

Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin (Text with EEA relevance)

### PART III

## **ANIMAL HEALTH REQUIREMENTS FOR ENTRY INTO THE UNION OF GERMINAL PRODUCTS AS REFERRED TO IN ARTICLES 3 AND 5**

### TITLE 1

## **ANIMAL HEALTH REQUIREMENTS FOR GERMINAL PRODUCTS OF UNGULATES**

### CHAPTER 1

#### ***General animal health requirements for germinal products of ungulates***

#### *Article 79*

#### **The third country or territory of origin or zone thereof**

Consignments of semen, oocytes and embryos of bovine, porcine, ovine, caprine and equine animals shall only be permitted to enter the Union if they were collected from animals which come from third countries or territories which comply with the animal health requirements laid down in Article 22.

#### *Article 80*

#### **The residency period of donor animals**

Consignments of semen, oocytes and embryos of bovine, porcine, ovine, caprine and equine animals shall only be permitted to enter the Union if they were collected from animals which:

- (a) remained for a period of at least 6 months prior to the date of collection in a third country or territory or zone thereof which is listed for entry into the Union of the particular species and category of germinal product;
- (b) for a period of at least 30 days prior to the date of first collection of the germinal products and during the collection period:
  - (i) were kept on establishments not situated in a restricted zone established due to the occurrence in bovine, porcine, ovine, caprine and equine animals of a category A disease or of an emerging disease relevant for the bovine, porcine, ovine, caprine or equine animals;

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- (ii) were kept on a single establishment on which no category D diseases relevant for the bovine, porcine, ovine, caprine or equine animals were reported;
- (iii) were not in contact with animals from establishments, situated in a restricted zone referred to in (i) or from establishments referred to in (ii);
- (iv) were not used for natural breeding.

#### *Article 81*

### **Identification of donor animals**

Consignments of semen, oocytes and embryos of bovine, porcine, ovine, caprine and equine animals shall only be permitted to enter the Union if they were collected from animals which were identified in accordance with Article 21.

#### *Article 82*

### **The germinal product establishments**

1 Consignments of semen, oocytes and embryos of bovine, porcine, ovine, caprine and equine animals shall only be permitted to enter the Union if they were dispatched from approved germinal product establishments which are listed by competent authorities of listed third countries or territories or zones thereof.

2 Consignments of germinal products shall only be permitted to enter the Union from approved germinal product establishments referred to in paragraph 1 that comply with the following requirements set out in Annex I to Delegated Regulation (EU) 2020/686:

- a Part 1 of that Annex, in respect of a semen collection centre;
- b Part 2 of that Annex, in respect of an embryo collection team;
- c Part 3 of that Annex, in respect of an embryo production team;
- d Part 4 of that Annex, in respect of a germinal product processing establishment;
- e Part 5 of that Annex, in respect of a germinal product storage centre.

#### *Article 83*

### **The germinal products**

Consignments of semen, oocytes and embryos of animals of bovine, porcine, ovine, caprine and equine animals shall only be permitted to enter the Union if those germinal products comply with the following requirements:

- (a) they are marked in such a way that the following information can be readily established:
  - (i) the date of collection or production of those germinal products;
  - (ii) the species and identification of the donor animal(s);
  - (iii) the unique approval number, which shall include the ISO 3166-1 alpha-2 code of the country in which the approval is granted;

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- (iv) any other relevant information;
- (b) they fulfil animal health requirements for the collection, production, processing and storage set out in Annex III to Delegated Regulation (EU) 2020/686.

#### *Article 84*

### **The transport of germinal products**

1 Consignments of semen, oocytes and embryos of animals of bovine, porcine, ovine, caprine and equine animals shall only be permitted to enter the Union if:

- a they were placed in a container which complies with the following requirements:
  - (i) it was sealed and numbered prior to the dispatch from the approved germinal product establishment under the responsibility of a centre or a team veterinarian, or by an official veterinarian;
  - (ii) it was cleaned and either disinfected or sterilised before use, or is single-use container;
  - (iii) it was filled in with the cryogenic agent which was not previously used for other products;
- b only one type of germinal products of one species was placed in the container referred to in point (a).

2 By the way of derogation from paragraph 1(b), operators may place in one container semen, oocytes and embryos of the same species provided that:

- a straws or other packages in which germinal products are placed are securely and hermetically sealed;
- b the germinal products of different types are separated from each other by physical compartments or by being placed in secondary protective bags.

3 By way of derogation from paragraph 1(b), operators may place in one container semen, oocytes and embryos of ovine and caprine animals.

#### *Article 85*

### **Additional requirements for the transport of semen**

Consignments of semen bovine, porcine, ovine and caprine animals which has been collected from more than one donor animal and placed in a single straw or another package for the purposes of entry into the Union shall only be permitted to enter the Union if:

- (a) that semen was collected and dispatched from a single semen collection centre where it was collected;
- (b) there were procedures in place as regards processing of that semen in order to ensure that it complies with the marking requirements of point (a) of Article 83.

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## CHAPTER 2

### ***Specific animal health requirements for germinal products of bovine animals***

#### *Article 86*

#### **The establishment of origin of donor bovine animals**

Consignments of semen, oocytes and embryos of bovine animals shall only be permitted to enter the Union if they were collected from animals which came from establishments that comply with the following requirements and those animals have never been kept previously in any establishment of a lower health status:

- (a) comply with the requirements of Article 23;
- (b) in the case of donor animals of semen prior to their admission to a quarantine accommodation, were free from the following diseases:
  - (i) infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*);
  - (ii) infection with *Brucella abortus*, *B. melitensis* and *B. suis*;
  - (iii) enzootic bovine leukosis;
  - (iv) infectious bovine rhinotracheitis/infectious pustular vulvovaginitis.

#### *Article 87*

#### **Derogations from the requirements for the establishment of origin of donor bovine animals**

1 By the way of derogation from Article 86(b)(iii), consignments of semen of bovine animals shall be permitted to enter the Union if a donor animal comes from an establishment which is not free from enzootic bovine leukosis and:

- a is younger than 2 years of age and which has been produced by a dam which has been subjected, with negative results, to a serological test for enzootic bovine leukosis after removal of the animal from the dam;

or

- b has reached the age of 2 years and has been subjected, with a negative result, to a serological test for enzootic bovine leukosis.

2 By the way of derogation from Article 86(b)(iii), consignments of oocytes and embryos of bovine animals shall be permitted to enter the Union if a donor animal comes from an establishment which is not free from enzootic bovine leukosis and is less than 2 years of age, and provided that the official veterinarian responsible for the establishment of origin has certified that there has been no clinical case of enzootic bovine leukosis during a period of at least the preceding 3 years.

3 By the way of derogation from Article 86(b)(iv), consignments of semen, oocytes and embryos of bovine animals shall be permitted to enter the Union if a donor animal comes from an establishment which is not free from infectious bovine rhinotracheitis/infectious pustular vulvovaginitis, provided that:

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- a in the case of semen, the animal has been subjected, with a negative result, to a test required in accordance with point 1(b)(iv) of Chapter I of Part 1 of Annex II to Delegated Regulation (EU) 2020/686;
- b in the case of oocytes or embryos, the official veterinarian responsible for the establishment of origin has certified that there has been no clinical case of infectious bovine rhinotracheitis/infectious pustular vulvovaginitis during a period of at least the preceding 12 months.

#### *Article 88*

### **Specific animal health requirements for donor bovine animals**

Consignments of semen, oocytes or embryos shall only be permitted to enter the Union if they were collected from donor bovine animals that comply with the animal health requirements laid down in Part 1 and Chapters I, II and III of Part 5 of Annex II to Delegated Regulation (EU) 2020/686.

#### *CHAPTER 3*

### ***Specific animal health requirements for germinal products of porcine animals***

#### *Article 89*

### **The establishment of origin of donor porcine animals**

1 Consignments of semen, oocytes and embryos of porcine animals shall only be permitted to enter the Union if they were collected from animals which came from establishments:

- a which comply with the requirements laid down in Article 23;
- b in the case of donor animals of semen prior their admission to a quarantine accommodation, in which no clinical, serological, virological or pathological evidence of infection with Aujeszky's disease virus had been detected during the period of at least the preceding 12 months.

2 Consignments of semen of porcine animals shall only be permitted to enter the Union if they were collected from animals:

- a prior to their admission to a quarantine accommodation, which came from establishments which were free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* in accordance with requirements laid down in Chapter IV of Part 5 of Annex II to Delegated Regulation (EU) 2020/686;
- b which were kept at a quarantine accommodation which on the date of admission was free of infection with *Brucella abortus*, *B. melitensis* and *B. suis* for a period of at least the 3 months preceding that date;
- c which were kept in a semen collection centre in which no clinical, serological, virological or pathological evidence of infection with Aujeszky's disease virus was reported for the period of at least 30 days prior to the date of admission and of at least 30 days immediately prior to the date of collection;
- d which were kept, since birth or for at least 3 months prior to the date of entry into the quarantine accommodation, in an establishment in which no animals were vaccinated against infection with porcine reproductive and respiratory syndrome virus and no

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infection with porcine reproductive and respiratory syndrome virus was detected within that period.

#### *Article 90*

##### **Specific animal health requirements for donor porcine animals**

Consignments of semen, oocytes or embryos shall only be permitted to enter the Union if they were collected from donor porcine animals that:

- (a) comply with the specific animal health requirements laid down in Part 2 and Chapters I, II, III and IV of Part 5 of Annex II to Delegated Regulation (EU) 2020/686;
- (b) were not vaccinated against infection with porcine reproductive and respiratory syndrome virus.

#### *CHAPTER 4*

##### ***Specific animal health requirements for germinal products of ovine and caprine animals***

#### *Article 91*

##### **The establishment of origin of donor ovine and caprine animals**

Consignments of semen, oocytes and embryos of ovine and caprine animals shall only be permitted to enter the Union if they were collected from donor animals which:

- (a) did not come from an establishment, nor been in contact with animals from an establishment, in the case of a kept donor animal of semen prior to its admission to a quarantine accommodation, which has been subjected to movement restrictions as regards infection with *Brucella abortus*, *B. melitensis* and *B. suis*. The movement restrictions concerning the establishment are lifted after the period comprising at least 42 days from the date of the slaughter and the disposal of the last animal infected or susceptible to that disease;
- (b) come from an establishment, that was free from infection with *B. abortus*, *B. melitensis* and *B. suis* and has never been kept previously in any establishment of a lower status.

#### *Article 92*

##### **Specific animal health requirements for donor ovine and caprine animals**

Consignments of semen, oocytes or embryos of ovine and caprine animal shall only be permitted to enter the Union if they were collected from donor animals that fulfil specific animal health requirements laid down in Part 3 and Chapters I, II and III of Part 5 of Annex II to Delegated Regulation (EU) 2020/686.

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## CHAPTER 5

### ***Specific animal health requirements for germinal products of equine animals***

#### *Article 93*

#### **The establishment of origin of donor equine animals**

Consignments of semen, oocytes and embryos of equine animals shall only be permitted to enter the Union if they were collected from donor animals which come from establishments which comply with the requirements laid down in Article 23.

#### *Article 94*

#### **Specific animal health requirements for donor equine animals**

Consignments of semen, oocytes or embryos of equine animals shall only be permitted to enter the Union if the donor animals of those germinal products comply with the requirements laid down Article 24(1)(a)(ii) and (b)(ii) and Article 24(6) of this Regulation, and the additional specific animal health requirements laid down in Part 4 of Annex II to Delegated Regulation (EU) 2020/686.

## CHAPTER 6

### ***Special rules for germinal products of ungulates intended for confined establishments***

#### *Article 95*

#### **Germinal products intended for confined establishments in the Union**

Consignments of semen, oocytes and embryos of bovine, porcine, ovine, caprine and equine animals dispatched from confined establishments in third countries or territories listed in accordance with Article 29 shall only be permitted to enter the Union if they are dispatched to a confined establishment in the Union subject to compliance with the following requirements:

- (a) an assessment was carried out by the competent authority of the Member State of destination of the risks associated with the entry into the Union of those germinal products;
- (b) the donor animals of those germinal products originate from a confined establishment in the third country or territory of origin or zone thereof, which is included in a list established in accordance with Article 29 of confined establishments from which the entry of ungulates into the Union may be authorised;
- (c) the germinal products are destined to a confined establishment in the Union, which is approved in accordance with Article 95 of Regulation (EU) 2016/429;
- (d) the germinal products are transported directly to the confined establishment referred to in point (c).

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### *Article 96*

#### **Specific animal health requirements for donor animals kept in confined establishment**

Consignments of the germinal products referred to in Article 95 shall be only permitted to enter the Union if they were collected from donor animals that comply with the following requirements:

- (a) the donor animals did not come from an establishment, nor been in contact with animals from an establishment, situated in a restricted zone established due to the occurrence of a category A disease or of an emerging disease relevant for the bovine, porcine, ovine, caprine or equine animals;
- (b) the donor animals come from an establishment where none of the category D diseases relevant for bovine, porcine, ovine, caprine or equine animals have been reported for a period of at least 30 days prior to the date of collection of the semen, oocytes or embryos;
- (c) the donor animals remained in a single confined establishment of origin for a period of at least 30 days prior to the date of collection of semen, oocytes or embryos intended for entry into the Union and during the period of that collection;
- (d) the donor animals were clinically examined by the establishment veterinarian responsible for the activities carried out at confined establishment, and showed no disease symptoms on the day the semen, oocytes or embryos were collected;
- (e) as much as possible, the donor animals were not used for natural breeding during a period of at least 30 days prior to the date of first collection of semen, oocytes or embryos intended for entry into the Union and during the period of that collection;
- (f) the donor animals are identified in accordance with Article 21.

### *Article 97*

#### **The requirements for germinal products obtained in confined establishments**

Consignments of germinal products referred to in Article 95 shall only be permitted to enter the Union if they are:

- (a) marked in accordance with the information requirements provided for in point (a) of Article 83;
- (b) transported in accordance with Articles 84 and 85.



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## TITLE 2

### ANIMAL HEALTH REQUIREMENTS FOR HATCHING EGGS OF POULTRY AND CAPTIVE BIRDS

#### CHAPTER 1

##### *Animal health requirements for hatching eggs*

###### *Article 98*

###### **The residency period**

Consignments of hatching eggs shall only be permitted to enter the Union if, immediately prior to the date of loading of the hatching eggs for dispatch to the Union the flock of origin of the hatching eggs has complied, for a continuous period of time, with the residency periods requirements set out in Annex XXII, and during that time the flock of origin has:

- (a) remained in the third country or territory of origin or zone thereof;
- (b) remained in the establishment of origin, and no animals have been introduced into that establishment during that period of time prior to loading;
- (c) had no contact with poultry or hatching eggs of a lower health status, or with captive birds or wild birds.

###### *Article 99*

###### **Handling of hatching eggs during transport to the Union**

Consignments of hatching eggs shall only be permitted to enter the Union if the germinal products of the consignment comply with the following requirements:

- (a) the hatching eggs intended for entry into the Union must not have come into contact with poultry, captive birds or hatching eggs not intended for entry into the Union or of a lower health status from the time of loading at the establishment of origin for dispatch to the Union until the time of arrival in the Union;
- (b) the hatching eggs must not have been transported, unloaded in, or moved to another means of transport when transported by road, by sea or by air through a third country or territory or zone thereof which is not listed for entry of the particular species and category of hatching eggs into the Union.

###### *Article 100*

###### **Derogation and additional requirements for transshipment of hatching eggs in case of an incident in the means of transport by waterway or by air**

By way of derogation from point (b) of Article 99, consignments of hatching eggs which have been transhipped from the means of transport of dispatch into another means of transport for onward travel in a third country or territory or zone thereof which is not

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listed for entry of hatching eggs into the Union, shall only be permitted to enter the Union if the transshipment took place because of the occurrence of a technical problem or another unforeseen incident causing logistic problems during the transport of the hatching eggs to the Union by sea or by air, in order to complete the transport to the point of entry into Union, and provided that:

- (a) the entry into the Union of the hatching eggs is authorised by the competent authority of the Member State of destination and, where applicable, the Member States of passage until their arrival at their place of destination in the Union;
- (b) the transshipment was supervised by an official veterinarian or the responsible customs officer and throughout the operation:
  - (i) effective measures were put in place to avoid any direct or indirect contact between the hatching eggs intended for entry into the Union and any other hatching eggs or animals;
  - (ii) the hatching eggs were transferred directly and as quick as possible to the vessel or aircraft to be used for onward travel to the Union, which complies with requirements laid down in Article 17, without leaving the premises of the port or airport;
- (c) the hatching eggs are accompanied by a declaration from the competent authority of the third country or territory where the transfer took place, providing the necessary information on the transfer operation and attesting that the relevant measures were put in place to comply with the requirements laid down in point (b).

#### *Article 101*

#### **Transport by vessel of hatching eggs**

1 Consignments of hatching eggs transported by ship, even for part of the journey, shall only be permitted to enter the Union if the germinal products of the consignment comply with the following requirements:

- a hatching eggs:
  - (i) have remained on board the vessel during the whole transport;
  - (ii) have not been in contact with birds or other hatching eggs of a lower health status while on board the vessel;
- b hatching eggs transported in accordance with point (a) must be accompanied by a declaration, providing the following information:
  - (i) the port of departure in the third country or territory of origin or zone thereof;
  - (ii) the port of arrival in the Union;
  - (iii) where the vessel called at ports outside the third country or territory of origin or zone thereof of the consignment, indicating the ports of call;
  - (iv) that the hatching eggs complied during the transport with the requirements set out in point (a) and (i), (ii) and (iii) of this point.

2 The operator responsible for the consignment of hatching eggs shall ensure that the declaration provided for in paragraph 1, is attached to the animal health certificate and signed by the master of the vessel at the port of arrival on the day of arrival of the vessel.

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## Article 102

### **Preventive measures for the means of transport and the containers of hatching eggs**

Consignments of hatching eggs shall only be permitted to enter the Union if the germinal products of the consignment comply with the following requirements:

- (a) the hatching eggs must have been transported in vehicles which:
  - (i) are constructed in such a way that hatching eggs cannot fall out;
  - (ii) have been designed to allow cleaning and disinfection;
  - (iii) have been cleaned and disinfected with a disinfectant authorised by the competent authority of the third country or territory of origin, and dried or allowed to dry immediately before every loading of hatching eggs intended for entry into the Union;
- (b) the hatching eggs must have been transported in containers which comply with the following requirements:
  - (i) the requirements of point (a);
  - (ii) they contain only hatching eggs of the same species, category and type which come from the same establishment;
  - (iii) they were closed in accordance with the instructions of the competent authority of the third country or territory of origin to avoid any possibility of substitution of the content;
  - (iv) they were:
    - cleaned and disinfected before loading in accordance with the instructions of the competent authority of the third country or territory of origin,
    - or
    - they are disposable, clean and used for the first time;
  - (v) they bear the information for the particular species and category of hatching eggs set out in Annex XVI.

## Article 103

### **Movement and handling of hatching eggs after the entry**

Following their entry into the Union, operators, including transporters, shall ensure that consignments of hatching eggs are:

- (a) transported directly from the point of entry to their place of destination in the Union;
- (b) comply with the requirements for movement within the Union and handling following their entry into the Union as laid down for the particular species and category of hatching eggs in Chapters 5 and 7 of this Title.

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## CHAPTER 2

### **Specific animal health requirements for hatching eggs of poultry**

#### *Article 104*

#### **Hatching eggs originating from poultry imported into the third country or territory of origin or zone thereof**

Consignments of hatching eggs of poultry, which originate from flocks which were imported into the third country, or territory of origin or zone thereof from another third country or territory or zone thereof, shall only be permitted to enter the Union if the competent authority of the third country or territory of origin of the hatching eggs has provided guarantees that:

- (a) the flocks of origin of the hatching eggs were imported from a third country or territory or zone thereof, which is listed for entry into Union of such flocks;
- (b) the import of the flocks of origin of the hatching eggs into that third country or territory or zone thereof took place in accordance with animal health requirements that are at least as stringent as if they were directly entered into the Union.

#### *Article 105*

#### **The third country or territory of origin or zone thereof of the hatching eggs**

Consignments of hatching eggs of poultry shall only be permitted to enter the Union if they originate from a third country or territory or zone thereof which complies with the following requirements:

- (a) it has a disease surveillance programme for highly pathogenic avian influenza in place for a period of at least 6 months prior to the date of dispatch of the consignment to the Union and that surveillance programme complies with the requirements laid down in either:
  - (i) Annex II to this Regulation;
  - or
  - (ii) the relevant Chapter of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE);
- (b) which is considered to be free from highly pathogenic avian influenza in accordance with Article 38;
- (c) if it carries out vaccination against highly pathogenic avian influenza, the competent authority of the third country or territory of origin has provided guarantees that:
  - (i) the vaccination programme complies with the requirements set out in Annex XIII;
  - (ii) the surveillance programme referred to in point (a) of this Article, in addition to the requirements set out in Annex II, complies with the requirements set out in point 2 of Annex XIII;

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- (iii) it has undertaken to inform the Commission of any change to the vaccination programme in the third country or territory or zone thereof;
- (d) which:
  - (i) in the case of hatching eggs of poultry other than ratites, is considered to be free from infection with Newcastle disease virus in accordance with Article 39;
  - (ii) in the case of hatching eggs of ratites:
    - it is considered to be free from infection with Newcastle disease virus in accordance with Article 39,
    - or
    - it is not considered to be free from infection with Newcastle disease virus in accordance with Article 39, but the competent authority of the third country or territory of origin has provided guarantees regarding compliance with the requirements for infection with Newcastle disease virus in relation to isolation, surveillance and testing, as set out in Annex XIV;
- (e) if vaccination against infection with Newcastle disease virus is carried out, the competent authority of the third country or territory has provided guarantees that:
  - (i) the vaccines used comply with the general and the specific criteria for vaccines against infection with Newcastle disease virus set out in point 1 of Annex XV;
  - or
  - (ii) the vaccines used comply with the general criteria for vaccines against infection with Newcastle disease virus set out in point 1 of Annex XV and the poultry meet the animal health requirements set out in point 2 of Annex XV for poultry and hatching eggs originating from a third country or territory or zone thereof where vaccines used against infection with Newcastle disease virus do not meet the specific criteria set out in point 1 of Annex XV;
- (f) it has undertaken that following any outbreak of highly pathogenic avian influenza or an outbreak of infection with Newcastle disease virus, to submit the following information to the Commission:
  - (i) information on the disease situation within 24 hours of confirmation of any initial outbreak of highly pathogenic avian influenza or infection with Newcastle disease virus;
  - (ii) regular updates of the disease situation;
- (g) which has undertaken to submit virus isolates from initial outbreaks of highly pathogenic avian influenza or infection with Newcastle disease virus to the European Union Reference Laboratory for Avian Influenza and Newcastle disease.

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### *Article 106*

#### **The establishment of origin of the hatching eggs**

Consignments of hatching eggs of poultry shall only be permitted to enter the Union if they originate from:

- (a) hatcheries approved by the competent authority of the third country or territory of origin in accordance with requirements which are at least as stringent as those laid down in Article 7 of Delegated Regulation (EU) 2019/2035; and
  - (i) the approval of which has not been suspended or withdrawn;
  - (ii) within a 10 km radius of those hatcheries, including, where appropriate, the territory of a neighbouring country, there has been no outbreak of highly pathogenic avian influenza or infection with Newcastle disease virus for a period of at least 30 days prior to the time of loading of the hatching eggs for dispatch to the Union;
  - (iii) which have been assigned a unique approval number by the competent authority of the third country or territory of origin;
- (b) flocks which have been kept in establishments approved by the competent authority of the third country or territory of origin in accordance with requirements which are at least equivalent to those laid down in Article 8 of Delegated Regulation (EU) 2019/2035 and
  - (i) the approval of which has not been suspended or withdrawn;
  - (ii) within a 10 km radius of those establishments, including, where appropriate, the territory of a neighbouring country, there has been no outbreak of highly pathogenic avian influenza or infection with Newcastle disease virus for a period of at least 30 days prior to the date of collection of the hatching eggs for dispatch to the Union;
  - (iii) no confirmed case of infection with low pathogenic avian influenza viruses has been reported in those establishments within a period of at least 21 days prior to the date of collection of the eggs for dispatch to the Union.

### *Article 107*

#### **The flock of origin of the hatching eggs**

Consignments of hatching eggs of poultry shall only be permitted to enter the Union if they originate from flocks which comply with the following requirements:

- (a) where they have been vaccinated against highly pathogenic avian influenza, guarantees for compliance with the minimum requirements for vaccination programmes and additional surveillance set out in Annex XIII, have been provided by the third country or territory of origin;
- (b) where they have been vaccinated against infection with Newcastle disease virus:

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- (i) guarantees have been provided by the competent authority of the third country or territory of origin that the vaccines used comply with:
    - the general and the specific criteria for vaccines against infection with Newcastle disease virus set out in point 1 of Annex XV, or
    - the general criteria for recognised vaccines against infection with Newcastle disease virus set out in point 1 of Annex XV and the poultry and hatching eggs from which the day-old chicks originated meet the animal health requirements set out in point 2 of Annex XV for poultry and hatching eggs originating from a third country or territory or zone thereof where vaccines used against infection with Newcastle disease virus do not meet the specific criteria set out in point 1 of Annex XV;
  - (ii) the information set out in point 4 of Annex XV must be provided for each consignment;
- (c) they have undergone a disease surveillance programme that meets the requirement set out Annex II of Delegated Regulation (EU) 2019/2035 and were found not to be infected or showed any grounds for suspecting any infection by the following agents:
- (i) *Salmonella Pullorum*, *Salmonella Gallinarum* and *Mycoplasma gallisepticum* in case of *Gallus gallus*;
  - (ii) *Salmonella arizonae* (serogroup O:18(k)), *Salmonella Pullorum*, *Salmonella Gallinarum*, *Mycoplasma meleagridis* and *Mycoplasma gallisepticum* in case of *Meleagris gallopavo*;
  - (iii) *Salmonella Pullorum* and *Salmonella Gallinarum* in case of *Numida meleagris*, *Coturnix coturnix*, *Phasianus colchicus*, *Perdix perdix*, *Anas* spp.;
- (d) they were kept in establishments which, in case of confirmation of infection with *Salmonella Pullorum*, *S. Gallinarum* and *S. arizonae* during the last 12 months prior to date of collection of the eggs for dispatch to the Union have applied the following measures:
- (i) the infected flock has been slaughtered or it has been killed and destroyed;
  - (ii) following the slaughter or killing of the infected flock referred to in point (i), the establishment has been cleaned and disinfected;
  - (iii) following the cleaning and disinfection referred to in point (ii), all flocks on the establishment tested negative for infection with *Salmonella Pullorum*, *S. Gallinarum* and *S. arizonae* in two tests performed with an interval of at least 21 days in accordance with the disease surveillance programme referred to in point (c);
- (e) they were kept in establishments which in case of confirmation of avian mycoplasmosis (*Mycoplasma gallisepticum* and *M. meleagridis*) during the last 12 months prior to date of collection of the eggs for dispatch to the Union have applied the following measures:
- either
- (i) the infected flock tested negative for avian mycoplasmosis (*Mycoplasma gallisepticum* and *M. meleagridis*) in two tests performed in accordance with

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the disease surveillance programme referred to in point (c) on the entire flock with an interval of at least 60 days;

or

- (ii) the infected flock has been slaughtered or it has been killed and destroyed, the establishment has been cleaned and disinfected and following the cleaning and disinfection all flocks on the establishment tested negative for avian mycoplasmosis (*Mycoplasma gallisepticum* and *M. meleagridis*) in two tests performed with an interval of at least 21 days in accordance with the disease surveillance programme referred to in point (c);
- (f) they have been subjected to a clinical inspection, carried out by an official veterinarian in the third country or territory of origin or zone thereof, within a period of 24 hours prior to the time of loading of the consignment of hatching eggs for dispatch to the Union for the purpose of the detection of signs indicative of the occurrence of diseases, including the relevant listed diseases referred to in Annex I and emerging diseases and they showed no disease symptoms or grounds for suspecting the presence of any of those diseases.

#### *Article 108*

#### **The hatching eggs of the consignment**

Consignments of hatching eggs of poultry shall only be permitted to enter the Union if they comply with the following requirements:

- (a) if the hatching eggs have been vaccinated against highly pathogenic avian influenza, guarantees for compliance with the minimum requirements for vaccination programmes and additional surveillance set out in Annex XIII, have been provided by the third country or territory of origin;
- (b) if the hatching eggs have been vaccinated against infection with Newcastle disease virus:
  - (i) guarantees have been provided by the competent authority of the third country or territory of origin that the vaccines used comply with the general and the specific criteria for vaccines against infection with Newcastle disease virus set out in point 1 of Annex XV;
  - (ii) the information set out in point 4 of Annex XV must be provided for the consignment;
- (c) the hatching eggs must be marked:
  - (i) using colour ink;
  - (ii) in the case of hatching eggs of poultry other than ratites, with a stamp indicating the unique approval number of the establishment of origin referred to in Article 106;
  - (iii) in the case of hatching eggs of ratites, with a stamp indicating the ISO code of the third country or territory of origin and the unique approval number of the establishment of origin referred to in Article 106;



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- (d) the hatching eggs must have been disinfected in accordance with the instructions of the competent authority of the third country or territory of origin.

#### *Article 109*

##### **Entry of hatching eggs into Member States with status free from infection with Newcastle disease virus without vaccination**

Consignments of hatching eggs intended for a Member State with status free from infection with Newcastle disease virus without vaccination, shall only be permitted to enter the Union if they:

- (a) are not vaccinated against infection with Newcastle disease virus;
- (b) originate from flocks which comply with the requirements set out in one of the following points:
- (i) they have not been vaccinated against infection with Newcastle disease virus;
- or
- (ii) they have been vaccinated against infection with Newcastle disease virus using an inactivated vaccine;
- or
- (iii) they have been vaccinated against infection with Newcastle disease virus using a live vaccine at the latest within the period of 60 days prior to the date of collection of the eggs.

#### *CHAPTER 3*

##### ***Specific animal health requirements for consignments of less than 20 hatching eggs of poultry other than ratites***

#### *Article 110*

##### **Derogations and special requirements for consignments of less than 20 hatching eggs of poultry other than ratites**

By way of derogation from Articles 101, 102, 106, 107 and 108, consignments of less than 20 hatching eggs of poultry other than ratites shall be permitted to enter the Union if they comply with the following requirements:

- (a) they come from establishments:
- (i) registered by the competent authority of the third country or territory of origin;
- (ii) where no confirmed case of infection with low pathogenic avian influenza viruses was reported within the period of 21 days prior to the date of collection of the hatching eggs;

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- (iii) within a 10 km radius of the establishments, including, where appropriate, the territory of a neighbouring country, there has been no outbreak of highly pathogenic avian influenza or infection with Newcastle disease virus for a period of at least 30 days prior to the date of collection of the hatching eggs;
- (b) in relation to vaccination against highly pathogenic avian influenza:
  - (i) the hatching eggs have not been vaccinated against highly pathogenic avian influenza;
  - (ii) where the flocks of origin have been vaccinated against highly pathogenic avian influenza, guarantees for compliance with the minimum requirements for vaccination programmes and additional surveillance set out in Annex XIII, have been provided by the third country or territory of origin;
- (c) in relation to vaccination against Newcastle disease virus, the hatching eggs have not been vaccinated against Newcastle disease virus and where the flock of origin has been vaccinated against infection with Newcastle disease virus:
  - (i) guarantees have been provided by the competent authority of the third country or territory of origin that the vaccines used comply either with:
    - the general and the specific criteria for vaccines against infection with Newcastle disease virus set out in point 1 of Annex XV,
    - or
    - the general criteria for recognised vaccines against infection with Newcastle disease virus set out in point 1 of Annex XV and the hatching eggs meet the animal health requirements set out in point 2 of Annex XV for poultry and hatching eggs originating from a third country or territory or zone thereof where vaccines used against infection with Newcastle disease virus do not meet the specific criteria set out in point 1 of Annex XV;
  - (ii) the information set out in point 4 of Annex XV must be provided for the consignment;
- (d) they come from flocks which have been subjected to a clinical inspection, carried out by an official veterinarian in the third country or territory or origin or zone thereof, within 24 hours prior to the time of loading of the consignments of hatching eggs for dispatch to the Union for the purpose of the detection of signs indicative of the occurrence of diseases, including the relevant listed diseases referred to in Annex I and emerging diseases and the flocks showed no disease symptoms or grounds for suspecting the presence of any of those diseases;
- (e) they come from flocks which:
  - (i) have been isolated on the establishment of origin for a period of at least 21 days prior to the collection of the eggs;
  - (ii) were found not to be infected or showed any grounds for suspecting any infection by the following agents, in tests performed in accordance with the requirements for testing of consignments of less than 20 heads of poultry other than ratites and less than 20 hatching eggs thereof prior to the entry into the Union, set out in Annex XVII:

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- *Salmonella Pullorum, Salmonella Gallinarum and Mycoplasma gallisepticum in case of Gallus gallus,*
- *Salmonella arizonae (serogroup O:18(k)), Salmonella Pullorum, Salmonella Gallinarum, Mycoplasma meleagridis and Mycoplasma gallisepticum in case of Meleagris gallopavo,*
- *Salmonella Pullorum and Salmonella Gallinarum in case of Numida meleagris, Coturnix coturnix, Phasianus colchicus, Perdix perdix, Anas spp.*

## CHAPTER 4

### ***Specific animal health requirements for specified pathogen-free eggs***

#### *Article 111*

#### **Derogation and special requirements for specified pathogen-free eggs**

By way of derogation from the residency period requirements of Article 98, the specific animal health requirements of Articles 105 to 110 and Articles 112 to 114, consignments of specified pathogen-free eggs which do not comply with the animal health requirements laid down in those provisions, shall be permitted to enter the Union if they comply instead with the following animal health requirements:

- (a) they originate from flocks which:
  - (i) are free from specified pathogens as described in the European Pharmacopoeia and the results of all tests and clinical examinations required for this specific status have been favourable, including negative testing results for highly pathogenic avian influenza, infection with Newcastle disease virus and infection with low pathogenic avian influenza viruses carried out within the period of 30 days prior to the date of collection of the eggs for dispatch to the Union;
  - (ii) have been clinically examined at least once a week as described in the European Pharmacopoeia and no disease symptoms or ground for suspecting the presence of any disease were detected;
  - (iii) have been kept for a period of at least 6 weeks prior to the date of collection of the eggs for dispatch to the Union in establishments which comply with the conditions described in the European Pharmacopoeia;
  - (iv) have had no contact with poultry not meeting the requirements of this Article or with wild birds for a period of at least 6 weeks prior to the date of collection of the eggs for dispatch to the Union;
- (b) they have been marked using colour ink with a stamp bearing the ISO code of the third country or territory of origin and the unique approval number of the establishment of origin;
- (c) they have been disinfected in accordance with the instructions of the competent authority of the third country or territory of origin.

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## CHAPTER 5

### ***Specific animal health requirements for movement and handling of hatching eggs of poultry after entry into the Union and of poultry hatched from those eggs***

#### *Article 112*

#### **Obligations on operators as regards handling of hatching eggs following their entry into the Union and of poultry hatched from those hatching eggs**

1 Operators at the establishment of destination shall place hatching eggs of poultry which have entered into the Union from a third country or territory or zone thereof either in:

a separate incubators, including separate hatchers, from other hatching eggs;

or

b incubators, including hatchers, where other hatching eggs are already present.

2 Operators, as referred to in paragraph 1, shall ensure that breeding poultry and productive poultry which have been hatched from hatching eggs referred to in that paragraph, are kept for a continuous period of time:

a in the hatchery for a period of at least 3 weeks from the date of hatching;

or

b on the establishments to which the poultry has been sent after hatching, either in the same Member State or in another Member State, for a period of at least 3 weeks from the date of hatching.

3 During the periods provided for in paragraph 2, operators shall keep poultry, which have been hatched from hatching eggs that have entered into the Union, separate from other flocks of poultry.

4 Where breeding poultry and productive poultry, which have been hatched from hatching eggs that have entered into the Union from a third country or territory or zone thereof, were introduced into premises or enclosures where other poultry are present, the relevant periods provided for in paragraph 2 shall commence from the date of introduction of the last bird and no poultry shall be moved from the premises or enclosures before the end of those periods.

5 Where hatching eggs of poultry, which have entered into the Union from a third country or territory or zone thereof, were introduced in incubators, including hatchers, where other hatching eggs were already present:

a the provisions of paragraphs 2 to 4 shall apply to all poultry hatched from the hatching eggs in the same incubator, including hatcher, as the hatching eggs which have entered into the Union from a third country or territory or zone thereof;

b the relevant periods referred to in paragraph 2 shall commence from the date of hatching of the last hatching egg that has entered into the Union from a third country or territory or zone thereof.

#### *Article 113*

#### **Sampling and testing following the entry into the Union**

The competent authority of the Member State of destination shall ensure that breeding poultry and productive poultry which have been hatched from hatching eggs that have

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entered into the Union from a third country or territory or zone thereof undergo a clinical examination carried out by an official veterinarian on the establishment of destination no later than the date of expiry of the relevant periods as provided for Article 112(2), and, where necessary, shall be sampled for testing to monitor their state of health.

#### *Article 114*

##### **Obligation on the competent authorities as regards sampling and testing of ratites from hatching eggs originating from a third country or territory or zone thereof not free from infection with Newcastle disease virus**

The competent authority of the Member State of destination shall ensure that ratites which have hatched from hatching eggs that have entered into the Union from a third country or territory or zone thereof that is not free from infection with Newcastle disease virus, during the periods provided for in Article 112(2):

- (a) they undergo a virus detection test for infection with Newcastle disease virus carried out by the competent authority on a cloacal swab or faeces sample from each ratite;
- (b) in the case of ratites destined for a Member State with status free from infection with Newcastle disease virus without vaccination, in addition to the requirements referred to in point (a), they are subjected to a serological test for infection with Newcastle disease virus carried out by the competent authority on each ratite;
- (c) all ratites shall have tested negative to the tests provided for in points (a) and (b) prior to their release from isolation.

#### *CHAPTER 6*

##### ***Specific animal health requirements for hatching eggs of captive birds***

#### *Article 115*

##### **The hatching eggs of the consignment**

Consignments of hatching eggs of captive birds shall only be permitted to enter the Union if they were obtained from captive birds which comply with the requirements for entry into the Union set out in Articles 55 to 58.

#### *CHAPTER 7*

##### ***Specific animal health requirements for movement and handling of hatching eggs of captive birds after entry into the Union and of captive birds hatched from those eggs***

#### *Article 116*

##### **Handling of hatching eggs of captive birds following their entry into the Union and of captive birds hatched from those hatching eggs**

Operators at the establishment of destination shall:

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- (a) place the hatching eggs of captive birds which have entered into the Union from a third country or territory or zone thereof in separate incubators, including hatchers, from other hatching eggs;
- (b) ensure that captive birds which are hatched from the hatching eggs of captive birds referred to in Article 115 are kept in an approved quarantine establishment in accordance with the requirements of Articles 59 to 61.

### TITLE 3

#### **ANIMAL HEALTH REQUIREMENTS FOR GERMINAL PRODUCTS OF ANIMALS OTHER THAN UNGULATES AND OTHER THAN HATCHING EGGS OF POULTRY AND CAPTIVE BIRDS INTENDED FOR CONFINED ESTABLISHMENTS**

##### *Article 117*

#### **Requirements for entry into the Union of consignments of germinal products of animals other than those referred to in point (a) and (b) of Article 1(4) dispatched from confined establishments**

Consignments of semen, oocytes and embryos of animals other than those referred to in point (a) and (b) of Article 1(4) dispatched from confined establishments listed in accordance with Article 29 shall only be permitted to enter the Union if they are dispatched to a confined establishment located in the Union and provided that:

- (a) an assessment has been carried out by the competent authority of the Member State of destination of the risks that the entry of those germinal products may present for the Union;
- (b) the donor animals of those germinal products originate from a third country, territory or zone authorised for entry into the Union of the particular species and category of animals;
- (c) the donor animals of those germinal products originate from a confined establishment in the third country, territory or zone of origin, which is included in a list established in accordance with Article 29 of confined establishments from which the entry of animals of specific species into the Union may be authorised;
- (d) the germinal products are destined to a confined establishment in the Union, which is approved in accordance with Article 95 of Regulation (EU) 2016/429;
- (e) the germinal products are transported directly to the confined establishment referred to in point (d).

##### *Article 118*

#### **Specific animal health requirements for donor animals**

Consignments of semen, oocytes and embryos referred to in Article 117 shall only be permitted to enter the Union if they were collected from donor animals which comply with the following requirements:

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- (a) they do not come from an establishment, nor have been in contact with animals from an establishment, situated in a restricted zone established due to the occurrence of a category A disease or of an emerging disease relevant for the species of those kept terrestrial animals;
- (b) they come from an establishment where no category D disease relevant for the species of those kept terrestrial animals has been reported for a period of at least the preceding 30 days;
- (c) they have remained in a single confined establishment of origin for a period of at least 30 days prior to the collection of the semen, oocytes or embryos intended for entry into the Union;
- (d) they have been clinically examined by the establishment veterinarian responsible for the activities of the confined establishment, and showed no disease symptoms on the day the semen, oocytes or embryos were collected;
- (e) as much as possible, they were not used for natural breeding during a period of at least 30 days prior to the date of first collection and during the period of collection of semen, oocytes or embryos intended for entry into the Union;
- (f) they are identified and registered in accordance with the rules of that confined establishment.

#### *Article 119*

#### **The requirements for germinal products**

Consignments of semen, oocytes and embryos referred to in Article 117 shall only be permitted to enter the Union if they comply with the following requirements:

- (a) they are marked in such a way that the following information can be readily established:
  - (i) the date of collection or production of those germinal products;
  - (ii) the species, where necessary subspecies, and identification of the donor animal(s);
  - (iii) the unique approval number of the confined establishment, which shall include the ISO 3166-1 alpha-2 code of the country in which the approval is granted;
  - (iv) any other relevant information;
- (b) they are transported in the container which:
  - (i) is sealed and numbered prior to the dispatch from the confined establishment by the establishment veterinarian responsible for the activities of the confined establishment;
  - (ii) has been cleaned and either disinfected or sterilised before use, or is single-use container;
  - (iii) has been filled in with the cryogenic agent which not have been previously used for other products.

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