traceability of the animals in question is not compromised,

as well as transitional measures required for the practical application of such derogations.

2 When establishing the rules to be laid down in the delegated acts provided for in paragraph 1, the Commission shall base those rules on the following considerations:

- a the species and categories of kept terrestrial animals concerned;
- b the risks involved for those kept terrestrial animals;
- c the number of animals in the establishments concerned;
- d the type of production in the establishments where those terrestrial animals are kept;

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- e movement patterns for the species and categories of kept terrestrial animals concerned;
- f considerations concerning the protection and conservation of the species of kept terrestrial animals concerned;
- g the performance of the other traceability elements of the system for the identification and registration of kept terrestrial animals referred to in Article 108(3).

Article 120

Implementing powers concerning the traceability of kept terrestrial animals

- 1 The Commission shall, by means of implementing acts, adopt rules:
 - a for uniform access to data contained in, and the technical specifications and operational rules of, the computer databases referred to in points (a) to (d) of Article 109(1);
 - b on the technical conditions and modalities for the exchange of electronic data between computer databases of Member States and the recognition of full operability of the data exchange systems referred to in point (b) of Article 110(1).
- 2 The Commission may, by means of implementing acts, adopt rules:
 - a for the uniform application of the identification and registration system provided for in Article 108(1) for different species or categories of kept terrestrial animals, in order to ensure its efficient operation;
 - b for the uniform application of point (c) of Article 108(5) concerning the authorised bodies or natural persons referred to in Article 108(5) and the conditions for their designation;
 - c on the technical specifications and procedures, formats, design and operational rules for the means and methods of identification, including:
 - (i) the time periods for the application of the means and methods of identification;
 - (ii) the removal, modification or replacement of the means and methods of identification and the deadlines for such operations; and
 - (iii) the configuration of the identification code;
 - d on the technical specifications, formats and operational rules for the identification and movement documents provided for in point (b) of Article 112, point (b) of Article 113(1), point (c) of Article 114(1), point (b) of Article 115 and point (b) of Article 117;
 - e for uniform access to data contained in, and the technical specifications and operational rules of, the computer databases referred to in point (e) of Article 109(1);
 - f on the deadlines, obligations and procedures for the transmission of information by operators or other natural or legal persons and for the registration of kept terrestrial animals in the computer databases;
 - g on guidelines and procedures for electronic identification of animals, where relevant;
 - h on the practical application of exemptions from the identification and registration requirements provided for in the rules adopted pursuant to Article 119(1).
- 3 The implementing acts referred to in this Article shall be adopted in accordance with the examination procedure referred to in Article 266(2).

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Section 2

Germinal products

Article 121

Traceability requirements for germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species

- 1 Operators producing, processing or storing germinal products shall mark germinal products of kept animals of the bovine, caprine, ovine, porcine and equine species in such a way that they can be clearly traced to:
 - a the donor animals;
 - b the date of collection; and
 - c the germinal product establishments where they were collected, produced, processed and stored.
- 2 The marking provided for in paragraph 1 shall be designed in such a way as to ensure:
 - a the efficient application of the disease prevention and control measures provided for in this Regulation;
 - b the traceability of the germinal products, their movements within and between Member States and their entry into the Union.

Article 122

Delegation of powers concerning traceability requirements for germinal products

- 1 The Commission shall adopt delegated acts in accordance with Article 264 concerning traceability requirements for germinal products of kept terrestrial animals of the bovine, caprine, ovine, porcine and equine species supplementing the rules laid down in Article 121;
- 2 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning traceability requirements for germinal products of kept terrestrial animals of species other than of the bovine, caprine, ovine, porcine and equine species, where necessary for:
 - a the efficient application of the disease prevention and control measures provided for in this Regulation;
 - b the traceability of those germinal products, their movements within and between Member States and their entry into the Union.
- 3 When adopting the delegated acts provided for in paragraph 1, the Commission shall base those acts on the following matters:
 - a the species of kept terrestrial animals from which the germinal products originate;
 - b the health status of donor animals;
 - c the risk involved with such germinal products;
 - d the type of germinal products;
 - e the type of collection, production, processing or storage of germinal products;
 - f the movement patterns for the relevant species and categories of kept terrestrial animals and their germinal products;

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- g considerations concerning the protection and conservation of species of kept terrestrial animals;
- h other elements that may contribute to the traceability of germinal products.

Article 123

Implementing powers concerning traceability requirements for germinal products

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

- (a) technical requirements and specifications for marking as provided for in Article 121(1);
- (b) operational requirements for the traceability provided for in delegated acts adopted pursuant to Article 122(1).

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

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