

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;

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;

- 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.

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.

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;

- (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.

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;

- 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:

- (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.

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).

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;
 - 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;
- 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.

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:

- 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).

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).

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;

- 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).

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).

CHAPTER 3

Movements within the Union of kept terrestrial animals

Section 1

General requirements for movements

Article 124

General requirements for movements of kept terrestrial animals

1 Operators shall take appropriate preventive measures to ensure that the movement of kept terrestrial animals does not jeopardise the health status 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 kept terrestrial animals from their establishments and receive such animals if the animals in question fulfil the following conditions:

- a they come from establishments that have been:
 - (i) registered by the competent authority in accordance with Article 93; or
 - (ii) approved by the competent authority in accordance with Articles 97(1) and 98, when required by Article 94(1) or Article 95; or
 - (iii) granted a derogation from the registration requirement laid down in Article 84;
- b they fulfil the identification and registration requirements laid down in Articles 112, 113, 114, 115 and 117 and the rules adopted pursuant to Articles 118 and 120.

Article 125

Disease prevention measures in relation to transport

- 1 Operators shall take the appropriate and necessary preventive measures to ensure that:
 - a the health status of kept terrestrial animals is not jeopardised during transport;
 - b transport operations of kept terrestrial animals do not cause the potential spread of listed diseases as referred to in point (d) of Article 9(1) to humans and animals;
 - c cleaning and disinfection of, and control of insects and rodents with respect to, equipment and means of transport and other adequate biosecurity measures are taken, as appropriate to the risks involved with the transport operations concerned.
- 2 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:
 - a the conditions and requirements for cleaning and disinfection of, and control of insects and rodents with respect to, equipment and means of transport and the use of biocidal products for those purposes;
 - b other appropriate biosecurity measures as provided for in point (c) of paragraph 1 of this Article.

Section 2

Movements between Member States

Article 126

General requirements for movements of kept terrestrial animals between Member States

- 1 Operators shall only move kept terrestrial animals to another Member State if the animals in question fulfil the following conditions:
 - a they show no disease symptoms;
 - b they come from a registered or approved establishment:
 - (i) where there are no abnormal mortalities with an undetermined cause;
 - (ii) which is not subject to movement restrictions affecting the species to be moved in accordance with the rules laid down in Article 55(1), point (a) of Article 61(1), Article 62, point (c) of Article 65(1), Article 74(1) and Article 79 and the rules adopted pursuant to Article 55(2), Articles 63 and 67, Articles 71(3), 74(4), and 83(2) or the emergency measures provided for in Articles 257 and 258 and any rules adopted pursuant to Article 259, unless derogations from movement restrictions have been granted in accordance with those rules;
 - (iii) which is not situated in a restricted zone in accordance with rules laid down in point (f)(ii) of Article 55(1), Articles 64 and 65, Article 74(1), Article 79 and any rules adopted pursuant to Article 67, Article 71(3), Article 74(4) and Article 83(2) or the emergency measures provided for in Articles 257 and 258 and any rules adopted pursuant to Article 259, unless derogations have been granted in accordance with those rules;

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- c they have not been in contact with kept terrestrial animals which are subject to movement restrictions as referred to in point (b)(ii) and (iii) or kept terrestrial animals of a listed species of a lower health status, for an adequate period of time prior to the date of the intended movement to another Member State, thereby minimising the possibility of spreading disease, taking into account the following matters:
 - (i) the incubation period and routes of transmission of the listed diseases and emerging diseases in question;
 - (ii) the type of establishment concerned;
 - (iii) the species and category of kept terrestrial animals moved;
 - (iv) other epidemiological factors;
 - d they fulfil the relevant requirements provided for in Sections 3 to 8 (Articles 130 to 154).
- 2 Operators shall take all necessary measures to ensure that kept terrestrial animals moved to another Member State are consigned directly to their place of destination in that other Member State unless they need to stop at a place of resting for animal welfare reasons.

Article 127

Obligations of operators at the place of destination

- 1 Operators of establishments and slaughterhouses receiving kept terrestrial animals from another Member State shall:
- a check that:
 - (i) the means or methods of identification provided for in point (a) of Article 112, point (a) of Article 113(1), points (a) and (b) Article 114(1), point (a) of Article 115 and point (a) of Article 117 and the rules adopted pursuant to Articles 118 and 120 are in place;
 - (ii) the identification 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 117 and the rules adopted pursuant to Articles 118 and 120 are in place and are correctly completed;
 - b check that the animal health certificates provided for in Article 143 and in any rules adopted pursuant to points (b) and (c) of Article 144(1) or the self-declaration documents provided for in Article 151 and the rules adopted pursuant to Article 151(3) and (4) are in place;
 - c inform the competent authority of the place of destination, after checking the kept terrestrial animals received, of any irregularity with regard to:
 - (i) the kept terrestrial animals received;
 - (ii) the means or methods of identification referred to in point (a)(i);
 - (iii) the documents referred to in points (a)(ii) and (b).
- 2 In the event of any irregularity as referred to in point (c) of paragraph 1, the operator shall isolate the animals concerned by that irregularity until the competent authority of the place of destination has taken a decision regarding them.

Article 128

Prohibition on movements of kept terrestrial animals for disease eradication purposes outside the territory of a Member State

Operators shall not move kept terrestrial animals intended to be slaughtered for disease eradication purposes as part of an eradication programme, as provided for in Article 31(1) or (2), to another Member State unless the Member State of destination and, where relevant, the Member State of passage authorise the movement in advance.

Article 129

General requirement applicable to operators in respect of movements of kept terrestrial animals passing through Member States but intended for export from the Union to third countries or territories

Operators shall ensure that kept terrestrial animals intended for export to a third country or territory and passing through the territory of another Member State fulfil the requirements laid down in Articles 124, 125, 126 and 128.

Section 3

Specific requirements in respect of movements to other Member States of ungulates and poultry

Article 130

Movements of kept ungulates and poultry to other Member States

Operators shall only move kept ungulates and poultry from an establishment in one Member State to another Member State if the animals in question fulfil the following conditions as regards the listed diseases referred to in point (d) of Article 9(1):

- (a) they show no clinical symptoms or signs of listed diseases as referred to in point (d) of Article 9(1) at the time of movement;
- (b) they have been subject to a residency period appropriate to those listed diseases, taking into account the species and category of kept ungulates and poultry to be moved;
- (c) for a period of time appropriate for those listed diseases and the species and category of ungulates or poultry to be moved, no kept ungulates or poultry have been introduced into the establishment of origin when a requirement to that effect is laid down in the rules adopted in accordance with Article 131 or Article 135;
- (d) they are presumed not to pose a significant risk of spreading of those listed diseases at the place of destination, based on:
 - (i) the health status concerning relevant diseases for species or categories of kept ungulates and poultry moved, taking into account the health status at the place of destination;

- (ii) the results of laboratory or other examinations necessary in order to provide guarantees regarding the health status required for the movement in question;
- (iii) the application of vaccination or other disease prevention or risk-mitigation measures aimed at limiting the spread of the relevant disease to the places of destination or passage.

Article 131

Delegation of powers in respect of movements of kept ungulates and poultry to other Member States

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

- a residency periods as referred to in point (b) of Article 130;
- b the period of time necessary in order to limit the introduction of kept ungulates or poultry into establishments prior to movement as provided for in point (c) of Article 130;
- c supplementary requirements to ensure that kept ungulates and poultry do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1), as provided for in point (d) of Article 130);
- d other necessary risk-mitigation measures supplementing the requirements laid down in Article 130.

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 listed diseases referred to in point (d) of Article 9(1) relevant for the listed species or the category of kept ungulates or poultry to be moved;
- b the health status as regards listed diseases referred to in point (d) of Article 9(1) in the establishments, compartments, zones and Member States of origin and destination;
- c the type of establishment concerned and the type of production at the places of origin and destination;
- d the type of movement concerned;
- e the species and categories of kept ungulates or poultry to be moved;
- f the age of the kept ungulates or poultry to be moved;
- g other epidemiological factors.

Article 132

Kept ungulates and poultry moved to another Member State and intended for slaughter

1 Operators of slaughterhouses receiving kept ungulates and poultry from another Member State shall slaughter those animals as soon as possible following their arrival and at the latest within a timeframe to be laid down in delegated acts adopted pursuant to paragraph 2.

2 The Commission shall adopt delegated acts in accordance with Article 264 concerning the time of slaughter provided for in paragraph 1 of this Article.

Section 4

Assembly operations in respect of kept ungulates and poultry

Article 133

Derogation in respect of assembly operations

1 By way of derogation from Article 126(2), operators may subject kept ungulates and poultry to a maximum of three assembly operations during a movement from a Member State of origin to another Member State.

2 The assembly operations provided for in paragraph 1 of this Article shall only take place in an establishment approved for that purpose in accordance with Article 97(1) and Article 99(3) and (4).

However, the Member State of origin may allow an assembly operation on its territory to take place on a means of transport, collecting kept ungulates or poultry directly from their establishments of origin, provided that those animals are not unloaded again during that operation and before arriving:

- a at the establishment or final place of destination; or
- b for the subsequent assembly operation in an establishment approved for that purpose in accordance with Article 97(1) and Article 99(4) and (5).

Article 134

Disease prevention requirements in respect of assembly operations

Operators conducting assembly operations shall ensure that:

- (a) the kept ungulates and poultry assembled have the same health status; where they do not, the lower health status applies to all such animals assembled;
- (b) the kept ungulates and poultry are assembled and moved to their final place of destination in another Member State as soon as possible after leaving their establishment of origin, and at the latest within a timeframe to be laid down in delegated acts adopted pursuant to point (c) of Article 135;
- (c) the necessary biosecurity measures are taken to ensure that the kept ungulates and poultry assembled:
 - (i) do not come into contact with kept ungulates or poultry having a lower health status;
 - (ii) do not pose a significant risk for the spread of the listed diseases referred to in point (d) of Article 9(1) to the kept ungulates or poultry at the place where the assembly operation takes place;
- (d) the kept ungulates and poultry are identified where so required by this Regulation and are accompanied by the following documents:
 - (i) the identification and movement documents as 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 and any rules adopted pursuant

- to Articles 118 and 120, unless derogations are provided for in accordance with Articles 113(2) and 119;
- (ii) the animal health certificates as provided for in Article 143 and point (c) of Article 144(1), unless derogations are provided for in the rules adopted pursuant to point (a) of Article 144(1);
 - (iii) the self-declaration document as provided for in Article 151.

Article 135

Delegation of powers concerning assembly operations

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

- (a) specific rules for assembly operations, where other risk-mitigation measures, in addition to those provided for in points (b) and (c) of Article 134, are in place;
- (b) criteria under which Member States of origin may allow assembly operations to take place on means of transport, as provided for in the second subparagraph of Article 133(2);
- (c) the timeframe between the time of departure of the kept ungulates or poultry from their establishment of origin and their departure from the assembly operation to their final destination in another Member State, as referred to in point (b) of Article 134;
- (d) detailed rules as regards the biosecurity measures provided for in point (c) of Article 134.

Section 5

Movements to other Member States of kept terrestrial animals other than kept ungulates and poultry

Article 136

Movements of kept terrestrial animals other than kept ungulates and poultry to other Member States and delegated acts

1 Operators shall only move kept terrestrial animals other than kept ungulates or poultry from an establishment in one Member State to another Member State if the animals in question do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1) at the place of destination.

2 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning detailed rules to ensure that kept terrestrial animals other than kept ungulates or poultry do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1), as provided for in paragraph 1 of this Article.

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

- a the listed diseases referred to in point (d) of Article 9(1) relevant for the listed species or the category of kept terrestrial animals to be moved;

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- b the health status as regards the listed diseases referred to in point (d) of Article 9(1) in the establishments, compartments, zones and Member States of origin and the place of destination;
- c the types of establishment and the types of production at the place of origin and the place of destination;
- d the types of movement in respect of the final use of animals at the place of destination;
- e the species and categories of kept terrestrial animals to be moved;
- f the age of the kept terrestrial animals to be moved;
- g other epidemiological factors.

Section 6

DErogating from, and supplementing, risk-mitigation measures for movements of kept terrestrial animals

Article 137

Kept terrestrial animals intended for confined establishments and delegated acts

- 1 Operators shall only move kept terrestrial animals to a confined establishment if the animals in question fulfil the following conditions:
 - a they originate from another confined establishment;
 - b they 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 or to categories of animals at the confined establishment of destination, except where the movement in question is authorised for scientific purposes.
- 2 The Commission shall adopt delegated acts in accordance with Article 264 concerning:
 - a detailed rules for movements of kept terrestrial animals into confined establishments in addition to those provided for in paragraph 1 of this Article;
 - b specific rules for movements of kept terrestrial animals into confined establishments where the risk-mitigation measures in place guarantee that such movements do not pose a significant risk for the health of kept terrestrial animals within that confined establishment and the surrounding establishments.

Article 138

Movements of kept terrestrial animals 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 kept terrestrial animals into the territory of the Member State of destination, for scientific purposes, where those movements do not comply with the requirements of Sections 1 to 5 (Articles 124 to 136), with the exception of Articles 124 and 125, point (b)(ii) of Article 126(1) and Article 127.
- 2 The competent authority of the place of destination shall only grant derogations as provided for in paragraph 1 under the following conditions:
 - a the competent authorities of the places of destination and origin:

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

Article 139

Derogations concerning recreational use, sporting and cultural events, work near borders and grazing

1 The competent authority of the place of destination may grant derogations from the requirements of Sections 2 to 5 (Articles 126 to 136), with the exception of points (a),(b) and (c) of Article 126(1) and Articles 127 and 128, for intra-Union movements of kept terrestrial animals between Member States where such movements are for:

- a recreational use near borders;
- b exhibitions, and sporting, cultural and similar events, organised near borders;
- c grazing of kept terrestrial animals in grazing areas shared between Member States; or
- d work done by kept terrestrial animals near borders of Member States.

2 Derogations by the competent authority of the place of destination for movements of kept terrestrial animals for the purposes provided for in paragraph 1 shall be agreed on between the Member States of origin and destination and appropriate risk-mitigation measures shall be taken to ensure that such movements do not pose a significant risk.

3 The Member States referred to in paragraph 2 shall inform the Commission of the granting of derogations as provided for in paragraph 1.

4 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning rules for the granting of derogations by the competent authority of the place of destination, supplementing those provided for in paragraph 1 of this Article.

Article 140

Delegation of power concerning circuses, exhibitions, sporting events and recreational use, zoos, pet shops, animal shelters and wholesalers

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

- (a) specific requirements supplementing the rules laid down in Sections 2 to 5 (Articles 126 to 136) for movements of kept terrestrial animals for the following purposes:
 - (i) circuses, zoos, pet shops, animal shelters and wholesalers;
 - (ii) exhibitions and sporting, cultural and similar events;
- (b) derogations from Sections 2 to 5 (Articles 126 to 136), with the exception of points (a), (b) and (c) of Article 126(1) and Articles 127 and 128, for movements of kept terrestrial animals as referred to in point (a) of this Article.

Article 141

Implementing power to adopt temporary rules for movements of specific species or categories of kept terrestrial animals

1 The Commission may, by means of implementing acts, lay down temporary rules, by way of addition or alternative to those laid down in this Chapter, for movements of specific species or categories of kept terrestrial animals where:

- a the movement requirements provided for in Article 130, Article 132(1), Articles 133 and 134, Articles 136(1), 137(1) and 138(1) and (2) and Article 139 and the rules adopted pursuant to Articles 131(1) and 132(2), Article 135, Articles 136(2), 137(2), 138(3) and 139(4) and Article 140 are not effectively mitigating the risks posed by the movement of such animals; or
- b a listed disease as referred to in point (d) of Article 9(1) appears to be spreading despite the movement requirements laid down in accordance with Sections 1 to 6 (Articles 124 to 142).

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 diseases representing a risk of a highly significant impact and taking into account the matters referred to in Article 142, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure provided for in Article 266(3).

Article 142

Matters to be taken into account in the adoption of delegated and implementing acts as provided for in this Section

When establishing the rules to be laid down in the delegated and implementing acts provided for in Articles 137(2), 138(3) and 139(4) and Articles 140 and 141, the Commission shall base those rules on the following matters:

- (a) the risks involved with the movements referred to in those provisions;
- (b) the health status as regards the listed diseases referred to in point (d) of Article 9(1) at the places of origin, passage and destination;
- (c) listed animal species for the listed diseases referred to in point (d) of Article 9(1);
- (d) biosecurity measures in place at the places of origin, passage and destination

- (e) any specific conditions in establishments under which the kept terrestrial animals are kept;
- (f) specific movement patterns of the type of establishment and the species and category of kept terrestrial animals concerned;
- (g) other epidemiological factors.

Section 7

Animal health certification

Article 143

Obligation of operators to ensure that animals are accompanied by an animal health certificate

1 Operators shall only move the following species and categories of kept terrestrial animals to another Member State if the animals in question are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Article 149(1):

- a ungulates;
- b poultry;
- c kept terrestrial animals other than ungulates and poultry, intended for a confined establishment;
- d kept terrestrial animals other than those referred to in points (a), (b) and (c) of this paragraph, when required in accordance with delegated acts adopted pursuant to point (c) of Article 144(1).

2 In cases where kept terrestrial animals are allowed to leave a restricted zone as provided for in point (f)(ii) of Article 55(1), Article 56 and Article 64(1) and are subject to disease control measures as provided for in Articles 55(1), 65(1), 74(1), Article 79 or Article 80 or rules adopted pursuant to Article 55(2), Article 67, Articles 71(3) and 74(4), Article 83(3) or Article 259, and the animals in question are of species subject to those disease control measures, operators shall only move such kept terrestrial animals within a Member State or from one Member State to another Member State when the animals to be moved are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Article 149(1).

The competent authority may decide that such a certificate does not have to be issued for movements of kept terrestrial animals within the Member State in question when that authority considers that an alternative system is in place ensuring that the consignment of such animals is traceable and that those animals fulfil 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 of this Article accompanies the kept terrestrial animals from their place of origin to their final place of destination, unless specific measures are provided for in rules adopted pursuant to Article 147.

Article 144

Delegation of powers concerning the obligation of operators to ensure that animals are accompanied by an animal health certificate

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

- a derogations from the animal health certification requirements provided for in Article 143(1), for movements of kept terrestrial animals which do not pose a significant risk for the spread of a disease on account of:
 - (i) the species or categories of the kept terrestrial animals that are being moved and the listed diseases referred to in point (d) of Article 9(1) for which they are listed species;
 - (ii) the methods of keeping and the type of production of those species and categories of kept terrestrial animals;
 - (iii) the intended use of the kept terrestrial animals; or
 - (iv) the place of destination of the kept terrestrial animals; including those cases where their place of destination is in the same Member State as their place of origin but they pass through another Member State in order to reach their place of destination;
- b special rules for animal health certification as provided for in Article 143(1) where specific risk-mitigation measures concerning surveillance or biosecurity are taken, taking into account the matters provided for in paragraph 2 of this Article, which ensure:
 - (i) the traceability of the kept terrestrial animals being moved;
 - (ii) that the kept terrestrial animals being moved fulfil the animal health requirements for movements provided for in Sections 1 to 6 (Articles 124 to 142);
- c the requirement for animal health certification for movements of species and categories of kept terrestrial animals other than those referred to in points (a), (b) and (c) of Article 143(1) in cases where animal health certification is imperative in order to ensure that the movement in question complies with the animal health requirements for movements provided for in Sections 1 to 6 (Articles 124 to 142).

2 When establishing the special rules provided for in point (b) of paragraph 1, the Commission shall take the following matters into account:

- a the assessment by the competent authority of the biosecurity put in place by operators as provided for in point (b) of Article 10(1) and any rules adopted pursuant Article 10(6);
- b the ability of the competent authority, in so far as may be necessary and appropriate, to take measures and to engage in activities required by this Regulation as provided for in Article 13(1);
- c the level of knowledge of animal health as provided for in Article 11 and the encouragement thereof provided for in Article 13(2);
- d the carrying-out of the animal health visits provided for in Article 25 or other relevant surveillance or official controls in place;

- e the performance by the competent authority of its obligations under the Union notification and reporting system provided for in Articles 19 to 22 and in the rules adopted pursuant to Article 20(3) and Article 23;
 - f the application of surveillance as provided for in Article 26 and surveillance programmes as provided for in Article 28 and in any rules adopted pursuant to Articles 29 and 30.
- 3 The Commission shall take the matters referred to in point (a)(i) to (iv) of paragraph 1 into account when establishing the requirements for animal health certification provided for in point (c) of paragraph (1).

Article 145

Contents of animal health certificates

- 1 The animal health certificate referred to in Article 143 shall contain the following information:
- a the establishment or place of origin, the establishment or place of destination and, where relevant, establishments for assembly operations or for rests, of the kept terrestrial animals concerned;
 - b the means of transport and the transporter;
 - c a description of the kept terrestrial animals;
 - d the number of kept terrestrial animals;
 - e the identification and registration of kept terrestrial animals, where required by Articles 112, 113, 114, 115 and 117 and by any rules adopted pursuant to Articles 118 and 120, unless derogations are provided for in accordance with Article 119; and
 - f the information needed to demonstrate that the kept terrestrial animals fulfil the relevant animal health requirements in respect of movements provided for in Sections 1 to 6 (Articles 124 to 142).
- 2 The animal health certificate may include other information required under other Union legislation.

Article 146

Delegation of powers and implementing acts concerning the content of animal health certificates

- 1 The Commission shall adopt delegated acts in accordance with Article 264 concerning:
- a detailed rules on the content of animal health certificates as provided for in Article 145(1) for different species and categories of kept terrestrial animals and for specific types of movements as provided for in the rules adopted pursuant to Article 147;
 - b additional information to be contained in the animal health certificate provided for in Article 145(1).
- 2 The Commission may, by means of implementing acts, lay down rules for model forms of animal health certificates. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Article 147

Delegation of powers concerning specific types of movements of kept terrestrial animals

The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning specific measures derogating from, or supplementing, the obligation of operators to ensure that animals are accompanied by an animal health certificate as provided for in Article 143 and in the rules adopted pursuant to Article 144, for the following types of movements of kept terrestrial animals:

- (a) movements of kept ungulates and poultry passing through the assembly operations provided for in Article 133 prior to reaching their final place of destination;
- (b) movements of kept terrestrial animals which are required to return to their place of origin or to be moved to a different destination, for one or more of the following reasons:
 - (i) their intended journey was unexpectedly interrupted for animal welfare reasons;
 - (ii) unforeseen accidents or events during the journey;
 - (iii) they were rejected at the place of destination in a Member State or at the external border of the Union;
 - (iv) they were rejected at a place of assembly or resting;
 - (v) they were rejected in a third country or territory;
- (c) movements of kept terrestrial animals intended for exhibitions, and sporting, cultural and similar events, and their subsequent return to their place of origin.

Article 148

Operators' obligations to cooperate with the competent authority for the purposes of animal health certification

Operators shall:

- (a) provide the competent authority with all the information necessary to complete the animal health certificate provided for in Article 143(1) and (2) and in any rules adopted pursuant to Article 146(1) or Article 147, in advance of the intended movement;
- (b) where necessary, ensure that the kept terrestrial animals in question are subjected to documentary, identity and physical checks as provided for in Article 149(3).

Article 149

Responsibility of the competent authority for animal health certification

1 The competent authority shall, upon request by an operator, issue an animal health certificate for the movement of kept terrestrial animals, where required by Article 143 or by delegated acts adopted pursuant to Article 144(1), provided that the following movement requirements have been complied with:

- a those provided for in Article 124, Article 125(1), Articles 126, 128, 129, 130, 133 and 134, Articles 136(1) and 137(1), Article 138 and Article 139;
 - b those provided for in delegated acts adopted pursuant to Articles 125(2) and 131(1), Article 135, Articles 136(2), 137(2), 138(4) and 139(4) and Article 140;
 - c those provided for in implementing acts adopted pursuant to Article 141.
- 2 Animal health certificates shall:
- a be verified, stamped and signed by an official veterinarian;
 - b remain valid for the period of time provided for in the rules adopted pursuant to point (c) of paragraph 4, during which the kept terrestrial animals covered by it continue to fulfil the animal health guarantees contained in it.
- 3 Before signing an animal health certificate, the official veterinarian concerned shall verify, by means of documentary, identity and physical checks as provided for by delegated acts adopted pursuant to paragraph 4, that the kept terrestrial animals covered by it fulfil the requirements of this Chapter.
- 4 The Commission shall adopt delegated acts in accordance with Article 264 laying down rules concerning:
- a the types of documentary, identity and physical checks and examinations in relation to different species and categories of kept terrestrial animals that must be carried out by the official veterinarian in accordance with paragraph 3 in order to verify compliance with the requirements of this Chapter;
 - b the timeframes for the carrying-out of such documentary, identity and physical checks and examinations and the issuing of animal health certificates by the official veterinarian prior to the movement of consignments of kept terrestrial animals;
 - c the duration of the validity of animal health certificates.

Article 150

Electronic animal health certificates

Electronic animal health certificates, produced, handled and transmitted by means of Traces, may replace accompanying animal health certificates as provided for in Article 149(1) where:

- (a) such electronic animal health certificates contain all the information that the model form of animal health certificate is required to contain in accordance with Article 145 and any rules adopted pursuant to Article 146;
- (b) the traceability of the kept terrestrial animals in question and the link between those animals and the electronic animal health certificate is ensured;
- (c) the competent authorities of the Member States of origin, passage and destination are able to have access to the electronic documents at all times during the transport.

Article 151

Self-declaration by operators for movements to other Member States

1 Operators at the place of origin shall issue a self-declaration document for movements of kept terrestrial animals from their place of origin in one Member State to their place of destination in another Member State, and shall ensure that it accompanies such animals, where

they are not required to be accompanied by an animal health certificate as provided for in Article 143(1) and (2).

2 The self-declaration document provided for in paragraph 1 shall contain the following information concerning the kept terrestrial animals in question:

- a their place of origin, their place of destination and, when relevant, any places of assembly or rest;
- b the means of transport and the transporter;
- c a description of the kept terrestrial animals, their species, category and quantity;
- d identification and registration where required in accordance with Articles 112, 113, 114 and 115, point (a) of Article 117 and any rules adopted pursuant to Articles 118 and 120;
- e the information needed to demonstrate that the kept terrestrial animals fulfil the animal health requirements for movements provided for in Sections 1 to 6 (Articles 124 to 142).

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

- a detailed rules on the content of the self-declaration document provided for in paragraph 2 of this Article for different species and categories of animals;
- b information to be contained in the self-declaration document in addition to that provided for in paragraph 2 of this Article.

4 The Commission may, by means of implementing acts, lay down rules for the model forms of the self-declaration document provided for in paragraph 2 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

Section 8

Notification of movements of kept terrestrial animals to other Member States

Article 152

Obligation of operators concerning the notification of movements of kept terrestrial animals to other Member States

Operators other than transporters shall notify the competent authority in their Member State of origin in advance of intended movements of kept terrestrial animals from that Member State to another Member State where:

- (a) the animals must be accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Articles 149 and 150 and any rules adopted pursuant to Article 149(4);
- (b) the animals must be accompanied by an animal health certificate for kept terrestrial animals where they are being moved from a restricted zone and are subject to disease control measures as referred to in Article 143(2);
- (c) the animals are granted a derogation from the animal health certification requirement provided for in point (a) of Article 144(1) or are subject to special rules as provided for in point (b) of Article 144(1);

- (d) notification is required in accordance with delegated acts adopted pursuant to Article 154(1).

For the purposes of the first paragraph of this Article, operators shall provide the competent authority of their Member State of origin with all the necessary information to enable it to notify the movements of the kept terrestrial animals to the competent authority of the Member State of destination in accordance with Article 153(1).

Article 153

Responsibility of the competent authority to notify movements to other Member States

1 The competent authority of the Member State of origin shall notify the competent authority of the Member State of destination of movements of kept terrestrial animals as referred to in Article 152.

2 The notification referred to in paragraph 1 shall be carried out prior to the movement in question and, whenever possible, through Traces.

3 Member States shall designate regions for the management of notifications of movements as provided for in paragraph 1.

4 By way of derogation from paragraph 1, the competent authority of the Member State of origin may authorise the operator concerned to notify, partially or completely, movements of kept terrestrial animals through Traces to the competent authority of the Member State of destination.

Article 154

Delegation of power and implementing acts for the notification of movements by operators and by the competent authority

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

- a the requirement for advance notification by operators, in accordance with Article 152, of movements between Member States of kept terrestrial animals of species or categories other than those referred to in points (a) and (b) of that Article, where traceability of such movements of those species or categories is necessary in order to ensure compliance with the animal health requirements for movements laid down in Sections 1 to 6 (Articles 124 to 142);
 - b the information needed in order to notify movements of kept terrestrial animals as provided for in Articles 152 and 153;
 - c the emergency procedures for the notification of movements of kept terrestrial animals in the event of power cuts and other disturbances of Traces;
 - d the requirements for the designation of regions by Member States for the management of notifications of movements, as provided for in Article 153(3).
- 2 The Commission may, by means of implementing acts, lay down rules concerning:
- a the details concerning notifications of movements of kept terrestrial animals by:
 - (i) operators to the competent authority of their Member State of origin in accordance with Article 152;

- (ii) the competent authority of the Member State of origin to the Member State of destination in accordance with Article 153;
- b the deadlines for:
 - (i) the provision by the operator of the necessary information referred to in Article 152 to the competent authority of the Member State of origin;
 - (ii) the notification of movements of kept terrestrial animals by the competent authority of the Member State of origin as referred to in Article 153(1).

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

CHAPTER 4

Movements of wild terrestrial animals

Article 155

Wild terrestrial animals

- 1 Operators shall only move wild animals from a habitat in one Member State to a habitat or an establishment in another Member State where:
 - a the movements of the wild animals in question from their habitat are carried out in such a way that they do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1) or emerging diseases en route or at the place of destination;
 - b the wild animals do not come from a habitat in a restricted zone which is subject to movement restrictions concerning the animal species to which they belong due to the occurrence of a listed disease as referred to in point (d) of Article 9(1) or of an emerging disease, as provided for in Article 70(2) and in any rules adopted pursuant to point (b) of Article 70(3), Article 71(3) and Article 83(3) or the emergency measures provided for in Articles 257 and 258 and any rules adopted pursuant to Article 259, unless derogations have been granted in accordance with those rules;
 - c the wild animals are accompanied by an animal health certificate or other documents where animal health certification is necessary in order to ensure compliance with the animal health requirements for movements provided for in points (a) and (b) of this paragraph and the rules adopted pursuant to points (c) and (d) of Article 156(1);
 - d the movements are notified by the competent authority of the Member State of origin to the competent authority of the Member State of destination, where animal health certification is required by the rules adopted pursuant to point (c) of Article 156(1); and
 - e the competent authority of the Member State of origin and the competent authority of the Member State of destination have agreed to such movement.
- 2 When animal health certification is required by the rules adopted pursuant to point (c) of Article 156(1), the requirements provided for in Articles 145 and 148, Article 149(1), (2) and (3) and Article 150, and in the rules adopted pursuant to Articles 146 and 147 and Article 149(4) shall apply to movements of wild terrestrial animals.
- 3 When notification of movements is required in accordance with point (d) of paragraph 1 of this Article, the requirements provided for in Articles 152 and 153 and in the delegated acts adopted pursuant to Article 154(1) shall apply to movements of wild terrestrial animals.

Article 156

Empowerments concerning the movement of wild terrestrial animals

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

- a the animal health requirements for movements of wild terrestrial animals provided for in points (a) and (b) of Article 155(1);
- b the animal health requirements for the introduction of wild terrestrial animals when they are moved from the wild into establishments;
- c the types of movements of wild terrestrial animals for which, or the situations in which, an animal health certificate or other document is required to accompany such movements, and the requirements concerning the contents of such certificates or other documents;
- d the notification by the competent authority of the Member State of origin to the competent authority of the Member State of destination in the case of movements of wild terrestrial animals between Member States, and the information to be included in such notification.

2 The Commission may, by means of implementing acts, lay down rules specifying the requirements provided for in Article 155 and in the delegated acts adopted pursuant to paragraph 1 of this Article, concerning:

- a model forms of animal health certificates and other documents which are required to accompany movements of wild terrestrial animals, when provided for in delegated acts adopted pursuant to point (c) of paragraph 1 of this Article;
- b the details of the notification to be given by the competent authority of the Member State of origin and the deadlines for such notifications, when provided for in rules adopted pursuant to point (d) of paragraph 1 of this Article.

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

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.

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).

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);

Status: This is the original version (as it was originally adopted).

- 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.

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:

- 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, 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).

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:

- 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.

CHAPTER 6

Production, processing and distribution within the Union of products of animal origin

Article 166

General animal health obligations for operators and delegated acts

1 Operators shall take appropriate preventive measures to ensure that, during all stages of the production, processing and distribution of products of animal origin in the Union, such products do not cause the spread of:

- a listed diseases as referred to in point (d) of Article 9(1), taking into account the health status of the place of production, processing or destination;
- b emerging diseases.

2 Operators shall ensure that products of animal origin do not come from establishments or food businesses, or are not obtained from animals which come from establishments, that are subject to:

- a emergency measures as provided for in Articles 257 and 258 or any rules adopted pursuant to Article 259, unless derogations from the requirement provided for in paragraph 1 of this Article are provided for in rules adopted pursuant to Article 259;
- b movement restrictions applicable to kept terrestrial animals and products of animal origin, as provided for in point (c) of Article 32(1), point (e) of Article 55(1), Article 56, point (a) of Article 61(1), Article 62(1), point (c) of Article 65(1), point (b) of Article 70(1), point (a) of Article 74(1), point (b) of Article 76(2), Article 76(3), Article 79, Article 81 and Article 82(2) and (3) and in the rules adopted pursuant to Article 55(2), Articles 63 and 67, Article 70(3), Article 71(3), Article 74(4), Article 76(5) and Article 83(2), unless derogations from those movement restrictions have been provided for in those rules.

3 The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed requirements supplementing those referred to:

- a in paragraph 1 of this Article on preventive measures, including risk-mitigation measures, and
- b in paragraph 2 of this Article in relation to restrictions on movements of products of animal origin.

4 When adopting the delegated acts referred to in paragraph 3, the Commission shall base those acts on:

- a the listed disease in question, as referred to in point (d) of Article 9(1), and species concerned by it and
- b the risks involved.

Article 167

Operators' obligations with regard to animal health certificates and delegated acts

1 Operators shall only move the following products of animal origin within a Member State or to another Member State where the products in question are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with paragraph 3:

- a products of animal origin that:
 - (i) are allowed to be moved from a restricted zone subject to emergency measures as provided for in rules adopted pursuant to Article 259;
 - (ii) originate from animals of species subject to those emergency measures;
- b products of animal origin that:
 - (i) are allowed to be moved from a restricted zone subject to disease control measures in accordance with Article 32(1), point (f)(ii) of Article 55(1), Article 56, point (a) of Article 61(1), Article 62(1), Article 64, point (c) of Article 65(1), point (b) of Article 70(1), point (a) of Article 74(1) and Articles 79 and 80 and any rules adopted pursuant to Article 55(2), Articles 63 and 67 and Articles 71(3), 74(4) and 83(2),
 - (ii) originate from animals of species subject to those disease control measures.

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

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

3 The competent authority shall, upon request by the operator concerned, issue an animal health certificate for movements of products of animal origin as referred to in paragraph 1, provided that the relevant requirements referred to in this Article have been complied with.

4 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 movements of products of animal origin as referred to in paragraph 1 of this Article.

5 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 and the conditions for such derogations, in respect of movements of products of animal origin which do not pose a significant risk for the spread of diseases due to:

- a the types of products of animal origin concerned;
- b the risk-mitigation measures applied to the products of animal origin, thereby reducing the risks of the spread of diseases;
- c the intended use of the products of animal origin;
- d the place of destination of the products of animal origin.

Article 168

Content of animal health certificates and delegated and implementing acts

1 The animal health certificate for products of animal origin provided for in Article 167(1) shall contain at least the following information:

- a the establishment or place of origin and the establishment or place of destination;
- b a description of the products of animal origin concerned;
- c the quantity of the products of animal origin;
- d the identification of the products of animal origin, when required by point (h) of Article 65(1) or by any rules adopted pursuant to point (a) of the second paragraph of Article 67;
- e the information needed to demonstrate that the products of animal origin fulfil the movement restriction requirements provided for in Article 166(2) and in any rules adopted pursuant to Article 166(3).

2 The animal health certificate referred to in paragraph 1 may include other information required under other Union legislation.

3 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the information to be contained in the animal health certificate provided for in paragraph 1 of this Article.

4 The Commission may, by means of implementing acts, lay down rules concerning model forms of animal health certificates for products of animal origin referred to in paragraph

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

Article 169

Notification of movements of products of animal origin to other Member States

- 1 Operators shall:
 - a inform the competent authority in their Member State of origin in advance of intended movements of products of animal origin when the consignments in question are required to be accompanied by an animal health certificate in accordance with Article 167(1);
 - b provide all necessary information to enable the competent authority of the Member State of origin to notify the movement in question 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, prior to the movement and whenever possible through Traces, notify the competent authority of the Member State of destination of movements of products of animal origin 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 movements of products of animal origin by operators.
- 5 The Commission shall adopt delegated acts in accordance with Article 264 concerning:
 - a the information needed for the notification of movements of products of animal origin as provided for in paragraph 1 of this Article;
 - b the emergency procedures for the notification of movements of products of animal origin 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 information to be provided by operators to the competent authority of their Member State of origin concerning movements of products of animal origin in accordance with paragraph 1;
 - b notification of movements of products of animal origin to be given by the competent authority of the Member State of origin to the Member State of destination in accordance with paragraph 2;
 - c the deadlines for:
 - (i) provision of the information referred to in paragraph 1 by the operator concerned to the competent authority of the Member State of origin;
 - (ii) notification of movements of products of animal origin to be given by the competent authority of the Member State of origin as referred to in paragraph 2.

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

CHAPTER 7

Scope of national measures

Article 170

National measures concerning disease control and movements of animals and germinal products

1 Member States shall remain free to take national measures to control listed diseases as referred to in points (d) and (e) of Article 9(1) with regard to movements of terrestrial animals and germinal products thereof within their own territories.

2 Those national measures shall:

- a take account of the rules on movements of animals and germinal products laid down in Chapters 3 (Articles 124 to 154), 4 (Articles 155 and 156) and 5 (Articles 157 to 165), and shall not be inconsistent with those rules;
- b not hinder the movement of animals and products between Member States;
- c not exceed the limits of what is appropriate and necessary in order to prevent the introduction and spread of the listed diseases referred to in points (d) and (e) of Article 9(1).

Article 171

National measures designed to limit the impact of diseases other than listed diseases

Where a disease other than a listed disease constitutes a significant risk for the health of kept terrestrial animals in a Member State, the Member State concerned may take national measures to control that disease and may restrict movements of kept terrestrial animals and germinal products, provided those measures do not:

- (a) hinder the movement of animals and products between Member States;
- (b) exceed the limits of what is appropriate and necessary in order to control that disease.

TITLE II

**AQUATIC ANIMALS AND PRODUCTS OF
ANIMAL ORIGIN FROM AQUATIC ANIMALS**

CHAPTER 1

Registration, approval, record-keeping and registers

Section 1

Registration of aquaculture establishments

Article 172

Obligation of operators to register aquaculture establishments

1 Operators of aquaculture establishments shall, in order for their establishments to be registered in accordance with Article 173, before they commence such activities:

- a inform the competent authority of any aquaculture 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 species, categories and quantities (numbers, volume or weight) of aquaculture animals which they intend to keep on the aquaculture establishment and the capacity of the aquaculture establishment;
 - (iv) the type of aquaculture 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 aquaculture establishments referred to in paragraph 1 shall inform the competent authority in advance of:

- a any significant changes in the aquaculture establishment in question concerning the matters referred to in point (b) of paragraph 1;
- b any cessation of activity by the operator or aquaculture establishment concerned.

3 Aquaculture establishments which are subject to approval in accordance with Article 176(1) and Article 177 shall not be required to provide the information referred to in paragraph 1 of this Article.

4 An operator may apply for registration as provided for in paragraph 1 to cover a group of aquaculture establishments, provided that they fulfil either of the following conditions:

- a they are located in an epidemiologically linked area and all operators in that area operate under a common biosecurity system;

- b they are under the responsibility of the same operator and operate under a common biosecurity system, and the aquaculture animals of the establishments concerned form part of a single epidemiological unit.

Where an application for registration covers a group of establishments, the rules laid down in paragraphs 1 to 3 of this Article and in point (b) of the first paragraph of Article 173, and the rules adopted pursuant to Article 175 which are applicable to a single aquaculture establishment, shall be applicable to the group of aquaculture establishments as a whole.

Article 173

Obligations of the competent authority concerning the registration of aquaculture establishments

A competent authority shall register:

- (a) aquaculture establishments in the register of aquaculture establishments provided for in Article 185(1), where the operator concerned has provided the information required in accordance with Article 172(1);
- (b) groups of aquaculture establishment in that register, provided that the criteria laid down in Article 172(4) are complied with.

The competent authority shall assign each establishment or group of establishments as referred to in this Article with a unique registration number.

Article 174

Derogations from the obligation of operators to register aquaculture establishments

By way of derogation from Article 172(1), Member States may exempt from the registration requirement certain aquaculture establishments posing an insignificant risk, as provided for in an implementing act adopted in accordance with Article 175.

Article 175

Implementing powers concerning derogations from the obligation to register aquaculture 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 aquaculture establishments as provided for in Article 172(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 aquaculture establishments that may be exempted by Member States from the registration requirement in accordance with Article 174, based on:

- a the species, categories and quantity (number, volume or weight) of aquaculture animals on the aquaculture establishment in question and the capacity of that establishment;
- b the movements of aquaculture animals into and out of the aquaculture 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).

Section 2

Approval of certain types of aquaculture establishments

Article 176

Approval of certain aquaculture establishments and delegated acts

1 Operators of the following types of aquaculture establishments shall apply to the competent authority for approval in accordance with Article 180(1):

- a aquaculture establishments where aquaculture animals are kept with a view to their being moved therefrom, either alive or as products of aquaculture animal origin;
- b other aquaculture establishments which pose a significant risk due to:
 - (i) the species, categories and number of aquaculture animals kept there;
 - (ii) the type of aquaculture establishment concerned;
 - (iii) movements of aquaculture animals into and out of the aquaculture establishment concerned.

2 By way of derogation from paragraph 1, Member States may exempt from the obligation to apply for approval operators of the following types of establishment:

- a aquaculture establishments producing a small quantity of aquaculture animals for supply for human consumption either:
 - (i) to the final consumer directly; or
 - (ii) to local retail establishments directly supplying the final consumer;
- b ponds and other installations where the population of aquatic animals is maintained only for recreational fishing purposes, by restocking with aquaculture animals which are confined and unable to escape;
- c aquaculture establishments keeping aquaculture animals for ornamental purposes in closed facilities,

provided that the establishment in question does not pose a significant risk.

3 Unless a derogation has been granted under paragraph 4 of this Article, operators shall not commence activity at an aquaculture establishment as referred to in paragraph 1 of this Article until that establishment has been approved in accordance with Article 181(1), and shall cease such activity at an aquaculture establishment referred to in paragraph 1 of this Article where:

- a the competent authority withdraws or suspends its approval in accordance with Article 184(2); or
- b in the event of conditional approval, granted in accordance with Article 183(3), the aquaculture establishment concerned fails to comply with the outstanding requirements referred to in Article 183(4) and does not obtain a final approval in accordance with Article 183(3).

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

- a derogations from the requirement for operators to apply to the competent authority for approval of the types of aquaculture establishments referred to in point (a) of paragraph 1, concerning types of establishments other than those specified in points (a)(i) and (ii) of paragraph 2, where those establishments do not pose a significant risk;
- b the types of aquaculture establishments which must be approved in accordance with point (b) of paragraph 1.

5 When adopting delegated acts as provided for in paragraph 4, the Commission shall base those acts on the following criteria:

- a the species and categories of aquaculture animals kept in an aquaculture establishment;
- b the type of aquaculture establishment and the type of production; and
- c typical movement patterns of the type of aquaculture establishment concerned and of the species or category of aquaculture animals concerned.

6 An operator may apply for approval of a group of aquaculture establishments, provided that the requirements provided for in points (a) and (b) of the first paragraph of Article 177 are complied with.

Article 177

Approval by the competent authority of groups of aquaculture establishments

The competent authority may grant approval as provided for in Article 181(1) covering a group of aquaculture establishments, provided that the aquaculture establishments in question comply with either of the following conditions:

- (a) they are located in an epidemiologically linked area and all operators in that area operate under a common biosecurity system; however, any on-shore or off-shore establishment for the reception, conditioning, washing, cleaning, grading, wrapping and packaging of live bivalve molluscs intended for human consumption (so-called 'dispatch centres'), establishment with tanks fed by clean seawater in which live bivalve molluscs are placed for the time necessary to reduce contamination to make them fit for human consumption (so-called 'purification centres') and similar establishments located inside such an epidemiologically linked area must be approved individually;
- (b) they are under the responsibility of the same operator; and
 - (i) operate under a common biosecurity system; and
 - (ii) the aquaculture animals of the establishments concerned form part of the same epidemiological unit.

When a single approval is granted for a group of aquaculture establishments, the rules laid down in Article 178 and Articles 180 to 184 and the rules adopted pursuant to Articles 180(2) and 181(2), which are applicable to a single aquaculture establishment, shall be applicable to the whole group of aquaculture establishments.

Status: This is the original version (as it was originally adopted).

Article 178

Approval of status of confined aquaculture establishments

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

- (a) apply to the competent authority for approval in accordance with Article 180(1);
- (b) move aquaculture animals to or from their establishment in accordance with the requirements provided for in Article 203(1) and any delegated acts adopted in accordance with Article 203(2) only after their establishment has obtained an approval of that status from the competent authority in accordance with Article 181 or 183.

Article 179

Approval of disease control aquatic food establishments

Operators of disease control aquatic food establishments shall:

- (a) ensure that the necessary approval in accordance with Article 4 of Regulation (EC) No 853/2004 of the European Parliament and of the Council⁽¹⁾ has been obtained; and
- (b) apply to the competent authority, in accordance with Article 180(1), for approval to slaughter or process aquatic animals for disease control purposes in accordance with point (b) of Article 61(1), Article 62 and Articles 68(1), 79 and 80 and the rules adopted pursuant to Article 63 and Articles 70(3) and 71(3).

Article 180

Obligation of operators to provide information with a view to obtaining approval

1 Operators shall, for the purposes of their application for approval of their establishment as provided for in Article 176(1), Article 177, point (a) of Article 178 and Article 179, 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 species, categories and quantities (numbers, volume or weight) of aquaculture animals relevant for the approval which are kept on the establishment;
- d the type of aquaculture establishment;
- e in cases of approval of a group of aquaculture establishments, details showing that the group in question complies with the conditions laid down in Article 177;
- f other aspects of the mode of operation of the aquaculture establishment in question which are relevant for determining the risk, posed by it;
- g the water supply to, and discharge of water from, the establishment;
- h the establishment's biosecurity measures.

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

- a any changes in the establishments concerning the matters referred to in 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, including the time-limits by which such information is to be provided.

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

Article 181

Granting of, and conditions for, approval and delegated acts

1 The competent authority shall only grant approvals of aquaculture establishments as referred to in Article 176(1) and point (a) of Article 178, groups of aquaculture establishments as referred to in Article 177 and disease control aquatic food establishments as referred to in Article 179, where such establishments:

- a comply with the following requirements, where appropriate, in relation to:
 - (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(6);
 - (ii) surveillance requirements as provided for in Article 24, where relevant for the type of establishment concerned and the risk involved, in Article 25;
 - (iii) record-keeping as provided for in Articles 186 to 188 and any rules adopted pursuant to Articles 189 and 190;
- 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 species, categories and quantity (numbers, volume or weight) of aquatic animals 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 in place a system which enables the operator concerned to demonstrate to the competent authority that the requirements laid down in points (a), (b) and (c) are fulfilled.

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.

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 aquaculture or aquatic animals relevant for the approval;
- c the type of production concerned;

- d typical movement patterns of the type of aquaculture establishment and species and categories of animals kept in those establishments.

Article 182

Scope of the approval of establishments

The competent authority shall expressly specify in the approval of an aquaculture establishment or a disease control aquatic food establishment granted pursuant to Article 181(1) following an application made in accordance with Article 176, Article 177, point (a) of Article 178 or Article 179:

- (a) for which of the types of aquaculture establishments referred to in Article 176(1) and point (a) of Article 178, groups of aquaculture establishments referred to in Article 177 and disease control aquatic food establishments referred to in Article 179, and in any rules adopted pursuant to point (b) of Article 176(4), the approval applies;
- (b) for which species and categories of aquaculture animals the approval applies.

Article 183

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 176(1) and Articles 178 and 179.

2 Upon receipt of an application for approval from an operator in accordance with Article 176(1), Article 178 or Article 179, the competent authority shall make an on-site visit.

3 Provided that the requirements referred to in Article 181 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 181, 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 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 from 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 181(1) and the rules adopted pursuant to Article 181(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 184

Review, suspension and withdrawal of approvals by the competent authority

1 The competent authority shall keep approvals of establishments granted in accordance with Article 181(1) 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 181(1) and the rules adopted pursuant to Article 181(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.

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

Register of aquaculture establishments and disease control aquatic food establishments

Article 185

Register of aquaculture establishments and disease control aquatic food establishments

1 Each competent authority shall establish and keep up to date a register of:

- a all aquaculture establishments registered in accordance with Article 173;
- b all aquaculture establishments approved in accordance with Article 181(1);
- c all disease control aquatic food establishments approved in accordance with Article 181(1).

2 The register of aquaculture establishments provided for in paragraph 1 shall contain the following information:

- a the name and address of the operator and the registration number of the establishment in question;
- b the location of the aquaculture establishment or, as the case may be, of the group of aquaculture establishments concerned;
- c the type of production at the establishment;
- d the water supply to, and discharge from, the establishment, when relevant;
- e the species of aquaculture animals kept at the establishment;
- f up-to-date information on the health status of the registered aquaculture establishment, or, as the case may be, of the group of establishments, as regards the listed diseases referred to in point (d) of Article 9(1).

Status: This is the original version (as it was originally adopted).

3 For establishments approved in accordance with Article 181(1), the competent authority shall make publicly available by electronic means at least the information referred to in points (a), (c), (e) and (f) of paragraph 2 of this Article, subject to data protection requirements.

4 Where appropriate and relevant, a competent authority may combine the registration provided for in paragraph 1 with registration for other purposes.

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

- a the relevant detailed information to be included in the register of aquaculture establishments provided for in paragraph 1 of this Article;
- b the public availability of that register.

Section 4

Record-keeping and traceability

Article 186

Record-keeping obligations of operators of aquaculture establishments

1 Operators of aquaculture establishments subject to the requirement of registration in accordance with Article 173, or approval in accordance with Article 181(1), shall keep and maintain records containing at least the following information:

- a the species, categories and quantities (numbers, volume or weight) of aquaculture animals on their establishment;
- b movements of aquaculture animals and products of animal origin obtained from those 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 animal health certificates, in paper or electronic form, required to accompany movements of aquaculture animals arriving at the aquaculture establishment in accordance with Article 208 and the rules adopted pursuant to points (a) and (c) of Article 211(1) and Article 213(2);
- d mortality in each epidemiological unit and other disease problems at the aquaculture establishment as relevant for the type of production;
- e biosecurity measures, surveillance, treatments, test results and other relevant information as appropriate for:
 - (i) the species and categories of the aquaculture animals on the establishment;
 - (ii) the type of production at the aquaculture establishment;
 - (iii) the type and size of the aquaculture 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 Aquaculture 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 points (c), (d) and (e) of paragraph 1, provided that traceability is ensured.

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

- a keep them in such a way that the tracing of the place of origin and destination of aquatic animals can be guaranteed;
- b make them available to the competent authority on request;
- c retain them for a minimum period to be prescribed by the competent authority, which may not be less than three years.

By way of derogation from the requirement that the records are to be kept on their establishment concerned, as set out in the first subparagraph, when it is physically not possible to keep the records on that establishment, they shall be kept in the office from which the business is administered.

Article 187

Record-keeping obligations of disease control aquatic food establishments

1 Operators of disease control aquatic food establishments subject to approval in accordance with Article 179 shall keep and maintain records of:

- a all movements into and from their establishment of aquaculture animals and products of animal origin obtained from such animals;
- b discharge of water and relevant biosecurity measures.

2 Operators of disease control aquatic food establishments shall:

- a keep the records provided for in paragraph 1 on their establishment and shall make them 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.

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

Article 188

Record-keeping obligations of transporters

1 Transporters of aquatic animals intended for aquaculture establishments or to be released into the wild shall keep and maintain records in relation to:

- a the species, categories and quantities (numbers, volume or weight) of aquatic animals transported by them;
- b mortality rates of the aquaculture animals and wild aquatic animals in question during transport, in so far as is practicable for the type of transport and the species of aquaculture animals and wild aquatic animals transported;
- c aquaculture establishments and disease control aquatic food establishments visited by the means of transport;
- d any exchange of water that took place during transport, specifying the sources of new water and sites of release of water;
- e the cleaning and disinfection of the means of transport.

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, provided that traceability is ensured.

3 Transporters shall keep the records provided for in paragraph 1:

- 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 189

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 186, 187 and 188, as regards information to be recorded by operators in addition to that provided for in Articles 186(1), 187(1) and 188(1).

2 The Commission shall take the following matters into account when adopting the delegated acts provided for in paragraph 1:

- a the risks posed by each type of aquaculture establishment or transport;
- b the species and categories of aquatic animals kept on the aquaculture establishment concerned, or transported to or from that establishment;
- c the type of production of the establishment;
- d typical movement patterns for the type of aquaculture establishment or disease control aquatic food establishment;
- e the numbers, volume or weight of aquatic animals kept on the establishment or transported to or from it.

Article 190

Implementing powers concerning exemptions from the record-keeping requirements

The Commission may, by means of implementing acts, lay down rules concerning the types of aquaculture establishments and operators that may be exempted by Member States from the record-keeping requirements provided for in Articles 186 and 188, as regards:

- (a) operators of certain categories of aquaculture establishments and transporters;
- (b) aquaculture establishments keeping, or transporters transporting, respectively, a small number of aquaculture animals or a small number of aquatic animals;
- (c) certain species and categories of aquatic animals.

When adopting those implementing acts, the Commission shall base those acts on the criteria provided for in Article 189(2).

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

CHAPTER 2

Movements within the Union of aquatic animals

Section 1

General requirements for movements

Article 191

General requirements for movements of aquatic animals

1 Operators shall take appropriate measures to ensure that the movement of aquatic animals does not jeopardise the health status 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 aquatic animals into an aquaculture establishment or for human consumption purposes, or release them into the wild, if the animals in question fulfil the following conditions:

- a they come, except in the case of wild aquatic animals, from establishments that have been:
 - (i) registered by the competent authority in accordance with Article 173,
 - (ii) approved by that competent authority in accordance with Articles 181 and 182, when required by Article 176(1), Article 177 or Article 178, or
 - (iii) granted a derogation from the registration requirement laid down in Article 173.
- b they are not subject to:
 - (i) movement restrictions affecting the species and categories concerned in accordance with the rules laid down in Article 55(1), Article 56, Article 61(1), Articles 62, 64 and 65, point (b) of Article 70(1), Article 74(1), Article 79 and Article 81 and the rules adopted pursuant to Article 55(2), Articles 63 and 67 and Articles 70(3), 71(3), 74(4) and 83(2); or
 - (ii) the emergency measures laid down in Articles 257 and 258 and the rules adopted pursuant to Article 259.

However, operators may move those aquatic animals where derogations from the movement restrictions for such movements or release are provided for in Title II of Part III (Articles 53–83) or derogations from emergency measures are provided for in rules adopted pursuant to Article 259.

3 Operators shall take all necessary measures to ensure that aquatic animals, after leaving their place of origin, are consigned directly to the final place of destination.

Article 192

Disease prevention measures in relation to transport

1 Operators shall take the appropriate and necessary disease prevention measures to ensure that:

- a the health status of aquatic animals is not jeopardised during transport;
- b transport operations of aquatic animals do not cause the potential spread of listed diseases as referred to in point (d) of Article 9(1) to humans or animals en route, and at places of destination;
- c cleaning and disinfection of equipment and means of transport and other adequate biosecurity measures are taken, as appropriate to the risks involved with the transport operations concerned;
- d any exchanges of water and discharges of water during the transport of aquatic animals intended for aquaculture or release into the wild are carried out at places and under conditions which do not jeopardise the health status with regard to the listed diseases referred to in point (d) of Article 9(1) of:
 - (i) the aquatic animals being transported;
 - (ii) any aquatic animals en route to the place of destination;
 - (iii) aquatic animals at the place of destination.

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

- a the conditions and requirements for cleaning and disinfection of equipment and means of transport in accordance with point (c) of paragraph 1 of this Article and the use of biocidal products for such purposes;
- b other appropriate biosecurity measures during transport as provided for in point (c) of paragraph 1 of this Article;
- c water exchanges and discharges of water during transport as provided for in point (d) of paragraph 1 of this Article.

Article 193

Change of intended use

1 Aquatic animals which are moved for destruction or slaughter in accordance with the following measures shall not be used for any other purpose:

- a any of the disease control measures provided for in point (c) of Article 32(1) and Article 55(1), Articles 56, 61, 62, 64, 65 and 70, Articles 74(1) and (2) and Articles 79, 80, 81 and 82 and in the rules adopted pursuant to Article 55(2), Articles 63 and 67, Articles 70(3), 71(3) and 74(4), and Article 83(2);
- b emergency measures as provided for in Articles 257 and 258 and in rules adopted pursuant to Article 259.

2 Aquatic animals moved for human consumption, aquaculture, release into the wild or any other purpose, shall not be used for any purpose other than the intended one.

3 By way of derogation from paragraph 2, the competent authority of the place of destination may authorise a change of use of aquatic animals for a purpose other than that originally intended, provided that the new use does not pose a higher risk to the health status of the aquatic animals at the place of destination than the originally intended use.

Article 194

Obligations of operators at the place of destination

1 Operators of aquaculture establishments and disease control aquatic food establishments receiving aquatic animals and operators receiving aquatic animals for release into the wild shall, before the aquatic animals are unloaded:

- a check that, where required, one of the following documents is present:
 - (i) the animal health certificates provided for in Article 208(1), Article 209 and Article 223(1) and in the rules adopted pursuant to Articles 189, 211 and 213;
 - (ii) the self-declaration documents provided for in Article 218(1) and in the rules adopted pursuant to Article 218(3) and (4);
- b inform the competent authority of the place of destination, after checking the aquatic animals received, of any irregularity with regard to:
 - (i) the aquatic animals received;
 - (ii) the documents referred to in point (a)(i) and (ii).

2 In the event of any irregularity as referred to in point (b) of paragraph 1, the operator shall isolate the aquatic animals concerned by that irregularity until the competent authority of the place of destination has taken a decision regarding them.

Article 195

General requirements in respect of movements of aquaculture animals passing through Member States but intended for export from the Union to third countries or territories

Operators shall ensure that aquaculture animals intended for export to a third country or territory and passing through the territory of another Member State fulfil the requirements laid down in Articles 191, 192 and 193.

Section 2

Aquatic animals intended for aquaculture establishments or release into the wild

Article 196

Abnormal mortalities or other serious disease symptoms

1 Operators shall only move aquatic animals from an aquaculture establishment or from the wild to another aquaculture establishment, or release them into the wild, if the animals in question:

- a show no disease symptoms; and

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- b originate from an aquaculture establishment or environment where there are no abnormal mortalities with an undetermined cause.

2 By way of derogation from paragraph 1, the competent authority may, on the basis of an evaluation of the risks involved, authorise the movement or release of aquatic animals as referred to in that paragraph, provided that the animals in question originate from a part of the aquaculture establishment or from the wild that is independent of the epidemiological unit where the abnormal mortalities or other disease symptoms have occurred.

If the movement or release referred to in this paragraph is to be made to another Member State, it shall only be authorised by the competent authority if the competent authorities of the Member State of destination and, where relevant, of the Member States of passage have given their consent to such movement or release.

Article 197

Movements of aquaculture animals intended for Member States, zones or compartments which have been declared disease-free or which are subject to an eradication programme, and delegated acts

1 Operators shall only move aquaculture animals of listed species relevant for one or more of the listed diseases referred to in points (b) or (c) of Article 9(1) to an aquaculture establishment, or for release into the wild, in a Member State, zone or compartment which has been declared free of those listed diseases in accordance with Article 36(4) or 37(4), if the animals in question originate from a Member State, or a zone or compartment thereof, which has been declared free of those diseases.

2 Operators shall only move aquaculture animals of listed species relevant for one or more of the listed diseases referred to in points (b) or (c) of Article 9(1) to an aquaculture establishment, or for release into the wild, in a Member State, zone or compartment subject to an eradication programme for one or more of those listed diseases as provided for in Article 31(1) or (2), if the animals in question originate from a Member State, or a zone or compartment thereof, which has been declared free of those listed diseases.

3 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning derogations from the movement or release requirements laid down in paragraphs 1 and 2 of this Article which do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1) on account of:

- a the species, categories, and life stage of the aquaculture animals concerned;
- b the type of establishment of origin and of destination;
- c the intended use of the aquaculture animals;
- d the place of destination of the aquaculture animals;
- e treatments, processing methods and other special risk-mitigation measures applied at the place of origin or destination.

Article 198

Derogations by Member States concerning the obligation of operators for movement of aquaculture animals between Member States, zones or compartments which are subject to an eradication programme

By way of derogation from Article 197(1) and (2), Member States may authorise operators to move aquaculture animals into a zone or compartment for which an eradication programme has been established in accordance with Article 31(1) and (2) as regards the listed diseases referred to in points (b) and (c) of Article 9(1), from another zone or compartment for which such a programme has also been established for the same listed diseases, provided that such movement will not jeopardise the health status of the Member State, zone or compartment of destination.

If such movements are to be made to another Member State, the competent authority shall only authorise them if the competent authorities of the Member State of destination and, where relevant, of the Member States of passage, have given their consent to them.

Article 199

Member States' measures concerning the release of aquatic animals into the wild

Member States may require that aquatic animals may be released into the wild only if they originate from a Member State, or a zone or compartment thereof, which has been declared disease-free in accordance with Article 36(1) or Article 37(1) as regards one or more of the listed diseases referred to in points (b) and (c) of Article 9(1) for which the species of aquatic animals to be moved is a listed species, regardless of the health status of the area where those aquatic animals are to be released.

Article 200

Movements of wild aquatic animals intended for Member States, or zones or compartments thereof, which have been declared disease-free or which are subject to an eradication programme, and delegated acts

1 Articles 196, 197 and 198 shall apply to movements of wild aquatic animals intended for an aquaculture establishment or for release into the wild.

2 Operators shall take the appropriate and necessary disease prevention measures when moving wild aquatic animals between habitats to ensure that:

- a such movements do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1) to aquatic animals at the place of destination; and
- b risk-mitigation or other adequate biosecurity measures are in place where necessary to ensure compliance with point (a).

3 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the disease prevention and risk-mitigation measures to be taken by operators as provided for in paragraph 2 of this Article. Pending the adoption of such delegated acts, the competent authority of the place of destination may decide on such measures.

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Section 3

Aquatic animals intended for human consumption

Article 201

Movements of live aquaculture animals intended for human consumption in Member States, or in zones or compartments thereof, which have been declared disease-free or which are subject to an eradication programme, and delegated acts

1 Operators shall only move live aquaculture animals of listed species relevant for listed diseases as referred to in points (b) or (c) of Article 9(1) intended for human consumption to a Member State, or to a zone or compartment thereof, which has been declared disease-free in accordance with Article 36(4) or Article 37(4) or for which an eradication programme has been established in accordance with Article 31(1) or (2), as regards one or more of the listed diseases referred to in points (b) and (c) of Article 9(1), if the animals in question originate from a Member State, or a zone or compartment thereof, which has been declared disease-free in accordance with Article 36(4) or Article 37(4).

2 By way of derogation from paragraph 1 of this Article, Member States may authorise operators to introduce live aquaculture animals into a zone or compartment for which an eradication programme has been established in accordance with Article 31(1) or (2) as regards the listed diseases referred to in points (b) and (c) of Article 9(1), from another zone or compartment for which such a programme has also been established as regards the same diseases within that Member State, provided that such movement will not jeopardise the health status of the Member State or of the zone or compartment thereof.

3 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning the derogations provided for in paragraph 2 of this Article in respect of movements of live aquaculture animals which do not pose a significant risk of spreading of diseases on account of:

- a the species, categories, and live stage of the aquaculture animals concerned;
- b the methods of keeping the aquaculture animals and the type of production in the aquaculture establishments of origin and of destination;
- c the intended use of the aquaculture animals;
- d the place of destination of the aquaculture animals;
- e treatments, processing methods and other special risk-mitigation measures applied at the place of origin or the place of destination.

Article 202

Movements of live wild aquatic animals intended for Member States, or zones or compartments thereof, which have been declared disease-free or which are subject to an eradication programme, and delegated acts

1 Article 201(1) and (2) and the rules adopted pursuant to Article 201(3) shall apply to movements of live wild aquatic animals intended for human consumption and which are intended for Member States, or zones or compartments thereof, which have been declared disease-free in accordance with Articles 36(4) or 37(4) or which are subject to an eradication programme in accordance with Article 31(1) or (2), where the measures adopted pursuant thereto are necessary in order to ensure that the animals in question do not pose a significant

risk for the spread of listed diseases as referred to in point (d) of Article 9(1) to aquatic animals at the place of destination.

2 Paragraph 1 of this Article shall also apply to live aquatic animals not covered by the definition of aquaculture animals contained in Article 4(7).

3 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning movement requirements for wild aquatic animals intended for human consumption, supplementing paragraphs 1 and 2 of this Article.

Section 4

Derogations from Sections 1 to 3 (Articles 191 to 202) and additional risk-mitigation measures

Article 203

Aquatic animals intended for confined establishments for aquaculture and delegated acts

1 Operators shall only move aquatic animals to a confined establishment for aquaculture if the animals in question fulfil the following conditions:

- a they originate from another confined establishment for aquaculture;
- b they 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 of animals at the confined establishment for aquaculture of destination, except where the movement in question is authorised for scientific purposes.

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

- a detailed rules for movements of aquaculture animals to confined establishments for aquaculture in addition to those provided for in paragraph 1 of this Article;
- b specific rules for movements of aquaculture animals to confined establishments for aquaculture where the risk-mitigation measures in place guarantee that such movements do not pose a significant risk for the health of aquaculture animals within that confined establishment for aquaculture and the surrounding establishments.

Article 204

Movements of aquatic animals 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 aquatic animals into the territory of the Member State of destination, for scientific purposes, where those movements do not fulfil the requirements of Sections 1 to 3 (Articles 191 to 202), with the exception of Article 191(1) and (3) and Articles 192, 193 and 194.

2 The competent authority referred to in paragraph 1 shall only grant derogations as provided for in that paragraph under the following conditions:

- a the competent authorities of the places of destination and origin:
 - (i) have agreed on the conditions for such movements;

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- (ii) ensure that the necessary risk-mitigation measures are in place so that movements of the aquatic animals in question do not jeopardise the health status in places en route and in the places 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 the 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, the competent authorities of the Member States of passage.
- 3 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning rules for the granting of derogations by competent authorities, supplementing those provided for in paragraphs 1 and 2 of this Article.

Article 205

Other specific uses of aquatic animals, specific requirements and derogations and delegation of powers

- 1 Operators shall take the necessary preventive measures to ensure that movements of aquatic animals intended for the specific purposes or uses listed in point (a)(i) to (vi) of paragraph 2 of this Article do not pose a risk for the spread of listed diseases as referred to in point (d) of Article 9(1) to aquatic animals at the place of destination.
- 2 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:
- a specific requirement supplementing the rules laid down in Sections 1 to 3 (Articles 191 to 202) and for movements of aquatic animals for the following purposes:
 - (i) zoos, pet shops, wholesalers and garden ponds;
 - (ii) exhibitions;
 - (iii) sports fishing, including fishing baits;
 - (iv) cultural and similar events;
 - (v) commercial aquaria; or
 - (vi) health care and other similar uses.
 - b derogations from Sections 1 to 3 (Articles 191 to 202) with the exception of Article 191(1) and (3) and Articles 192, 193 and 194 for the movements of aquatic animals referred to in point (a) of this paragraph, provided that adequate biosecurity provisions are in place to ensure that those movements do not pose a significant risk to the health status of the place of destination.

Article 206

Implementing power to adopt temporary rules for movements of specific species or categories of aquatic animals

1 The Commission may, by means of implementing acts, lay down temporary rules, by way of addition or alternative to those laid down in this Chapter, for movements of specific species or categories of aquatic animals where:

- a the movement requirements provided for in Article 196, Article 197(1), Articles 198 and 199, Article 200(1) and (2), Article 201 and Articles 202(1), 203(1), 204(1) and (2) and the rules adopted pursuant to Articles 197(3), 200(3), 202(3), 203(2) and 204(3) and Article 205 do not efficiently mitigate the risks posed by the movement of those aquatic animals; or
- b a listed disease as referred to in point (d) of Article 9(1) appears to be spreading despite the movement requirements laid down in accordance with Sections 1 to 4 (Articles 191 to 207).

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 listed disease representing a risk of a highly significant impact and taking into account the matters referred to in Article 205, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure provided for in Article 266(3).

Article 207

Matters to be taken into account in the adoption of delegated and implementing acts as provided for in this Section

When establishing the rules to be laid down in the delegated and implementing acts provided for in Article 203(2), Article 204(3) and Articles 205 and 206, the Commission shall base those rules on:

- (a) the risks involved with the movements referred to in those provisions;
- (b) the health status as regards the listed diseases referred to in point (d) of Article 9(1) at the places of origin, passage and destination;
- (c) listed aquatic animal species for the listed diseases referred to in point (d) of Article 9(1);
- (d) biosecurity measures in place at the places of origin, passage and destination;
- (e) any specific conditions under which the aquaculture animals are kept;
- (f) specific movement patterns of the type of aquaculture establishment and the species or category of aquatic animals concerned;
- (g) other epidemiological factors.

Section 5

Animal health certification

Article 208

Obligation of operators to ensure that aquaculture animals are accompanied by an animal health certificate

1 Operators shall only move aquaculture animals if they are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Article 216(1), where the animals in question are of listed species for the listed diseases referred to in points (b) and (c) of Article 9(1) and are intended for introduction into a Member State, or a zone or compartment thereof, which has been declared disease-free in accordance with Articles 36(4) and 37(4) or for which an eradication programme has been established as provided for in Article 31(1) or (2) as regards one or more of the listed diseases referred to in points (b) and (c) of Article 9(1).

2 Operators shall only move aquaculture animals if they are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Article 216(1), where the animals in question are of listed species for the relevant disease(s) referred to in points (a) and (b) of Article 9(1) and are allowed to leave a restricted zone subject to disease control measures as provided for in point (f)(ii) of Article 55(1), Articles 56 and 64 or Articles 65(1), 74(1), 79 and rules adopted pursuant to Article 55(2), Articles 67 and 68, Articles 71(3), 74(4) and 83(2) and Article 259 for one or more of the listed diseases referred to in points (a) and (b) of Article 9(1).

3 Operators shall take all necessary measures to ensure that the animal health certificate accompanies the aquaculture animals from their place of origin to their final place of destination, unless specific measures are provided for in rules adopted pursuant to Article 214.

Article 209

Obligation of operators to ensure that other aquatic animals are accompanied by an animal health certificate and implementing power

1 In cases where, due to the risk involved with the movement of aquatic animals other than aquaculture animals, animal health certification is required in accordance with the rules provided for in point (a) of Article 211(1), operators shall only move those aquatic animals if the animals in question are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Article 216(1).

2 Article 208 shall also apply to aquatic animals other than aquaculture animals intended for an aquaculture establishment or release into the wild. Where the competent authority of the Member State of origin concludes that certification is not feasible due to the nature of the place of origin of the aquatic animals in question, it may authorise their movement without an animal health certificate subject to the consent of the competent authority of the place of destination.

3 This Article shall not apply to wild aquatic animals harvested or caught for direct human consumption.

Article 210

Grant of derogations by Member States in respect of national animal health certification

By way of derogation from the animal health certification requirements laid down in Articles 208 and 209, Member States may grant derogations for movements of certain consignments of aquatic animals without an animal health certificate within their territories provided that they have in place an alternative system to ensure that consignments of such animals are traceable and those consignments comply with the animal health requirements for such movements provided for in Sections 1 to 4 (Articles 191 to 207).

Article 211

Delegation of powers and implementing acts concerning animal health certification in respect of aquatic animals

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

- a the requirement for animal health certification for movements of aquatic animals other than aquaculture animals as referred to in Article 209(1), in cases where animal health certification is imperative in order to ensure that the movement in question complies with the following animal health requirements for the listed species of animals concerned:
 - (i) the requirements provided for in Sections 1 to 4 (Articles 191 to 207) and the rules adopted pursuant to those Sections;
 - (ii) disease control measures as provided for in Article 55(1), Article 56, Article 61(1), Articles 62 and 64, and Article 65(1), Article 74(1), and Articles 79 and 80 or the rules adopted pursuant to Article 55(2), Articles 63, 67 and 68, and Articles 71(3), 74(4) and 83(2);
 - (iii) emergency measures as provided for in the rules adopted pursuant to Article 259;
- b special rules for animal health certification as provided for in Articles 208 and 209 where specific risk-mitigation measures are taken by the competent authority to ensure:
 - (i) the traceability of the aquatic animals being moved;
 - (ii) that the aquatic animals being moved fulfil the animal health requirements for movements provided for in Sections 1 to 4 (Articles 191 to 207);
- c derogations from the animal health certificate requirements provided for in Articles 208 and 209 and the conditions for such derogations for movements of aquatic animals which do not pose a significant risk of the spread of diseases, on account of:
 - (i) species, the categories or live stage of the aquatic animals concerned;
 - (ii) the methods of keeping and the type of production of those species and categories of aquaculture animals;
 - (iii) the intended use of the aquatic animals; or

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(iv) the place of destination of the aquatic animals.

2 The Commission shall, by means of implementing acts, lay down rules concerning the obligation of operators, as provided for in Article 209(2), to ensure that wild aquatic animals intended for an aquaculture establishment are accompanied by an animal health certificate.

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

Article 212

Contents of animal health certificates

1 The animal health certificate referred to in Articles 208, 209 and 210 shall contain at least the following information:

- a the establishment or place of origin, the establishment or place of destination and, where relevant for the spread of diseases, any establishment or place visited en route;
- b a description, including the species and category, of the aquatic animals concerned;
- c the quantity (number, volume or weight) of aquatic animals;
- d the information needed to demonstrate that the aquatic animals fulfil the relevant animal health requirements in respect of movements provided for in Sections 1 to 4 (Articles 191 to 207).

2 The animal health certificate may include other information required under other Union legislation.

Article 213

Delegation of powers and implementing acts concerning the content of animal health certificates

1 The Commission shall adopt delegated acts in accordance with Article 264 concerning the content of animal health certificates as provided for in Article 212(1):

- a detailed rules on the content of those animal health certificates provided for in Article 212(1) for different species and categories of aquatic animals;
- b additional information to be contained in the animal health certificate provided for in Article 212(1).

2 The Commission may, by means of implementing acts, lay down rules concerning the model forms for the animal health certificates.

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

Article 214

Delegation of powers concerning specific types of movements of aquatic animals to the place of destination

The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning specific measures supplementing the requirements for animal health

certification provided for in Article 208 and 209 for the following types of movements of aquatic animals:

- (a) movements of aquatic animals which are required to return to their place of origin or to be moved to a different destination, for one or more of the following reasons:
 - (i) their intended journey was unexpectedly interrupted for animal welfare reasons;
 - (ii) unforeseen accidents or events during the journey;
 - (iii) they were rejected at the place of the destination in another Member State or at the external border of the Union;
 - (iv) they were rejected in a third country or territory;
- (b) movements of aquaculture animals intended for exhibitions and for sporting, cultural and similar events, and their subsequent return to their place of origin.

Article 215

Operators' obligations to cooperate with the competent authorities for the purposes of animal health certification

Operators shall:

- (a) provide the competent authority with all the information necessary to complete the animal health certificate provided for in Articles 208 and 209 and in the rules adopted pursuant to Articles 211, 213 and 214, in advance of the intended movement;
- (b) where necessary, ensure that the aquatic animals in question are subjected to documentary, identity and physical checks as provided for in Article 216(3) and in the rules adopted pursuant to Article 216(4).

Article 216

Responsibility of the competent authority for animal health certification and delegated acts

1 The competent authority shall, upon request by an operator, issue an animal health certificate for the movement of aquatic animals, where required by Articles 208 and 209, or by rules adopted pursuant to Articles 211 and Article 214, provided that the following animal health requirements have been complied with, as relevant:

- a those provided for in Article 191, Article 192(1), Articles 193, 195 and 196, Article 197(1), Articles 198 and 199, Article 200(1) and (2), Article 201, Article 203(1) and Article 204(1) and (2);
- b those provided for in delegated acts adopted pursuant to Articles 192(2), 197(3), 200(3), 201(3), 202(3), 203(2) and 204(3) and Article 205;
- c those provided for in implementing acts adopted pursuant to Article 206.

2 Animal health certificates shall:

- a be verified, stamped and signed by an official veterinarian;

- b remain valid for the period of time, provided for in the rules adopted pursuant to point (c) of paragraph 4, during which the aquatic animals covered by it must continue to fulfil the animal health guarantees contained in it.

3 Before signing an animal health certificate, the official veterinarian concerned shall verify, by means of documentary, identity and physical checks as provided for by delegated acts adopted pursuant to paragraph 4 where appropriate, that the aquatic animals covered by it fulfil the requirements of this Chapter, taking into account the species and categories of aquatic animals concerned and the animal health requirements.

4 The Commission shall adopt delegated acts in accordance with Article 264 laying down rules concerning:

- a the types of documentary, identity and physical checks and examinations in relation to different species and categories of aquatic animals that must be carried out by the official veterinarian in accordance with paragraph 3 in order to verify compliance with the requirements of this Chapter;
- b the timeframes for the carrying-out of such documentary, identity and physical checks and examinations, and the issuing of animal health certificates by the official veterinarian prior to the movement of consignments of aquatic animals;
- c the duration of the validity of animal health certificates.

Article 217

Electronic animal health certificates

Electronic animal health certificates, produced, handled and transmitted by means of Traces, may replace accompanying animal health certificates as provided for in Article 216(1) where such electronic animal health certificates:

- (a) contain all the information that the model form of animal health certificate is required to contain in accordance with Article 212(1) and the rules adopted pursuant to Article 213;
- (b) ensure the traceability of the aquatic animals in question and the link between those animals and the electronic animal health certificate;
- (c) ensure that the competent authorities of the Member States of origin, passage and destination are able to have access to the electronic documents at all times during the transport.

Article 218

Self-declaration by operators for movements of aquaculture animals to other Member States and delegated acts

1 Operators at the place of origin shall issue a self-declaration document for movements of aquaculture animals from their place of origin in one Member State to their place of destination in another Member State, and shall ensure that it accompanies such aquaculture animals, where they are not required to be accompanied by an animal health certificate as provided for in Articles 208 and 209 or in any rules adopted pursuant to Articles 211 and Article 214.

2 The self-declaration document provided for in paragraph 1 shall contain at least the following information concerning the aquaculture animals in question:

- a their places of origin and destination, and, when relevant, any places en route;
- b the means of transport
- c a description of the aquaculture animals, and their categories, species and quantity (numbers, volume or weight), as relevant for the animals concerned;
- d the information needed to demonstrate that the aquaculture animals fulfil the movement requirements provided for in Sections 1 to 4 (Articles 191 to 207).

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

- a detailed rules on the content of the self-declaration document provided for in paragraph 2 of this Article for different species and categories of aquaculture animals;
- b additional information to be contained in the self-declaration document to the one provided for in paragraph 2 of this Article.

4 The Commission may, by means of implementing acts, lay down rules for a model form of the self-declaration document provided for in paragraph 1.

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

Section 6

Notification of movements of aquatic animals to other Member States

Article 219

Obligation of operators concerning the notification of movements of aquatic animals to other Member States

1 Operators other than transporters shall notify the competent authority in their Member State of origin in advance of intended movements of aquatic animals from one Member State to another Member State where:

- a the aquatic animals are required to be accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with Articles 208 and 209 and any rules adopted pursuant to Article 211 and Article 214(2);
- b the aquatic animals are required to be accompanied by an animal health certificate for aquatic animals when they are being moved from a restricted zone as referred to in Article point (a) of 208(2);
- c the aquaculture animals and wild aquatic animals being moved are intended for:
 - (i) an establishment subject to registration in accordance with Article 173 or approval in accordance with Articles 176 to 179;
 - (ii) release into the wild;
- d notification is required in accordance with delegated acts adopted pursuant to Article 221.

2 For the purposes of the notification provided for in paragraph 1 of this Article, operators shall provide the competent authority of their Member State of origin with all the

necessary information to enable it to notify the movement to the competent authority of the Member State of destination in accordance with Article 220(1).

Article 220

Responsibility of the competent authority to notify movements of aquatic animals to other Member States

1 The competent authority of the Member State of origin shall notify the competent authority of the Member State of destination of movements of aquatic animals as referred to in Article 219, unless a derogation has been granted in accordance with point (c) of Article 221(1) as regards such notification.

2 The notification referred to in paragraph 1 shall be carried out prior to the movement in question and, whenever possible, through Traces.

3 Member States shall designate regions for the management of notifications of movements as provided for in paragraph 1.

4 By way of derogation from paragraph 1, the competent authority of Member State of origin may authorise the operator concerned to notify, partially or completely, movements of aquatic animals through Traces to the competent authority of the Member State of destination.

Article 221

Delegation of powers and implementing acts for the notification of movements of aquatic animals by operators and by the competent authority

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

- a the requirement for advance notification by operators, in accordance with Article 219, of movements between Member States of aquatic animals of species or categories other than those referred to in points (a), (b) and (c) of Article 219(1), where traceability of such movements is necessary in order to ensure compliance with the animal health requirements laid down in this Chapter;
- b the information needed in order to notify movements of aquatic animals as provided for in Articles 219 and 220(1);
- c derogations from the notification requirements provided for in point (c) of Article 219(1) for species and categories of aquatic animals or types of movements which pose an insignificant risk;
- d the emergency procedures for notification of movements of aquatic animals in the event of power cuts or other disturbances of Traces;
- e the requirements for the designation of regions by Member States as provided for in Article 220(3).

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

- a the details of notifications by:
 - (i) operators to the competent authority of the Member State of origin of movements of aquatic animals in accordance with Article 219;

- (ii) the competent authority of the Member State of origin to the Member State of destination of movements of aquatic animals in accordance with Article 220(1);
- b the deadlines for:
 - (i) the provision by operators of the necessary information referred to in Article 219(2) to the competent authority of the Member State of origin;
 - (ii) the notification of movements by the competent authority of the Member State of origin as referred to in Article 220(1).

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

CHAPTER 3

Production, processing and distribution within the Union of products of animal origin from aquatic animals, other than live aquatic animals

Article 222

General animal health obligations for operators and delegated acts

- 1 Operators shall take appropriate preventive measures to ensure that, during all stages of the production, processing and distribution of products of animal origin from aquatic animals, other than live aquatic animals, those products do not cause the spread of:
 - a listed diseases as referred to in point (d) of Article 9(1), taking into account the health status of the place of production, processing and destination;
 - b emerging diseases.
- 2 Operators shall ensure that products of animal origin from aquatic animals, other than live aquatic animals, do not come from establishments or food businesses, or are not obtained from animals which come from such establishments or food businesses, that are subject to:
 - a emergency measures as provided for in Articles 257 and 258 and any rules adopted pursuant to Article 259, unless derogations have been provided for in respect of those rules in Part VII (Articles 257 to 262);
 - b movement restrictions applicable to aquatic animals and products of animal origin from aquatic animals, as provided for in point (c) of Article 32(1), point (e) of Article 55(1), Article 56, point (a) of Article 61(1), Article 62(1), point (c) of Article 65(1), point (b) of Article 70(1), point (a) of Article 74(1), point (b) of Article 76(2), Article 76(3), Article 79, Article 81 and Article 82(2) and (3) and the rules adopted pursuant to Article 55(2), Articles 63 and 67, and Articles 70(3), 71(3), 74(4), 76(5) and 83(2), unless derogation from those movement restrictions have been provided for in those rules.
- 3 The Commission shall adopt delegated acts in accordance with Article 264 concerning detailed requirements supplementing those referred to in paragraph 2 of this Article in relation to movements of products of animal origin from aquatic animals other than live aquatic animals, as regards:
 - a the diseases, and species of aquatic animals concerned by the diseases, for which emergency measures or movement restrictions as referred to in paragraph 2 of this Article apply;

- b the types of products of animal origin from aquatic animals;
 - c the risk-mitigation measures applied to the products of animal origin from aquatic animals at the places of origin and destination;
 - d the intended use of the products of animal origin from aquatic animals;
 - e the place of destination of the products of animal origin from aquatic animals.
- 4 This Article shall not apply to products of animal origin from wild aquatic animals harvested or caught for direct human consumption.

Article 223

Animal health certificates and delegated acts

1 Operators shall only move the following products of animal origin from aquatic animals other than live aquatic animals where those products are accompanied by an animal health certificate issued by the competent authority of the Member State of origin in accordance with paragraph 3:

- a products of animal origin from aquatic animals that:
 - (i) are allowed to leave a restricted zone subject to emergency measures as provided for in rules adopted pursuant to Article 259; and
 - (ii) originate from aquatic animals of species subject to those emergency measures;
- b products of animal origin from aquatic animals that:
 - (i) are allowed to leave a restricted zone subject to disease control measures in accordance with point (c) of Article 32(1), point (c) of Article 55(1), Article 56, point (a) of Article 61(1), Articles 62(1) and 63(1), point (c) of Article 65(1), point (b) of Article 70(1), point (a) of Article 74(1) and Article 79 and the rules adopted pursuant to Article 55(2), Articles 63 and 67 and Articles 71(3), 74(4) and 83(2); and
 - (ii) originate from aquatic animals of species subject to those disease control measures.

2 By way of derogation from paragraph 1, such a certificate shall not be required for movements of products of animal origin from wild aquatic animals, provided that:

- a alternative risk-mitigation measures authorised by the competent authority are in place to ensure that those movements do not pose a risk of the spread of listed diseases;
- b consignments of such products are traceable.

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

4 The competent authority shall, upon request by the operator concerned, issue an animal health certificate for movements of products of animal origin other than live aquatic animals as referred to in paragraph 1, provided that the relevant requirements referred to in this Article have been complied with.

5 Article 212 and Articles 214 to 217 and the rules adopted pursuant to Article 213 and Article 216(4) shall apply to the animal health certification of movements of products of animal origin other than live aquatic animals as referred to in paragraph 1 of this Article.

6 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning requirements and detailed rules on the animal health certificate to accompany products of animal origin other than live aquatic animals, as referred to in paragraph 1 of this Article, taking into account:

- a the types of products of animal origin concerned;
- b the risk-mitigation measures applied to the products concerned which reduce the risks of the spread of diseases;
- c the intended use of those products;
- d the place of destination of those products.

Article 224

Content of animal health certificates and delegated and implementing acts

1 The animal health certificate for products of animal origin from aquatic animals, other than live aquatic animals, shall contain at least the following information:

- a the establishment or place of origin and the establishment or place of destination;
- b a description of the products of animal origin concerned;
- c the quantity (numbers, volume or weight) of the products of animal origin;
- d the identification of the products of animal origin, when required by point (h) of Article 65(1) or by any rules adopted pursuant to Article 67;
- e the information needed to demonstrate that the products concerned fulfil the movement restriction requirements provided for in Article 222(2) and in any rules adopted pursuant to Article 222(3).

2 The animal health certificate referred to in paragraph 1 may include other information required under other Union legislation.

3 The Commission shall adopt delegated acts in accordance with Article 264 concerning amending and supplementing the information to be contained in the animal health certificate as provided for in paragraph 1 of this Article.

4 The Commission may, by means of implementing acts, lay down rules concerning model forms of animal health certificates as provided for in paragraph 1 of this Article.

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

Article 225

Notification of movements of products of animal origin to other Member States

1 Operators shall:

- a inform the competent authority in the Member State of origin in advance of intended movements of products of animal origin from aquatic animals, other than live aquatic animals, when the consignments in question are required to be accompanied by an animal health certificate in accordance with Article 223(1);
- b provide all necessary information to enable the competent authority of the Member State of origin to notify the movement in question to the Member State of destination in accordance with paragraph 2 of this Article.

2 The competent authority of the Member State of origin shall notify the competent authority of the Member State of destination of movements of products of animal origin from aquatic animals, other than live aquatic animals, in accordance with Article 220(1).

3 Articles 219 and 220 and any rules adopted pursuant to Article 221 shall be applicable to the notification of products of animal origin from aquatic animals, other than live aquatic animals.

CHAPTER 4

National measures

Article 226

National measures designed to limit the impact of diseases other than listed disease

1 Where a disease other than a listed disease as referred to in point (d) of Article 9(1) constitutes a significant risk for the health of aquatic animals in a Member State, the Member State concerned may take national measures to prevent the introduction, or to control the spread, of that disease.

Member States shall ensure that those national measures do not exceed the limits of what is appropriate and necessary in order to prevent the introduction, or to control the spread, of the disease in question within the Member State concerned.

2 Member States shall notify the Commission in advance of any proposed national measures as referred to in paragraph 1 that may affect movements of aquatic animals and products of animal origin from aquatic animals between Member States.

3 The Commission shall approve and, if necessary, amend the national measures referred to in paragraph 2 of this Article by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

4 The approval referred to in paragraph 3 shall only be granted where the establishment of movement restrictions between Member States is necessary in order to prevent the introduction, or to control the spread, of the disease referred to in paragraph 1, taking into account the overall impact on the Union of the disease in question and of the measures taken.

TITLE III

ANIMALS OF SPECIES OTHER THAN THOSE DEFINED AS TERRESTRIAL AND AQUATIC ANIMALS, AND GERMINAL PRODUCTS AND PRODUCTS OF ANIMAL ORIGIN FROM SUCH OTHER ANIMALS

Article 227

Animal health requirements concerning other animals, and germinal products and products of animal origin of such other animals

Where other animals are of a listed species for a listed disease as referred to in point (d) of Article 9(1), and those other animals or their germinal products or products of

animal origin represent a risk to public or animal health in the Union, one or more of the following requirements shall apply:

- (a) the requirements concerning registration, approval, record-keeping and registers for establishments and transporters provided for in Chapter 1 of Title I and Chapter 1 of Title II (Articles 84 to 101 and Articles 172 to 175);
- (b) the requirements concerning traceability provided for in Articles 108 to 111 and Article 117 for other animals and Article 122 for germinal products;
- (c) movement requirements:
 - (i) as regards other animals mainly living in a terrestrial environment or that are normally affected by diseases of terrestrial animals, taking into account the criteria provided for in points (d) and (e) of Article 228(3), the requirements provided for in Section 1 (Articles 124 and 125) and Section 6 of Chapter 3 of Title I of Part IV (Articles 137 to 142) and Chapter 4 of Title I of Part IV (Articles 155 and 156);
 - (ii) as regards other animals mainly living in aquatic environment or that are normally affected by diseases of aquatic animals, taking into account the criteria provided for in points (d) and (e) of Article 228(3), the requirements provided for in Sections 1 to 4 of Chapter 2 of Title II of Part IV (Articles 191 to 207);
 - (iii) as regards germinal products, the general requirements for movements provided for in Articles 157 and 158 and the special requirements for movements to other Member States provided for in Articles 164 and 165;
 - (iv) as regards products of animal origin, the general animal health obligations incumbent on operators in respect of the production, processing and distribution within the Union of products of animal origin provided for in Articles 166 and 222;
- (d) the animal health certification obligation incumbent on operators and competent authorities and the self-declaration incumbent on operators:
 - (i) as regards other animals, pursuant to the rules provided for in Articles 143 to 151 or Articles 208 to 218;
 - (ii) as regards germinal products, pursuant to the rules provided for in Articles 161 and 162;
 - (iii) as regards products of animal origin, pursuant to the rules provided for in Articles 165 and 168 or Articles 223 and 224;
- (e) the obligation to notify movements incumbent on operators and competent authorities, taking into account the requirements provided for in Articles 152, 153, 154, 163 and 169 and in Articles 219 to 221 and 225.

Article 228

Delegation of powers and implementing acts concerning animal health requirements for other animals, and germinal products and products of animal origin of other animals

1 The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning any specific requirements for other animals, and their germinal products or products of animal origin, which are necessary in order to mitigate the risk of the listed diseases referred to in point (d) of Article 9(1), as provided for in Article 227.

2 The Commission may adopt implementing acts concerning detailed rules for the implementation of the disease control and prevention measures provided for in paragraph 1.

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

3 When adopting the delegated acts and implementing acts provided for in paragraphs 1 and 2, the Commission shall base those acts on the following criteria:

- a the species or categories of other animals listed in accordance with Article 8(2) as listed species for one or more listed diseases, for which certain disease prevention and control measures provided for in this Regulation apply;
- b the profile of the listed disease in question, which concerns species and categories of other animals referred to in point (a);
- c the feasibility, availability and effectiveness of disease prevention and control measures for the listed species concerned by those measures;
- d the prevailing terrestrial or aquatic living environment of those other animals;
- e the types of diseases that are affecting such other animals, which can be either diseases normally affecting terrestrial or aquatic animals, regardless of the prevailing living environment referred to in point (d).

Status: This is the original version (as it was originally adopted).

- (1) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin ([OJ L 139, 30.4.2004, p. 55](#)).