

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 1

Registration, approval, record-keeping and registers

Section 1

Registration of establishments and certain types of operators

Article 84

Obligation of operators to register establishments

1 Operators of establishments keeping terrestrial animals or collecting, producing, processing or storing germinal products shall, in order for their establishments to be registered in accordance with Article 93, before they commence such activities:

- a inform the competent authority of any such establishment under their responsibility;
- b provide the competent authority with the following information:
 - (i) the name and address of the operator concerned;
 - (ii) the location of the establishment and a description of its facilities;
 - (iii) the categories, species and numbers or quantities of kept terrestrial animals or germinal products which they intend to keep on the establishment, and the capacity of the establishment;
 - (iv) the type of establishment; and
 - (v) any other aspects of the establishment which are relevant for the purpose of determining the risk posed by it.

2 Operators of establishments referred to in paragraph 1 shall inform the competent authority of:

- a any changes in the establishment in question concerning the matters referred to in point (b) of paragraph 1;

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b any cessation of activity by the operator or establishment concerned.

3 Establishments which are subject to approval in accordance with Article 94(1) shall not be required to provide the information referred to in paragraph 1 of this Article.

Article 85

Derogations from the obligation of operators to register establishments

By way of derogation from Article 84(1), Member States may exempt from the registration requirement certain categories of establishments posing an insignificant risk, as provided for in an implementing act adopted in accordance with Article 86(2). Member States shall inform the Commission of such exemptions.

Article 86

Implementing powers concerning the obligation of operators to register establishments

1 The Commission may, by means of implementing acts, lay down rules concerning the information to be provided by operators for the purpose of the registration of establishments as provided for in Article 84(1), including the time-limits by which such information is to be provided.

2 The Commission shall, by means of implementing acts, lay down rules concerning the types of establishments that may be exempted by the Member States from the registration requirement in accordance with Article 85, on the basis of:

- a the species, categories and numbers of kept terrestrial animals and germinal products on the establishment in question and the capacity of that establishment;
- b the type of establishment; and
- c the movements of kept terrestrial animals or germinal products into and out of the establishment.

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

Article 87

Registration obligations of transporters of kept ungulates and delegated acts

1 Transporters of kept ungulates engaged in the transportation of those animals between Member States or between a Member State and a third country shall, in order to be registered in accordance with Article 93, before they commence such activities:

- a inform the competent authority of their activity;
- b provide that competent authority with information on:
 - (i) the name and address of the transporter concerned;
 - (ii) the categories, species and numbers of kept ungulates for which transportation is planned;
 - (iii) the type of transport;
 - (iv) the means of transport.

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- 2 Transporters as referred to in paragraph 1 shall inform the competent authority of:
- a any changes concerning the matters referred to in point (b) of paragraph 1;
 - b any cessation of the transport activity.

3 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 supplementing the rules provided for in paragraph 1 of this Article, requiring other types of transporters whose transport activity poses specific and significant risks for certain species or categories of animals to provide adequate information for the purposes of registration of their activity.

Article 88

Derogations from the registration obligation of transporters of kept ungulates

By way of derogation from Article 87(1), Member States may exempt from the registration requirement certain categories of transporters whose transport activity poses an insignificant risk, as provided for in an implementing act adopted in accordance with Article 89(2). Member States shall inform the Commission of such exemptions.

Article 89

Implementing powers concerning the registration obligation of transporters

1 The Commission may, by means of implementing acts, lay down rules concerning the information to be provided by transporters for the purposes of registration of their activity, as provided for in Article 87(1) and (3), including the time-limits by which such information is to be provided.

2 The Commission shall, by means of implementing acts, lay down rules concerning the types of transporters that may be exempted by Member States from the registration requirement in accordance with Article 86, on the basis of:

- a the distances over which they transport the ungulates in question; and
- b the categories, species and number of ungulates which they transport.

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

Article 90

Registration obligation of operators conducting assembly operations independently of an establishment

1 Operators conducting assembly operations for kept ungulates and poultry, independently of an establishment, including those who buy and sell animals, shall, in order to be registered in accordance with Article 93, before they commence their activities, provide the competent authority with information on:

- a the name and address of the operator concerned;
- b the species and categories of kept ungulates and poultry covered by their activity.

2 Operators as referred to in paragraph 1 shall inform the competent authority of:

- a any changes concerning the matters referred to in paragraph 1;

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- b any cessation of activity by the operator concerned.

Article 91

Derogations from the registration obligation of operators conducting assembly operations

By way of derogation from Article 90(1), Member States may exempt from the registration requirement certain categories of operators conducting assembly operations posing an insignificant risk, as provided for in an implementing act adopted in accordance with Article 92(2). Member States shall inform the Commission of such exemptions.

Article 92

Implementing powers concerning the registration obligation of operators conducting assembly operations

1 The Commission may, by means of implementing acts, lay down rules concerning the information to be provided by operators for the purpose of registration as provided for in Article 90(1), including the time-limits by which such information is to be provided.

2 The Commission shall, by means of implementing acts, lay down rules concerning the types of operators that may be exempted by Member States from the registration requirement in accordance with Article 91, provided that the activity of such operators poses an insignificant risk and on the basis of species, the categories and numbers of kept terrestrial animals covered by their activity.

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

Article 93

Obligation of the competent authority concerning registration

A competent authority shall register:

- (a) establishments in the register provided for in Article 101(1), where the operator concerned has provided the information required in accordance with Article 84(1);
- (b) transporters in the register provided for in Article 101(1), where the transporter concerned has provided the information required in accordance with Article 87(1) and (3);
- (c) operators conducting assembly operations independently of an establishment, in the register provided for in Article 101(1), where the operator concerned has provided the information required in accordance with Article 90(1).

The competent authority shall assign each establishment, transporter and operator as referred to in points (a) to (c) of the first paragraph with a unique registration number.

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Section 2

Approval of certain types of establishments

Article 94

Approval of certain establishments and delegated acts

- 1 Operators of the following types of establishments shall apply to the competent authority for approval in accordance with Article 96(1) and shall not commence their activities until their establishment has been approved in accordance with Article 97(1):
 - a establishments for assembly operations of ungulates and poultry from which those animals are moved to another Member State or which receive animals from another Member State;
 - b germinal product establishments for bovine, porcine, ovine, caprine and equine animals from which germinal products of those animals are moved to another Member State;
 - c hatcheries from which hatching eggs or poultry are moved to another Member State;
 - d establishments keeping poultry from which poultry intended for purposes other than slaughter or hatching eggs are moved to another Member State;
 - e any other type of establishment for kept terrestrial animals which poses a significant risk and is required to be approved in accordance with rules laid down in a delegated act adopted in accordance with point (b) of paragraph 3.
- 2 Operators shall cease activity at an establishment as referred to in paragraph 1 where:
 - a the competent authority withdraws or suspends its approval in accordance with Article 100(2); or
 - b in the event of conditional approval, granted in accordance with Article 99(3), the establishment in question fails to comply with the outstanding requirements referred to in Article 99(3) and does not obtain a final approval in accordance with Article 97(1).
- 3 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:
 - a derogations from the requirement for operators of the types of establishments referred to in points (a) to (d) of paragraph 1 to apply to the competent authority for approval, where those establishments pose an insignificant risk;
 - b the types of establishments which must be approved in accordance with point (e) of paragraph 1;
 - c special rules for the cessation of activities for germinal product establishments as referred to in point (b) of paragraph 1.
- 4 When adopting delegated acts as provided for in paragraph 3, the Commission shall base those acts on the following criteria:
 - a the species and categories of kept terrestrial animals or germinal products in an establishment;
 - b the number of species and number of kept terrestrial animals or germinal products kept in an establishment;
 - c the type of establishment and type of production; and
 - d the movements of kept terrestrial animals or germinal products into and out of those types of establishments.

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Article 95

Approval of status of confined establishments

Operators of establishments wishing to obtain the status of a confined establishment shall:

- (a) apply to the competent authority for approval in accordance with Article 96(1);
- (b) move kept animals to or from their establishment in accordance with the requirements provided for in Article 137(1) and any delegated acts adopted in accordance with Article 137(2) only after their establishment has obtained an approval of that status from the competent authority in accordance with Articles 97 and 99.

Article 96

Obligation of operators to provide information with a view to obtaining approval and implementing acts

1 Operators shall, for the purposes of their application for approval of their establishment as provided for in Article 94(1) and point (a) of Article 95, provide the competent authority with the following information:

- a the name and address of the operator concerned;
- b the location of the establishment concerned and a description of its facilities;
- c the categories, species and number of kept terrestrial animals or germinal products relevant for the approval which are kept on the establishment;
- d the type of establishment;
- e other aspects of the establishment, related to its specificity, which are relevant in determining the risk, if any, posed by it.

2 Operators of establishments as referred to in paragraph 1 shall inform the competent authority of:

- a any changes in the establishments concerning the matters referred to in points (a), (b) or (c) of paragraph 1;
- b any cessation of activity by the operator or establishment concerned.

3 The Commission may, by means of implementing acts, lay down rules concerning the information to be provided by operators in their application for approval of their establishment in accordance with paragraph 1, and the time-limits by which the information referred to in paragraph 1 and in point (b) of paragraph 2 is to be provided.

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

Article 97

Granting of, and conditions for, approval of establishments and delegated acts

1 Competent authorities shall only grant approval of establishments as provided for in Article 94(1) and point (a) of Article 95 where such establishments:

- a comply with the following requirements, where appropriate, in relation to:

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- (i) quarantine, isolation and other biosecurity measures taking into account the requirements provided for in point (b) of Article 10(1) and any rules adopted pursuant to Article 10(2);
 - (ii) surveillance requirements as provided for in Article 24 and, where relevant for the type of establishment concerned and the risk involved, in Article 25;
 - (iii) record-keeping as provided for in Articles 102 and 103 and any rules adopted pursuant to Articles 106 and 107;
- b have facilities and equipment that are:
- (i) adequate to reduce the risk of the introduction and spread of diseases to an acceptable level, taking into account the type of establishment concerned;
 - (ii) of a capacity adequate for the number of kept terrestrial animals or the volume of germinal products concerned;
- c do not pose an unacceptable risk as regards the spread of diseases, taking into account the risk-mitigation measures in place;
- d have adequately trained personnel for the activity of the establishment concerned;
- e have in place a system which enables the operator concerned to demonstrate to the competent authority compliance with points (a) to (d).
- 2 The Commission shall adopt delegated acts in accordance with Article 264 concerning:
- a quarantine, isolation and other biosecurity measures as referred to in point (a)(i) of paragraph 1;
 - b surveillance as referred to in point (a)(ii) of paragraph 1;
 - c facilities and equipment as referred to in point (b) of paragraph 1;
 - d responsibilities, competence and specialised training of personnel and veterinarians as provided for in point (d) of paragraph 1 for the activity of germinal products establishments and establishments for assembly operations of ungulates and poultry;
 - e the necessary supervision by the competent authority of germinal products establishments and establishments for assembly operations of ungulates and poultry.
- 3 When establishing the rules to be laid down in the delegated acts to be adopted pursuant to paragraph 2, the Commission shall base those rules on the following matters:
- a the risks posed by each type of establishment;
 - b the species and categories of kept terrestrial animals relevant for the approval;
 - c the type of production concerned;
 - d typical movement patterns of the type of establishment and species and categories of animals kept in those establishments.

Article 98

Scope of the approval of establishments

The competent authority shall expressly specify in the approval of an establishment granted pursuant to Article 97(1), following an application made in accordance with Article 94(1) or point (a) of Article 95:

- (a) for which of the types of establishments referred to in Article 94(1) and Article 95, and in the rules adopted pursuant to point (b) of Article 94(3), the approval applies;

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- (b) for which species and categories of kept terrestrial animals or germinal products of those species the approval applies.

Article 99

Procedures for the granting of approval by the competent authority

1 The competent authority shall establish procedures for operators to follow when applying for approval of their establishments in accordance with Article 94(1), Article 95 or Article 96(1).

2 Upon receipt of an application for approval from an operator, the competent authority shall, in accordance with Article 94(1) or point (a) of Article 95, make an on-site visit.

3 Provided that the requirements referred to in Article 97 and paragraphs (1) and (2) of this Article are fulfilled, the competent authority shall grant the approval.

4 Where an establishment does not fulfil all requirements for approval as referred to in Article 97, the competent authority may grant conditional approval of an establishment if it appears, on the basis of the application by the operator concerned and the subsequent on-site visit as provided for in paragraph 2 of this Article, that the establishment meets all the main requirements that provide sufficient guarantees that the establishment does not pose a significant risk.

5 Where conditional approval has been granted by the competent authority in accordance with paragraph 4 of this Article, it shall grant full approval only where it appears from another on-site visit to the establishment, carried out within three months of the date of the grant of conditional approval, or from documentation provided by the operator within three months from that date, that the establishment meets all the requirements for approval provided for in Article 97(1) and the rules adopted pursuant to Article 97(2).

Where the on-site visit or the documentation referred to in the first subparagraph shows that clear progress has been made but that the establishment still does not meet all of those requirements, the competent authority may prolong the conditional approval. However, conditional approval shall not be granted for a period exceeding, in total, six months.

Article 100

Review, suspension and withdrawal of approvals by the competent authority

1 The competent authority shall keep approvals of establishments granted in accordance with Articles 97 and 99 under review, at appropriate intervals based on the risk involved.

2 Where a competent authority identifies serious deficiencies in an establishment as regards compliance with the requirements laid down in Article 97(1) and the rules adopted pursuant to Article 97(2), and the operator of that establishment is not able to provide adequate guarantees that those deficiencies will be eliminated, the competent authority shall initiate procedures to withdraw the approval of the establishment.

However, the competent authority may merely suspend, rather than withdraw, approval of an establishment where the operator can guarantee that it will eliminate those deficiencies within a reasonable period of time.

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3 Approval shall only be granted after withdrawal or restored after suspension in accordance with paragraph 2 when the competent authority is satisfied that the establishment fully complies with all the requirements of this Regulation appropriate for that type of establishment.

Section 3

Registers of the competent authority

Article 101

Registers to be kept by the competent authority

- 1 Each competent authority shall establish and keep up to date registers of:
- a all establishments and operators registered with it pursuant to Article 93;
 - b all establishments approved by it in accordance with Articles 97 and 99.

It shall make the registers referred to in points (a) and (b) of the first subparagraph available to the Commission and to the competent authorities of other Member States in so far as the information contained therein is relevant for movements of kept terrestrial animals and germinal products thereof between Member States.

It shall make the register of approved establishments as referred to in point (b) of the first subparagraph available to the public in so far as the information contained therein is relevant for movements of kept terrestrial animals and germinal products thereof between Member States.

2 Where appropriate and relevant, a competent authority may combine the registration referred to in point (a) of the first subparagraph of paragraph 1 and the approvals referred to in point (b) of the first subparagraph of paragraph 1 with registration for other purposes.

3 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the detailed information to be included in the registers provided for in points (a) and (b) of the first subparagraph of paragraph 1, and the availability to the public of the register provided for in point (b) of the first subparagraph of paragraph 1.

Section 4

Record-keeping

Article 102

Record-keeping obligations of operators of establishments other than germinal products establishments

1 Operators of establishments subject to the requirement of registration in accordance with Article 93, or approval in accordance with Article 97(1), shall keep and maintain records containing at least the following information:

- a the species, categories, number and, where applicable, identification of kept terrestrial animals on their establishment;

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- b movements of kept terrestrial animals into and out of their establishment, stating as appropriate:
 - (i) their place of origin or destination;
 - (ii) the date of such movements;
- c the documents required to accompany kept terrestrial animals arriving at or leaving their establishment in accordance with point (b) of Article 112, point (b) of Article 113(1), point (c) of Article 114(1), point (b) of Article 115, point (b) of Article 117, Article 143(1) and (2), Article 164(2) and any rules adopted pursuant to Articles 118 and 120 and points (b) and (c) of Article 144(1);
- d mortality of kept terrestrial animals on their establishment;
- e biosecurity measures, surveillance, treatments, test results and other relevant information as appropriate for:
 - (i) the species and categories of kept terrestrial animals in the establishment;
 - (ii) the type of production;
 - (iii) the type and size of the establishment;
- f the results of any animal health visits required in accordance with Article 25(1).

The records shall be kept and maintained in paper or electronic form.

2 Establishments presenting a low risk of spreading listed or emerging diseases may be exempted by the Member State concerned from the requirement to keep records of all or some of the information listed in paragraph 1.

3 Operators of establishments shall keep the records provided for in paragraphs 1 and 2 on their establishment concerned and shall:

- a make them immediately available to the competent authority on request;
- b retain them for a minimum period to be prescribed by the competent authority, which may not be less than three years.

4 By way of derogation from paragraph 3, operators may be exempted from the obligation to keep records of some or all of the matters provided for in paragraph 1 when the operator concerned:

- a has access to the computerised database referred to in Article 109 for the relevant species and the database already contains the information to be included in the records; and
- b has the up-to-date information entered directly into the computerised database.

Article 103

Record-keeping obligations of germinal product establishments

1 Operators of germinal product establishments shall keep and maintain records containing at least the following information:

- a the breed, age, identification and health status of donor animals used for the production of germinal products;
- b the time and place of collection, and the processing and storage, of germinal products collected, produced or processed;

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- c the identification of the germinal products together with details of their place of destination, if known;
 - d the documents required to accompany germinal products arriving at or leaving the establishment in question in accordance with Article 162 and Article 164(2) and any rules adopted pursuant to Article 162(3) and (4);
 - e where relevant, the results of clinical and laboratory tests;
 - f laboratory techniques used.
- 2 Establishments presenting a low risk of spreading listed or emerging diseases may be exempted by the Member State concerned from the requirement to keep records of all or some of the information listed in paragraph 1.
- 3 Operators of germinal product establishments shall keep the records provided for in paragraphs 1 and 2 on their establishment and:
- a make them immediately available to the competent authority on request;
 - b retain them for a minimum period to be prescribed by the competent authority, which may not be less than three years.

Article 104

Record-keeping obligations of transporters

- 1 Transporters shall keep and maintain records containing at least the following information:
- a the establishments visited by them;
 - b the categories, species and number of kept terrestrial animals transported by them;
 - c the cleaning, disinfection and disinfestation of the means of transport used;
 - d details of the documents accompanying the animals in question, including their document numbers.

The records shall be kept and maintained in paper or electronic form.

- 2 Transporters presenting a low risk of spreading listed or emerging diseases may be exempted by the Member State concerned from the requirement to keep records of all or some of the information listed in paragraph 1.
- 3 Transporters shall keep the records provided for in paragraphs 1 and 2:
- a in such a manner that they can be made immediately available to the competent authority on request;
 - b for a minimum period to be prescribed by the competent authority, which may not be less than three years.

Article 105

Record-keeping obligations of operators conducting assembly operations

- 1 Operators conducting assembly operations subject to the registration requirement laid down in Article 93 shall keep and maintain records containing at least the following information:
- a the species, categories, numbers and identification of kept terrestrial animals under their responsibility;
 - b movements of kept terrestrial animals under their responsibility, stating as appropriate:

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- (i) their place of origin and destination;
- (ii) the date of such movements;
- c the documents required to accompany kept terrestrial animals moved under their responsibility in accordance with point (b) of Article 112, point (b) of Article 113(1), point (c) of Article 114(1), point (b) of Article 115, point (b) of Article 117, Article 143(1) and (2), Article 164(2) and any rules adopted pursuant to Articles 118 and 120 and points (b) and (c) of Article 144(1);
- d mortality of kept terrestrial animals under their responsibility; and
- e biosecurity measures, surveillance, treatments, test results and other relevant information as appropriate for the species and categories of kept terrestrial animals under their responsibility.

The records shall be kept and maintained in paper or electronic form.

2 Operators whose activities present a low risk of spreading listed or emerging diseases may be exempted by the Member State concerned from the requirement to keep records of all or some of the information listed in paragraph 1.

3 Operators shall:

- a make the records referred to in paragraph 1 available to the competent authority on request;
- b retain those records for a minimum period to be prescribed by the competent authority, which may not be less than three years.

Article 106

Delegation of powers concerning record-keeping

1 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning rules supplementing the record-keeping requirements provided for in Articles 102, 103, 104 and 105, as regards:

- a information to be recorded in addition to that provided for in Articles 102(1), 103(1), 104(1) and 105(1);
- b additional requirements for record-keeping in respect of germinal products collected, produced or processed in a germinal products establishment after that establishment ceased its activities.

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

- a the risks posed by each type of establishment or activity;
- b the species and categories of kept terrestrial animals or germinal products in the establishment concerned, or transported to or from that establishment;
- c the type of production on the establishment or the type of activity;
- d the typical movement patterns and categories of the animals concerned;
- e the number of kept terrestrial animals or volume of germinal products under the responsibility of the operator concerned.

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Article 107

Implementing powers concerning exemptions from the record-keeping requirements

The Commission may, by means of implementing acts, lay down rules concerning the types of establishments and operators that may be exempted by Member States from the record-keeping requirements provided for in Articles 102, 103, 104 and 105, as regards:

- (a) establishments keeping, or operators handling or transporting, a small number of kept terrestrial animals or a small volume or number of germinal products;
- (b) species or categories of kept terrestrial animals or germinal products.

When adopting those implementing acts, the Commission shall base those acts on the criteria laid down in Article 106(2).

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

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Changes to legislation:

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