



# Amendments to CDR (EU) 2020/686 and 2020/688 (horses)

DG SANTE/G2

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# 2020/686 – germinal products

# Outline

- Amendments related to **Bluetongue** and **EHD** (Articles 16,18 and 38; Chapters II and III of Part 5 of Annex II)
- Amendments related to **CEM** (Part 4 of Annex II)

# BTV and EHD: background

- A request from Member States and industry to exclude BTV and EHD from the category D diseases which must be absent in an establishment where donor animals are kept (including a semen collection centre), for at least 30 days in order to move germinal products to other Member States
- Vector born diseases with specific frequent testing regimes in the case the diseases are reported during a period of at least 60 days prior to and during collection of the semen, oocytes or embryos in a Member State or zone thereof
- BTV: re-categorisation from a category C+D+E disease to a category D+E disease (the requirements related to a country freedom and a country carrying out an eradication programme will cease to exist)

# BTV and EHD: proposed way forward

Amendment to CDR (EU) 2020/686 to:

switch from a double guarantee to a single guarantee approach:  
delete the establishment status approach with regard to BTV and EHD and keep only an individual animal status approach (making the following condition not applicable to BTV and EHD:

.....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.....

# BTV and EHD: Article 16 – establishment of origin of donors

Article 16 is amended as follows:

(a) point (d)(ii) is replaced by the following:

‘(ii) they have been kept in establishments where no category D diseases, **except infection with bluetongue virus (serotypes 1-24) and infection with haemorrhagic epizootic virus**, relevant for those animals have been reported;’;

(b) point (e) is replaced by the following:

‘(e) they showed neither symptoms nor clinical signs of any of the category D diseases referred to in point (d)(ii), **including infection with bluetongue virus (serotypes 1-24) and infection with haemorrhagic epizootic virus**, or of the emerging diseases on the day of collection of the semen, oocytes or embryos;’;

# BTV and EHD: Article 18 – quarantine accommodation and semen collection centre

Article 18 is amended as follows:

(a) point (a) is replaced by the following:

‘(a) they showed neither symptoms nor clinical signs of any of the category D diseases referred to in Article 16(d)(ii), **including infection with bluetongue virus (serotypes 1-24) and infection with haemorrhagic epizootic virus**, on the day of their admission to a semen collection centre;’;

(b) point (b)(i) is replaced by the following:

‘(i) none of the category D diseases, **except infection with bluetongue virus (serotypes 1-24) and infection with haemorrhagic epizootic virus**, relevant for the bovine, porcine, ovine or caprine animals has been reported for a period of at least the preceding 30 days;’;

(c) point (c)(i) is replaced by the following:

‘(i) during a period which comprises at least 30 days prior to date of collection and at least 30 days following the date of collection of the semen or, in the case of fresh semen, until the date of dispatch of the consignment of semen, none of the category D diseases, **except infection with bluetongue virus (serotypes 1-24) and infection with haemorrhagic epizootic virus**, relevant for bovine, porcine, ovine, caprine or equine animals have been reported.’;

# BTV and EHD: Article 38 — germinal products of animals of the families *Camelidae* and *Cervidae*

- point (g) related to EHD is deleted;
- point (k) is replaced by the following:  

‘(k) fulfil animal health requirements as regards infection with bluetongue virus (serotypes 1-24) and infection with epizootic haemorrhagic disease virus laid down in Chapters I and II of Part 5 of Annex II;’



# BTV – Annex II, Part 5, Chapter II

- Semen

- (i) point 1(a) is replaced by the following:
  - ‘(a) they have been kept for a period of at least 60 days prior to and during collection of the semen in a Member State or zone thereof where infection with bluetongue virus (serotypes 1-24) has not been reported for a period of at least the preceding 2 years withing a radius of 150 km of the establishment;’;
- (ii) point 1(b) is replaced by the following:
  - ‘(b) they have been kept for a period of at least 60 days prior and during collection of semen in a Member State or zone thereof seasonally free from infection with bluetongue virus (serotypes 1-24);’;

- Oocytes and embryos

- (iii) point 2(a) is replaced by the following:
  - ‘(a) they have been kept for a period of at least 60 days prior to and during collection of the oocytes or embryos in a Member State or zone thereof where infection with bluetongue virus (serotypes 1-24) has not been reported for a period of at least the preceding 2 years withing a radius of 150 km of the establishment;’;
- (iv) point 2(b) is replaced by the following:
  - ‘(b) they have been kept for a period of 60 days prior and during collection of the oocytes or embryos, in a Member State or zone thereof seasonally free from infection with bluetongue virus (serotypes 1-24);’;

Removal of references to a free Member State or zone and to the approved eradication programme

# EHD – Annex II, Part 5, Chapter III

- (i) the title is replaced by the following:  
‘Requirements for bovine, ovine and caprine animals and for animals of the families *Camelidae* and *Cervidae* as regards infection with the epizootic haemorrhagic disease virus’;
- (ii) point 1(d) is replaced by the following:  
‘(d) they have been subjected to a serological test to detect antibodies to infection with epizootic haemorrhagic disease virus, with negative results, ~~at least every 60 days throughout the collection period and~~ between 28 and 60 days from the date of the final collection of the semen;’.

# CEM: background

- Alignment with the Manual of Diagnostic Tests and Vaccines for Terrestrial of the Animals World Organisation Animal Health (WOAH), Chapter 3.6.2 on Contagious Equine Metritis (May 2022 version)
- For **PCR** testing it is not necessary to use **transport medium** to convey swabs to the laboratory and such swabs for PCR should be tested no more than **7 days** after sampling

# CEM: proposal

## Annex II, Part 4, Chapter I, **semen**

The specimens subject to culture shall be placed in a transport medium with activated charcoal, such as Amies medium, before being dispatched to the laboratory.

The specimens shall be subjected to at least one of the following tests:

- culture under microaerophilic conditions for a period of at least 7 days for the isolation of *Taylorella equigenitalis*, set up within 24 hours from the time of taking the specimens from the donor animal, or 48 hours where the specimens are kept cool during transport;
- or
- PCR or real-time PCR for the detection of genome of *Taylorella equigenitalis*, carried out within ~~48 hours~~ 7 days from the time of taking the specimens from the donor animal';

## Annex II, Part 4, Chapter II, **oocytes and embryos**

The specimens referred to in point (i) below shall be placed in a transport medium with activated charcoal, such as Amies medium, before being dispatched to the laboratory.

The specimens shall be subjected to at least one of the following tests:

- (i) culture under microaerophilic conditions for a period of at least 7 days for the isolation of *Taylorella equigenitalis*, set up within 24 hours from the time of taking the specimens from the donor animal, or 48 hours where the specimens are kept cool during transport;
- or
- (ii) PCR or real-time PCR for the detection of genome of *Taylorella equigenitalis*, carried out within 7 days ~~48 hours~~ from the time of taking the specimens from the donor animal.';

# 2020/688 – new Article 69a

# Background

- Operators moving their registered equine animals from one establishment to another, both located in the territory of the same Member State, but passing through another Member State
- Routes logistically more suitable
- A request from a MS to use Article 144(a)(iv) of AHL

# Proposal — derogation from certification requirements

- Compliance with the general requirements laid down in **Article 124 of AHL** (preventive measures not to spread diseases; registration and identification requirements)
- Compliance with the diseases prevention measures in relation to transport laid down in **Article 125 of AHL** and in **Articles 4, 5 and 6(2) of CDR (EU) 2020/688**
- **The authorisation** by the Member State of passage
- The Commission, the other Member States and the public **informed** (by the MS of passage)
- During the passage registered equine animals:
  - physically separated from equine animals of the Member State of passage (direct movement)
  - accompanied with **a self-declaration document** issued by the operator
  - show no disease symptoms



***Derogation for movements of registered equine animals passing through another Member State to reach their place of destination in Member State of origin***

1. By way of derogation from animal health certification requirements laid down in Article 143(1) of Regulation (EU) 2016/429, the operators may move registered equine animals 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 provided that they are accompanied during the movement by a self-declaration document issued by the operator demonstrating the following:
    - (a) the registered equine animals fulfil at least the animal health requirements laid down in Article 124 of Regulation (EU) 2016/429;
    - (b) the registered equine animals show no disease symptoms on the day of the movement;
    - (c) the operator ensured that the transport conditions fulfil at least the animal health requirements laid down in Article 125 of Regulation (EU) 2016/429 and in Articles 4, 5 and 6(2) of this Regulation;
    - (d) the operator has taken the necessary measures to ensure that the registered equine animals are consigned directly to their place of destination without contact with other equine animals while in the Member State of passage;
  2. (e) the following information concerning the movement must be included in the self declaration document:
    - (i) the address and registration number of the establishment of dispatch;
    - (ii) the address and registration number of the establishment of destination;
    - (iii) the date of the movement;
    - (iv) the species of registered equine animals moved;
    - (v) the unique codes of registered equine animals moved;
    - (f) the operator is aware that the authorisation of the Member State of passage referred to in paragraph 2 is applicable and exists for the time of the movement.
- The competent authority of the Member State of passage has informed the Commission, the other Member States and the public that such movements are authorised.;



Questions, comments?