Verenigde Staten, Paardenembryo's

Code: **PRDEU-01** Versie: 1.0.2

Ingangsdatum: 01-04-2024

Eigenaar: NVWA O&O, Team Export

Versie	Datum	Wijziging ten opzichte van vorige versie
1.0.1	13-05-2019	In mei 2019 is de instructie geactualiseerd. Het gaat om niet-inhoudelijke aanpassingen. Daarnaast is aangegeven dat het certificaat nog niet opgenomen is in e-CertNL.
1.0.2	01-04-2024	Aanpassing ten gevolge van wijzigingen in de Regeling erkenning veterinaire laboratoria (REVL).

1 DOEL EN TOEPASSINGSGEBIED

Deze instructie geldt voor het exporteren van paardenembryo's naar de USA. De instructie beschrijft de voorwaarden die gelden voor de invoer in de USA, de controles die de NVWA hiervoor moet uitvoeren, en de gegevens die het bedrijfsleven moet aanleveren aan de NVWA.
Over de certificeringseisen die gelden voor de export van paardenembryo's naar de USA zijn officiële bilaterale afspraken gemaakt tussen de EU en de USA. Deze afspraken zijn bindend, van deze afspraken kan dus niet worden afgeweken.

2 WETTELIJKE BASIS

2.1 EU-regelgeving
- Richtlijn 92/65/EEG

2.2 Nationale wetgeving
- Gezondheids- en welzijnswet voor dieren, artikel 79
- Regeling handel levende dieren en levende producten

2.3 Overige
- Afspraken gemaakt tussen de Europese Unie en de USA.

3 DEFINITIES

Begrip	**Definitie**
Embryoteam	Een officieel erkende groep technici of organisatievorm onder toezicht van een teamdierenarts, bevoegd om zich met de verzameling, behandeling en opslag van embryo's te belasten.
Teamdierenarts	De dierenarts die verantwoordelijk is voor het toezicht op een embryoteam.

4 WERKWIJZE

De certificering van paardenembryo's naar USA is toegestaan.

4.1 Paardenembryo's

- *Certificaat: zie bijlage 1*

Algemeen:
Certificering van paardenembryo's verloopt via het systeem e-CertNL. Voor paardenembryo's naar de USA geldt dat er nog geen certificaat beschikbaar is, omdat er al langere tijd geen vraag was naar dit certificaat. Er dient daarom voor het exporteren van paardenembryo's naar de USA alsnog een e-CertNL certificaat samengesteld te worden. Houdt u dus rekening met extra verwerkingstijd en maak uw voornemen tijdig kenbaar via export@nvwa.nl .

Diagnostische laboratoriumtesten dienen te worden uitgevoerd door een laboratorium welk conform het werkvoorschrift K-O&O-IE-WV05 is toegestaan.

Hoofdstuk D, "Health Certification", is onderverdeeld in twee "Sections": Section A en Section B. Section A moet worden ondertekend door de teamdierenarts. Tegelijkertijd geldt deze (getekende) Section A ook als basis waarop de officiële NVWA-dierenarts het gehele certificaat kan ondertekenen.

Algemeen:
Voor de certificering geldt dat erkende embryoteams opereren onder verantwoordelijkheid van een teamdierenarts op wiens naam de erkenning rust. De erkenning is gebaseerd op Richtlijn 92/65/EEG, bijlage D, hoofdstuk III. Hierin staan de voorwaarden voor laboratorium, materiaal en productieomstandigheden vermeld. Onderstaande verklaringen kunnen daarom worden afgegeven voor erkende embryoteams op basis van EU-regelgeving en als het team in het bezit is van een goedgekeurd VS-embryoproductieprotocol (want in de Europese regelgeving zijn de onderstaande eisen slechts gedeeltelijk opgenomen. Met name de eis betreffende scheiding in tijd met bewerking van niet VS-waardige embryo's, ongediertebestrijding en constructie van het laboratorium).

Section A
Dit gedeelte moet worden ondertekend door de teamdierenarts.

Section B
Dit gedeelte moet worden ondertekend door de certificerende dierenarts van de NVWA.

Verklaring 13.1.1.:
Afrikaanse paardenpest is aangifteplichtig. Deze verklaring is af te geven na controle van de dierziektesituatie. Informatie over de dierziektesituatie is hier te vinden.
De USDA heeft echter haar eigen lijst over de dierziektesituatie in andere landen, die bij twijfel geraadpleegd moet worden. Zie:
http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_ahs.shtml Als men deze opent krijgt men een overzicht van landen die volgens de USDA geïnfecteerd zijn met AHS.

Verklaring 13.1.2.:
Deze verklaring kan worden afgegeven op basis van EU- en nationale regelgeving.

Verklaring 13.2:
De inrichtingen voor spermawinning en embryocollectie moeten erkend zijn op basis van de Richtlijn 92/65/EEG, bijlage D, Hoofdstuk III.

Verklaring 13.3:
Deze verklaring kan na controle worden afgegeven.

Verklaring 13.4:
Deze verklaring bij een erkende inrichting op basis van EU- en nationale regelgeving worden afgegeven.

Verklaring 13.5:
Deze verklaring kan na controle worden afgegeven.

Verklaring 13.6:
Deze verklaring kan op basis van EU- en nationale regelgeving worden afgegeven.

Verklaring 13.7:
Het eerste deel van deze verklaring kan op basis van het goedgekeurd VS-embryo-productieprotocol worden afgegeven (zie algemeen).
Het tweede deel van deze verklaring kan na controle worden afgegeven.

Verklaring 13.8:
Deze verklaring kan worden afgegeven, als de data op de importpermit overeenkomen met de data die in hoofdstuk B zijn opgenomen.

5 BEVOEGDHEDEN EN VERANTWOORDELIJKHEDEN

De certificerend NVWA-dierenarts is bevoegd en verantwoordelijk voor het afgeven van het certificaat.
De teamdierenarts is bevoegd voor het ondertekenen van deel A van het certificaat.

Bijlage 1: certificaat paardenembryo's

Health certificate No:

HEALTH CERTIFICATE FOR EXPORT OF NON-MICROMANIPULATED EQUINE EMBRYOS INTO THE UNITED STATES OF AMERICA FROM COUNTRIES AFFECTED WITH CONTAGIOUS EQUINE METRITIS	
1. EU Member State of provenance and competent authority.	2. Health certificate No.
A. ORIGIN OF EMBRYOS	
3. **Approval number of the embryo collection/production team**:	
4. Name and address of the embryo collection/production team:	5. Name and address of the consignor
6. Country and place of loading	7. Means of transport
B. DESTINATION OF EMBRYOS	
8.1. Name and address of the consignee: 8.2. Port of entry into the United States:	
C. IDENTIFICATION OF THE EMBRYOS	
9. Identification of straws (Freeze Code):	

9.1. Identification mark	9.2. Number	9.3. Date of collection	9.4. Place of colletion

10. Seal number of container:

Health certificate No:

D. HEALTH INFORMATION
Section A (to be signed by the Team Veterinarian**)**
11. I the undersigned, Team Veterinarian of the described embryo collection team, hereinafter "ECT/EPT", certify that:
11.1. Prior to the collection of the embryos covered by this certificate, the donor mare 11.1.1. has been in the exporting country no less than 60 days ; 11.1.2. has resided at the holding of origin no less than 30 days, and 11.1.2.1. this holding has been free for no less than six months from dourine, glanders and equine infectious anemia (EIA), and 11.1..2.2.during the six months, no clinical signs of contagious equine metritis (CEM) have been detected in equidae kept on the holding.
11.2. The donor mare 11.2.1. has not been used for natural breeding for a period of no less than 60 days prior to the collection of embryos, 11.2.2. has been free from any quarantine or movement restrictions for a period of no less than 60 days prior to collection of embryos, 11.2.3. was in the centre isolated from equidae not certified and tested to the same standards under the supervision of the team veterinarian, 11.2.4. was subjected to the following health tests while in isolation 11.2.4.1. a complement fixation test for dourine carried out with negative results at a dilution of 1 in 5 on samples taken within 30 days after entry into isolation and at 180 day intervals, if it remains in supervised isolation, and 11.2.4.2. a culture test for CEM carried out on culture specimens taken from the mucosal surfaces of the clitoral fossa and clitoral sinuses on three separate occasions, with at least 72 hours between collections, and during one of these specimen collections, an additional culture specimen taken from the endometrium, all with negative results after a cultivation of 7 to 14 days, 11.2.5. was inspected on the date of the collection of the embryos covered by the certificate and was found free of clinical signs of contagious and infectious diseases.
11.3. The embryos covered by this certificate comply with the following processing conditions: 11.3.1. the laboratory processing the embryos is protected against rodents and insects and is constructed with materials which permit effective cleaning and disinfecting and is cleansed and disinfected following each embryo processing; 11.3.2. while embryos for the export to the United States are being handled prior to storage, no embryos of a lesser health status were processed, 11.3.3. during collection and processing of the embryos, any biological product of animal origin used in media or solutions for collection, washing, or storage is free of pathogenic microorganisms, and equipment is either new, disposable and discarded after use or has been sterilized prior to use by approved methods according to the Manual of the International Embryo Transfer Society, third edition (IETS Manual). Fetal bovine serum or serum albumin was sourced from Canada, the United States, Australia, or New Zealand, or has undergone irradiation treatment prior to use; 11.3.4. the embryos were washed according to the IETS Manual and enzymatic (trypsin) treatment was not used, 11.3.5. only embryos from the same flush were washed together, 11.3.6. following washing, each embryo was examined over the entire surface at not less than 50x magnification, found to have an intact zona pellucida, and found to be free from adherent material.

	The embryos covered by this certificate comply with the following storage and shipping conditions: following washing and microscopic examination, they were either processed for immediate shipment or were sealed in straws, frozen in virgin liquid nitrogen, and stored in virgin liquid nitrogen, frozen embryos were stored separately from any embryos not collected for shipment to the United States, straws contain only embryos obtained from the same donor, and have been identified in accordance with the IETS Manual.

	The embryos covered by this certificate were conceived as a result of artificial insemination of the donor mare or by fertilization of oocytes collected from the donor mare with semen: originating from a semen collection centre ("SCC"), that is approved or licensed by the national veterinary authorities in the Member State of origin as a SCC for export of equine semen to the United States; collected from a donor stallion that complies, based on supporting documentation, with the animal health requirements for export of fresh/chilled/frozen semen to the United States, and in particular, with the following requirements: the stallion was isolated from equidae not certified and tested to the same standards, the stallion was not used for natural breeding during at least 60 days prior to the collection of the semen, the stallion was tested:
11.5.2.3.1	with a complement fixation test for dourine with negative results at a dilution of 1 in 5 within 30 days after entry into isolation and at 180 days interval, if it remains in the supervised isolation, and
11.5.2.3.2	for 5 consecutive days, the prepuce, penis and urethral sinus of the stallion has been aseptically cleaned and washed with a solution of not less than 0,2 percent chlorhexidine while in full erection. The entire penile area was then thoroughly coated with an antibiotic ointment effective against CEM agent.
11.5.2.3.3	beginning no fewer than 7 days after the last consecutive day of cleaning, a culture of CEM was carried out during isolation on culture specimens taken from the surfaces of the prepuce, urethral sinus, fossa glandis, and diverticulum of the fossa glandis on three separate occasions, with at least 72 hours between collections, all with negative results after a cultivation of 7 to 14 days, and
11.5.2.3.4	the procedure and tests described above were performed under the supervision of a veterinarian.

12.1. Date and place	12.2. Name and qualification of the Team Veterinarian	12.3. Signature and stamp of the Team Veterinarian

Health certificate No:

Section B (to be signed by the Official Veterinarian after the Team Veterinarian has signed)

13.	I, the undersigned Official Veterinarian of The Netherlands certify that:
13.1.	the Member State in which the embryos were collected,
13.1.1.	is not considered by the USDA to be affected with African horse sickness (AHS) in accordance with the list of USDA-recognized animal health status of countries/areas regarding specific livestock or poultry diseases, as last amended. (http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_ahs.shtml)
13.1.2.	has import procedures in place to ensure that horses infected with AHS are not entered into the country;
13.2.	the ECT/EPT is approved by the competent authority of the Member State where the embryos were collected;
13.3.	the Team Veterinarian that completed Section A of this certificate is authorized by the National Veterinary Service to perform this service,
13.4.	the processing laboratory is under the direct supervision of the team veterinarian, and is subjected to regular inspection by the national veterinary services,
13.5.	the laboratory tests mentioned in 11.2.4.1., 11.2.4.2., 11.5.2.3.1. and 11.5.2.3.3. were carried out with the required negative results in laboratories approved by the competent veterinary services;
13.6.	health tests required for export to the United States of equine embryos were performed by testing methods recognized by the Office International des Epizooties (OIE) Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, as acceptable for international trade;
13.7.	the embryos were maintained in the custody of the team veterinarian and stored separately from any embryos not collected for shipment to the United States, until placed in the shipping container and sealed with official seals of the country of origin. The seal numbers have been recorded on the health certificate.
13.8.	the embryos are routed directly to the United States from the Member State in which they were collected with no stops en route other than those provided on the USDA import permit.

14.1. Date and place	14.2. Name and qualification of the Official Veterinarian	14.3. Signature and stamp of the Official Veterinarian

Notes:

(a) A separate certificate must be issued for each consignment of embryos.

(b) The original of this certificate must accompany the shipment.