CHAPTER 63: MODEL ANIMAL HEALTH CERTIFICATE FOR ENTRY INTO THE UNION OF CONSIGNMENTS OF OOCYTES AND EMBRYOS OF EQUINE ANIMALS COLLECTED OR PRODUCED, PROCESSED AND STORED IN ACCORDANCE WITH REGULATION (EU) 2016/429 AND DELEGATED REGULATION (EU) 2020/692 AFTER 20 APRIL 2021, DISPATCHED BY THE EMBRYO COLLECTION OR PRODUCTION TEAM BY WHICH THE OOCYTES OR EMBRYOS WERE COLLECTED OR PRODUCED (MODEL 'EQUI-OOCYTES-EMB-A-ENTRY')

COUNTRY UNITED STATES				Animal health certificate to the EU		
Part I: Description of consignment	I.1	**Consignor/Exporter** Name Address Country ISO country code		I.2	**Certificate reference**	I.2a **IMSOC reference**
				I.3	**Central Competent Authority**	**QR CODE**
				I.4	**Local Competent Authority**	
	I.5	**Consignee/Importer** Name Address Country ISO country code		I.6	**Operator responsible for the consignment** Name Address Country ISO country code	
	I.7	**Country of origin** ISO country code		I.9	**Country of destination** ISO country code	
	I.8	**Region of origin** Code		I.10	**Region of destination** Code	
	I.11	**Place of dispatch** Name Registration/Approval No Address Country ISO country code		I.12	**Place of destination** Name Registration/Approval No Address Country ISO country code	
	I.13	**Place of loading**		I.14	**Date and time of departure**	
	I.15	**Means of transport** ☐ Aircraft ☐ Vessel ☐ Railway ☐ Road vehicle Identification		I.16	**Entry Border Control Post**	
				I.17		
	I.18	**Transport conditions**	☐ Ambient	☐ Chilled	☐ Frozen	
	I.19	**Container number/Seal number** Container No Seal No				
	I.20	**Certified as or for**				
		☐ Germinal products				
	I.21	☐ **For transit** Third country ISO country code		I.22	☐ **For internal market**	
				I.23		

I.24 Total number of packages	I.25 Total quantity	I.26

I.27 Description of consignment

CN code	Species	Subspecies/Category	Identification number	Quantity

Type	Approval or registration number of plant/establishment/centre	Identification mark	Date of collection/production	Test

COUNTRY UNITED STATES **Certificate model EQUI-OOCYTES-EMB-A-ENTRY**

Part II: Certification

II. Health information | **II.a Certificate reference** | **II.b IMSOC reference**

I, the undersigned official veterinarian, hereby certify that:

II.1. The oocytes[(1)]/ *in vivo* derived embryos[(1)]/ *in vitro* produced embryos[(1)]/ micromanipulated embryos[(1)] described in Part I are intended for artificial reproduction and were obtained from donor animals which originate

II.1.1. from a third country, territory or zone thereof

II.1.1.1. authorised for entry into the Union of oocytes[(1)]/ embryos[(1)] of equine animals and listed in Annex XII to Commission Implementing Regulation (EU) 2021/404;

II.1.1.2. in which African horse sickness, Venezuelan equine encephalomyelitis, infection with *Burkholderia mallei* (glanders), surra (*Trypanosoma evansi*), dourine (*Trypanosoma equiperdum*), equine infectious anaemia, infection with rabies virus, anthrax, infection with equine arteritis virus and contagious equine metritis (*Taylorella equigenitalis*) are notifiable diseases;

II.1.1.3. free from African horse sickness for a period of at least 24 months immediately prior to collection[(1)]/ production[(1)] of the oocytes[(1)]/ embryos[(1)] and until their date of dispatch in accordance with Article 22(2)(a) of Commission Delegated Regulation (EU) 2020/692, and where no systematic vaccination against African horse sickness has been carried out for a period of at least 12 months immediately prior to collection[(1)]/ production[(1)] of the oocytes[(1)]/ embryos[(1)] and until their date of dispatch in accordance with Article 22(4)(b) of that Regulation;

II.1.1.4. where Venezuelan equine encephalomyelitis was not reported for a period of at least 24 months immediately prior to collection[(1)]/ production[(1)] of the oocytes[(1)]/ embryos[(1)] and until their date of dispatch;

II.1.2. from an establishment in a third country, territory or zone thereof

[(1)]*either* [II.1.2.1. where infection with *Burkholderia mallei* (glanders) was not reported for a period of at least 36 months immediately prior to collection[(1)]/ production[(1)] of the oocytes[(1)]/ embryos[(1)] and until their date of dispatch;]

[(1)]*or* [II.1.2.1. where infection with *Burkholderia mallei* (glanders) was not reported for a period of at least 6 months immediately prior to collection[(1)]/ production[(1)] of the oocytes[(1)]/ embryos[(1)] and until their date of dispatch, and the Commission has recognised the surveillance programme carried out in breeding equine animals in the establishment of origin to demonstrate absence of infection during that period of 6 months;]

[(1)]*either* [II.1.2.2. where dourine not reported for a period of at least 24 months immediately prior to collection[(1)]/ production[(1)] of the oocytes[(1)]/ embryos[(1)] and until their date of dispatch;]

[(1)]*or* [II.1.2.2. where dourine was not reported for a period of at least 6 months immediately prior to collection[(1)]/ production[(1)] of the oocytes[(1)]/ embryos[(1)] and until their date of dispatch, and the Commission has recognised the surveillance programme carried out in breeding equine

animals in the establishment of origin to demonstrate absence of infection during that period of 6 months;]

[(1)*either* [II.1.2.3. where surra (*Trypanosoma evansi*) was not reported for a period of at least 24 months immediately prior to collection(1)/ production(1) of the oocytes(1)/ embryos(1) and until their date of dispatch;]

[(1)*or* [II.1.2.3. where surra (*Trypanosoma evansi*) was not reported for a period of at least 6 months immediately prior to collection(1)/ production(1) of the oocytes(1)/ embryos(1) and until their date of dispatch, and the Commission has recognised the surveillance programme carried out in breeding equine animals in the establishment of origin to demonstrate absence of infection during that period of 6 months.]

II.2. The oocytes(1)/ embryos(1) described in Part I were obtained from donor animals which originate from establishments

II.2.1. in which surra (*Trypanosoma evansi*) has not been reported during the period of the preceding 30 days prior to collection(1)/ production(1) of the oocytes(1)/ embryos(1), and

[(1)*either* [surra has not been reported in the establishment during the period of the preceding 2 years prior to collection(1)/ production(1) of the oocytes(1)/ embryos(1);]

[(1)*or* [surra has been reported in the establishment during the period of the preceding 2 years prior to collection(1)/ production(1) of the oocytes(1)/ embryos(1) and following the last outbreak the establishment has remained under movement restrictions

[(1)*either* [until the remaining animals in the establishment have been subjected to a test for surra with one of the diagnostic methods provided for in Part 3 of Annex I to Commission Delegated Regulation (EU) 2020/688, carried out, with negative results, on samples taken at least 6 months after the last infected animal has been removed from the establishment;]]

[(1)or [for at least 30 days from the date of cleaning and disinfection after the last animal of listed species on the establishment was either killed and destroyed or slaughtered.]]

II.2.2. in which dourine has not been reported during the period of the preceding 6 months prior to collection(1)/ production(1) of the oocytes(1)/ embryos(1), and

[(1)*either* [dourine has not been reported in the establishment during the period of the preceding 2 years prior to collection(1)/ production(1) of the oocytes(1)/ embryos(1);]

[(1)*or* [dourine has been reported in the establishment during the period of the preceding 2 years prior to collection(1)/ production(1) of the oocytes(1)/ embryos(1) and following the last outbreak, the establishment has remained under movement restrictions

[(1)*either* [until the remaining equine animals in the establishment, except castrated male equine animals, have been subjected to a test for dourine with the diagnostic method provided for in Part 8 of Annex I to Delegated Regulation (EU) 2020/688, carried out, with negative results, on samples taken at least 6 months after the infected animals have been killed and destroyed or slaughtered, or the infected entire male equine animals have been castrated;]]

[(1)*or* [for at least 30 days after the last equine animal on the establishment was either killed and destroyed or slaughtered, and the premises were cleaned and disinfected;]]

II.2.3. in which equine infectious anaemia has not been reported during the period of the preceding 90 days prior to collection(1)/ production(1) of the oocytes(1)/ embryos(1), and

[(1)*either* [equine infectious anaemia has not been reported on the establishment during the period of the preceding 12 months prior to collection(1)/ production(1) of the oocytes(1)/ embryos(1);]

[(1)*or* [equine infectious anaemia has been reported on the establishment during the period of the preceding 12 months prior to collection(1)/ production(1) of the oocytes(1)/ embryos(1) and following the last outbreak the establishment has remained under movement restrictions

[(1)*either* [until the remaining equine animals in the establishment have been subjected to a test for equine infectious anaemia with the diagnostic method provided for in Part 9 of Annex I to Delegated Regulation (EU) 2020/688, carried out, with negative results, on samples taken on two occasions with a minimum interval of 3 months after the infected animals have been killed and destroyed or slaughtered and the establishment was cleaned and disinfected.]]

[1]*or* [for at least 30 days after the last equine animal on the establishment was either killed and destroyed or slaughtered, and the premises were cleaned and disinfected.]]

[1][II.3. The *in vivo* derived embryos described in Part I have been collected, processed and stored, and dispatched by the embryo collection team[2] which

II.3.1. is approved and listed by the competent authority of the third country or territory;

II.3.2. complies with requirements as regards responsibilities, operational procedures, facilities and equipment set out in Part 2 of Annex I to Commission Delegated Regulation (EU) 2020/686.]

[1][II.3. The oocytes[1]/ *in vitro* produced embryos[1]/ micromanipulated embryos[1] described in Part I have been collected or produced, processed and stored, and dispatched by the embryo production team[2] which

II.3.1. is approved and listed by the competent authority of the third country or territory;

II.3.2. complies with requirements as regards responsibilities, operational procedures, facilities and equipment set out in Parts 2 and 3 of Annex I to Delegated Regulation (EU) 2020/686.]

II.4. The oocytes[1]/ embryos[1] described in Part I were obtained from donor animals which

II.4.1. were not vaccinated against African horse sickness at least in the last 40 days prior to collection[1]/ production[1] of the oocytes[1]/ embryos[1];

II.4.2. were not vaccinated against Venezuelan equine encephalomyelitis at least in the last 60 days prior to collection[1]/ production[1] of the oocytes[1]/ embryos[1];

II.4.3. remained for a period of at least 3 months prior to the date of collection[1]/ production[1] of the oocytes[1]/ embryos[1] in a third country or territory or zone thereof referred to in Box I.7.;

II.4.4. for a period of at least 30 days prior to the date of collection[1]/ production[1] of the oocytes[1]/ embryos[1] and during the collection period

II.4.4.1. were kept on establishments not situated in a restricted zone established due to the occurrence of African horse sickness, infection with *Burkholderia mallei* (glanders) or of an emerging disease relevant for equine animals;

II.4.4.2. were kept on establishments where Venezuelan equine encephalomyelitis, dourine, surra (*Trypanosoma evansi*), equine infections anaemia, contagious equine metritis (*Taylorella equigenitalis*), infection with rabies virus and anthrax have not been reported;

II.4.4.3. were not in contact with animals from establishments situated in a restricted zone due to the occurrence of diseases referred to in point II.4.4.1. or from establishments which do not meet the conditions referred to in point II.4.4.2.;

II.4.5. were not used for natural breeding during a period of at least 30 days prior to the date of the collection of the oocytes[1]/ embryos[1] and between the date on which the first samples referred to in points II.4.8.1. and II.4.8.2. were taken and the date of the collection of the oocytes[1]/ embryos[1];

II.4.6. were examined by the team veterinarian or a team member and did not show symptoms or clinical signs of transmissible animal diseases on the day of collection[1]/ production[1] of the oocytes[1]/ embryos[1];

II.4.7. are individually identified as provided for in Article 21(2) of Delegated Regulation (EU) 2020/692;

II.4.8. have been subjected to the following tests, referred to in points 2(b) and (c) of Chapter II of Part 4 of Annex II to Delegated Regulation (EU) 2020/686, as follows:

[3][II.4.8.1. for equine infectious anaemia (EIA), an agar-gel immuno-diffusion test (AGID or Coggins test) or an enzyme-linked immunosorbent assay (ELISA) with a negative result carried out on a blood sample taken on …….[4], being not less than 14 days following the date of commencement of the period referred to in point II.4.5, and the test was last carried out on a blood sample taken on ……[4]; being not more than 90 days prior to the date of the collection of the oocytes[1]/embryos[1] intended for entry into the Union;]

II.4.8.2. for contagious equine metritis (CEM), an agent identification test carried out with a negative result on at least two specimens (swabs) taken during the period referred to in point II.4.5. from at least the mucosal surfaces of the clitoral fossa and the clitoral sinuses of the donor mare

[(1)]*either* [II.4.8.2.1. on two occasions with an interval of not less than 7 days on……[(4)] and on……..[(4)], in the case of isolation of *Taylorella equigenitalis* after cultivation under microaerophilic conditions for a period of at least 7 days, set up within 24 hour period after taking the specimens from the donor animal, or 48 hour period where the specimens are kept cool during transport.]

[(1)]*and/or* [II.4.8.2.2. on one occasion on……..[(4)], in the case of detection of genome of *Taylorella equigenitalis* by a polymerase chain reaction (PCR) or real-time PCR, carried out within 48 hour period after taking the specimens from the donor animal.]

The samples referred to in points II.4.8.2.1. and II.4.8.2.2. were in no case taken earlier than 7 days (systemic treatment) or 21 days (local treatment) after antimicrobial treatment of the donor mare and were placed in transport medium with activated charcoal, such as Amies medium, before dispatch to the laboratory.

II.5. The oocytes[(1)]/ embryos[(1)] described in Part I

II.5.1. has been collected, processed and stored in accordance with animal health requirements set out in Part 2[(1)]/Part 3[(1)]/Part 4[(1)]/Part 5[(1)] and Part 6 of Annex III to Delegated Regulation (EU) 2020/686;

II.5.2. are placed in straws or other packages on which the mark is applied in accordance with requirements provided for in Article 83(a) of Delegated Regulation (EU) 2020/692 and that mark is indicated in Box I.27;

II.5.3. are transported in a container which:

II.5.3.1. was sealed and numbered prior to the dispatch by the embryo collection or production team under responsibility of the team veterinarian, or by an official veterinarian, and the seal bears the number as indicated in Box I.19;

II.5.3.2. has been cleaned and either disinfected or sterilised before use, or is single-use container;

[(1)(5)][II.5.3.3. has been filled in with the cryogenic agent which not have been previously used for other products.]

[(1)(6)][II.5.4. are placed in straws or other packages which are securely and hermetically sealed;

II.5.5. are transported in a container where they are separated from each other by physical compartments or by being placed in secondary protective bags.]

[(1)(7)][II.6. The *in vivo* derived embryos[(1)]/ *in vitro* produced embryos[(1)]/ micromanipulated embryos[(1)] described in Part I were conceived by artificial insemination using semen coming from a semen collection centre, germinal product processing establishment or germinal product storage centre approved for the collection, processing and/or storage of semen by the competent authority of a third country, territory or zone thereof listed in Annex XII to Implementing Regulation (EU) 2021/404 for semen of equine animals or by the competent authority of a Member State[(8)].]

[(1)(9)][II.7. The following antibiotic or mixture of antibiotics[(10)] has been added to the collection, processing, washing or storage media: ……]

Notes

This certificate is intended for entry into the Union of oocytes and embryos of equine animals, including when the Union is not the final destination of the oocytes and embryos.

In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland / Northern Ireland in conjunction with Annex 2 to that Protocol, references to European Union in this certificate include the United Kingdom in respect of Northern Ireland.

This animal health certificate shall be completed according to the notes for the completion of certificates provided for in Chapter 4 of Annex I to Commission Implementing Regulation (EU) 2020/2235.

Part I:

Box reference I.11: "*Place of dispatch":* Indicate the unique approval number and the name and address of the embryo collection or production team of dispatch of the consignment of oocytes or embryos. Only embryo collection or production teams listed in accordance with Article

233(3) of Regulation (EU) 2016/429 on the Commission website: https://ec.europa.eu/food/animals/semen/equine_en

Box reference I.12: "*Place of destination":* Indicate the address and unique registration or approval number of the establishment of destination of the consignment of oocytes or embryos.

Box reference I.19: Seal number shall be indicated.

Box reference I.24: Total number of packages shall correspond to the number of containers.

Box reference I.27: "*Type":* Specify if *in vivo* derived embryos, *in vivo* derived oocytes, *in vitro* produced embryos or micromanipulated embryos.

"Identification number": Indicate identification number of each donor animal.

"Identification mark": Indicate mark on the straw or other packages where oocytes or embryos of the consignment are placed.

"Date of collection/production": Indicate the date on which oocytes or embryos of the consignment were collected or produced.

"Approval or registration number of plant/establishment/centre": Indicate the unique approval number of the embryo collection or production team by which the oocytes or embryos were collected or produced.

"Quantity": Indicate number of straws or other packages with the same mark.

Part II:

(1) Delete if not applicable.

(2) Only embryo collection or production teams listed in accordance with Article 233(3) of Regulation (EU) 2016/429 on the Commission website: https://ec.europa.eu/food/animals/semen/equine_en.

(3) The agar gel immunodiffusion test (AGID or Coggins test) or the ELISA for equine infectious anaemia are not required for donor equine animals which have continuously resided in Iceland since birth, provided that Iceland has remained officially free of equine infectious anaemia and no equine animals and their semen, ova and embryos have been introduced into Iceland from outside prior to and during the period the ova or embryos were collected and the semen was used for fertilisation.

(4) Insert date in the following format: dd.mm.yyyy.

(5) Applicable for frozen oocytes or embryos.

(6) Applicable for the consignment where in one container oocytes, *in vivo* derived embryos, *in vitro* produced embryos and micromanipulated embryos of equine animals are placed and transported.

(7) Does not apply to oocytes.

(8) Only a semen collection centre, germinal product processing establishment or germinal product storage centre listed on the Commission websites:

- a third country, territory or zone thereof: https://ec.europa.eu/food/animals/live_animals/approved-establishments_en
- of a Member State: https://ec.europa.eu/food/animals/semen/equine_en

(9) Mandatory attestation in case antibiotics were added.

(10) Insert the name(s) of the antibiotic(s) added and its(their) concentration.

Official veterinarian

Name (in capital letters)

Date Qualification and title

Stamp Signature