Verenigde Staten, runderembryo's

Code: **RNDEU-15** Versie: 1.0.5

Ingangsdatum: 01-04-2024

Eigenaar: NVWA O&O, Team Export

Versie	Datum	Wijziging ten opzichte van vorige versie
1.0.3	22-03-2017	Het certificaat is aangepast. Aan gesekst sperma zijn extra eisen gesteld.
1.0.4	19-12-2019	De instructie is geactualiseerd. Het gaat om niet-inhoudelijke aanpassingen zoals naamswijzigingen en de verwijzing naar de instructie over de dierziektesituatie. Ook is aangegeven dat het certificaat nog niet beschikbaar is in e-CertNL.
1.0.5	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 runderembryo's naar de USA. De instructie beschrijft de voorwaarden die worden gesteld aan 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 runderembryo's naar de USA zijn officiële bilaterale afspraken gemaakt. Deze afspraken zijn bindend, van deze afspraken kan dus niet worden afgeweken.

2 WETTELIJKE BASIS

2.1 EU-regelgeving
- Richtlijn 89/556/EEG

2.2 Nationale wetgeving
- Gezondheids- en welzijnswet voor dieren, artikel 79.

2.3 Overige
- Equivalentieakkoord tussen de USA en de Europese Unie.

3 DEFINITIES

Begrip	**Definitie**
Embryoteam	een officieel erkende groep technici of organisatievorm onder toezicht van een teamdierenarts, bevoegd om zich overeenkomstig de in bijlage A van Richtlijn 89/556/EEG vastgestelde eisen met de verzameling, behandeling en opslag van embryo's te belasten.
Teamdierenarts	de dierenarts die overeenkomstig de voorwaarden van Richtlijn 89/556/EEG verantwoordelijk is voor het toezicht op het embryoteam en in deze functie door de minister van LNV officieel is erkend.

4 WERKWIJZE

De export van runderembryo's naar USA is toegestaan.

Algemeen:

- Certificering van runderembryo's verloopt via het systeem e-CertNL. Voor runderembryo's naar 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 runderembryo's naar 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.

- *Certificaat: zie bijlage*

Toelichting bij het certificaat:

Section A: de verklaringen worden ingevuld en ondertekend door de officiële teamdierenarts van het embryoteam.
Section B: de verklaringen worden ingevuld en ondertekend door de NVWA-dierenarts nadat de teamdierenarts heeft getekend.

Section B, verklaring 1:
The Member State in which the embryos were collected is considered by the USDA to be free from foot-and-mouth disease (FMD) and rinderpest as listed in Title 9 Code of Federal Regulations, Part 94 and other official publications, and was free of these diseases at the time of embryo collection;
Nederland is op grond van de Code of Federal Regulations, hoofdstuk 9, paragraaf 94.1(a)(2) vrij verklaard van runderpest en mond-en-klauwzeer.
Deze verklaring is af te geven na controle van de dierziektesituatie. Informatie over de dierziektesituatie is hier te vinden.

Verklaring 2:
The Member State in which the embryos were collected is free from contagious bovine pleuropneumonia;
Deze verklaring is af te geven na controle van de dierziektesituatie. Informatie over de dierziektesituatie is hier te vinden.

Verklaring 3:
The donor dams were part of the national herd of the Member State in which the embryos were collected for a minimum of 60 days prior to collection and were free from any movement or quarantine restrictions;
Deze verklaring kan na controle worden afgegeven.

Verklaring 4:
The embryos were collected from live cattle of documented health history and processed in accordance with the standards of the International Embryo Transfer Society (IETS) by an embryo collection team approved by the competent authority of the Member State in accordance with EU legislation in force, notably Council Directive 89/556/EEC, as amended;
Deze verklaring kan na controle worden afgegeven.
Op basis van het bedrijvenregistratiesysteem van de NVWA kan worden nagegaan of het embryoteam beschikt over een erkenning op basis van Richtlijn 89/556/EEG.

Verklaring 5:
All diagnostic testing of the donor dams and sires were conducted in laboratories approved by the National Veterinary Services to conduct such tests for export;
Deze verklaring kan na controle worden afgegeven.

Verklaring 6:
All media additives of animal origin were sourced from countries considered by the USDA to be free from FMD and rinderpest. Trypsin of porcine origin was sourced from countries considered by USDA to be free from FMD, rinderpest, classical swine fever and African swine fever as listed in 9 CFR Part 94 and other official publications;
(https://www.aphis.usda.gov/wps/portal/aphis/ourfocus/importexport?1dmy&urile=wcm%3apath%3a%2Faphis_content_library%2Fsa_our_focus%2Fsa_animal_health%2Fsa_import_into_us%2Fct_animal_disease_status)
Deze verklaring kan worden afgegeven. Belanghebbende moet aantonen dat aan deze voorwaarde is voldaan.

Verklaring 7:
The embryos were maintained under lock and key or in the custody of the embryo collection team veterinarian until being sealed for direct transport to the United States;
Deze verklaring kan na controle worden afgegeven.

Verklaring 8:
The Team Veterinarian that completed Section A of this certificate is authorized by the National Veterinary Service to perform this service.
Deze verklaring kan na controle worden afgegeven.

5 BEVOEGDHEDEN EN VERANTWOORDELIJKHEDEN

De teamdierenarts is verantwoordelijk voor de verklaringen van Section A, de NVWA-dierenarts is verantwoordelijk voor de overige delen van het certificaat.

Bijlage: certificaat

HEALTH CERTIFICATE FOR EXPORT OF IN VIVO DERIVED BOVINE EMBRYOS FROM FOOT-AND-MOUTH DISEASE-FREE MEMBER STATES OF THE EUROPEAN UNION TO THE UNITED STATES OF AMERICA

I. IDENTIFICATION OF THE PRODUCTS

Product no.	Product	Identification no. of dam	Breed of dam

Product no.	Identification no. of sire	Breed of sire	Member state of embryo collection

Batch no.	Type of semen	Packing (Number of straws)	Date of embryo collection	Collection code
	sexed / nonsexed(*)			

Seal number :

II.ORIGIN OF THE PRODUCTS

Product no.	Approval no. embryo collection team	Name and address embryo collection team

Name and address of exporter :

- III. DESTINATION OF THE PRODUCTS

Means of conveyance :
Port of entry :
Name and address of consignee :

IV. HEALTH ATTESTATION

Section A (*to be signed by the Team Veterinarian***)**

I, the undersigned Team Veterinarian of the described embryo collection team, hereinafter "ECT," certify, either by direct examination or based on supporting documentation in my possession that has been separately attested to by an official veterinarian, that:

1. During the 12 months prior to the collection of embryos for export to the United States, there was no clinical or pathological evidence of brucellosis or tuberculosis (TB) found in the donor dams or on any premises on which the donor dams were located during that time;
2. During the 60 days prior to the collection of embryos for export to the United States, the donor dams were not corralled, pastured, or held with animals of lesser health status or under any restrictions which would make them ineligible as embryo donors for export to the United States
3. During the 60 days prior to the collection of embryos for export to the United States, the donor dams were inspected at least once and appeared healthy and were found clinically free of contagious or communicable diseases;
4. Each of the donors were examined on the day of embryo collection and appeared healthy and were clinically free of contagious or communicable diseases;
5. The donor dams originated from herds officially free of tuberculosis;
6. Either(*) The embryos were collected prior to June 1 2011;
   Or(*) The embryos were collected on or after June 1 2011 from donors that were negative to two serum neutralization tests (VNT) for Schmallenberg virus (using a 1 : 8 cutoff titer), with the first performed within 30 days prior to collection, and the second between 28 and 60 days after collection. Tests were performed in a laboratory approved by the national Competent Authority ;

7. 7.1. The semen used to fertilize the embryos for export to the United States was collected in an approved semen collection centre (SCC), in accordance with legislation in force, notably Council Directive 88/407/EEC, as amended. At the time of collection of the semen, the Member State in which the semen was collected was considered by the USDA to be free of foot-and-mouth disease and rinderpest, as listed in Title 9 Code of Federal Regulations, Part 94 and other official publications. In addition

   Either(*) The semen was collected prior to June 1 2011;

   Or(*) The semen was collected on or after June 1, 2011 from donors that were negative to two serum neutralization tests (VNT) for Schmallenberg virus (using a 1 : 8 cutoff titer), with the first performed within 30 days prior to collection, and the second between 28 and 60 days after collection;

   Tests were performed in a laboratory approved by the national Competent Authority.

   7.2.(*) If embryos were fertilized with sexed semen:

   7.2.1. The semen sexing facility used to sex the semen for export to the United States is located in the EU Member State where the semen was collected. The semen collection center is under the supervision of an approved Center Veterinarian, and is regularly inspected and approved in accordance with EU Directive 88/407/EEC. The sexing facility followed the United States Department of Agriculture approved "Cleaning and Disinfection Standard Operating Protocol" while processing this semen;

   7.2.2. The integrity of the semen shipment was maintained through the semen sexing process and no semen from other donors was mixed with semen during processing;

8. The embryos were collected using a closed collection system, and any instrument coming in contact with reproductive tract tissue or fluids was either new or equipment sterilized before use;
9. The embryos were washed at least 10 times and treated with trypsin in accordance with the latest edition of the Manual of the International Embryo Transfer Society. After the last wash, each embryo was examined microscopically over its entire surface at not less than 50x magnification. The zona pellucida of each embryo was found to be intact and free from any adherent material subsequent to washing;
10. Embryos from different donors were not washed together;
11. The storage and shipping containers were clean, recently disinfected, and empty prior to use for this project, and only fresh liquid nitrogen has been used.

(*)Delete as appropriate.

Gedaan te / Done at / Ausgefertigt in / Fait à / Hecho en
Op / On / Am / Le / El

Name and qualification of the team veterinarian

Signature and stamp of the team veterinarian

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

I, the undersigned Official Veterinarian of the Netherlands certify that:

1. The Member State in which the embryos were collected is considered by the USDA to be free from foot-and-mouth disease (FMD) and rinderpest as listed in Title 9 Code of Federal Regulations, Part 94 and other official publications, and was free of these diseases at the time of embryo collection;
2. The Member State in which the embryos were collected is free from contagious bovine pleuropneumonia;

3. The donor dams were part of the national herd of the Member State in which the embryos were collected for a minimum of 60 days prior to collection and were free from any movement or quarantine restrictions;
4. The embryos were collected from live cattle of documented health history and processed in accordance with the standards of the International Embryo Transfer Society (IETS) by an embryo collection team approved by the competent authority of the Member State in accordance with EU legislation in force, notably Council Directive 89/556/EEC, as amended;
5. All diagnostic testing of the donor dams and sires were conducted in laboratories approved by the National Veterinary Services to conduct such tests for export;
6. All media additives of animal origin were sourced from countries considered by the USDA to be free from FMD and rinderpest. Trypsin of porcine origin was sourced from countries considered by USDA to be free from FMD, rinderpest, classical swine fever and African swine fever as listed in 9 CFR Part 94 and other official publications; (https://www.aphis.usda.gov/wps/portal/aphis/ourfocus/importexport?1dmy&urile=wcm%3apath%3a%2Faphis_content_library%2Fsa_our_focus%2Fsa_animal_health%2Fsa_import_into_us%2Fct_animal_disease_status)
7. The embryos were maintained under lock and key or in the custody of the embryo collection team veterinarian until being sealed for direct transport to the United States;
8. The Team Veterinarian that completed Section A of this certificate is authorized by the National Veterinary Service to perform this service.

Notes:

- A separate certificate must be issued for each consignment of embryos.
- The original of this certificate must accompany the shipment.