

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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