USA, rundersperma

Code: **RNDSU-13** Versie: 1.2.2

Ingangsdatum: 30-05-2024

Eigenaar: NVWA O&O, team Export

Versie	Datum	Wijziging ten opzichte van vorige versie
1.2.0	12-09-2023	In augustus 2023 zijn met de Verenigde Staten nieuwe afspraken gemaakt over de export van rundersperma. Deze instructie en het bijgevoegde certificaat vormen de weerslag van deze afspraken. Met name Sectie A van het certificaat, in te vullen en te ondertekenen door de aan het spermawinningscentrum verbonden bevoegde dierenarts, is aangepast.
1.2.1	01-04-2024	Aanpassing ten gevolge van wijzigingen in de Regeling erkenning veterinaire laboratoria (REVL).
1.2.2	30-05-2024	Enkele tekstuele aanpassingen in (met name) Sectie A van het certificaat.

1 DOEL EN TOEPASSINGSGEBIED

Deze instructie geldt voor het exporteren van rundersperma naar de Verenigde Staten. De instructie beschrijft de voorwaarden die gelden voor de invoer in de Verenigde Staten, 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 rundersperma naar de Verenigde Staten zijn officiële bilaterale afspraken gemaakt. Deze afspraken zijn bindend, van deze afspraken kan dus niet worden afgeweken.

2 WETTELIJKE BASIS

2.1 EU-regelgeving

- Verordening (EU) 2016/429
- Verordening (EU) 2017/625
- Uitvoeringsverordening (EU) 2018/1882
- Gedelegeerde verordening (EU) 2020/686
- Uitvoeringsverordening (EU) 2020/999

2.2 Nationale wetgeving

- Wet dieren

2.3 Overige

- Bilaterale afspraken tussen de Verenigde Staten en Nederland.

3 DEFINITIES

n.v.t.

4 WERKWIJZE

De export van rundersperma naar de Verenigde Staten is toegestaan.

Toelichting bij het certificaat:

4.1 Algemeen:

- Raadpleeg vooraf de instructie Tijdelijke Maatregelen Derde Landen (TMDL-01) op mogelijke exportbeperkingen. Als in de TMDL-01 informatie staat die in strijd is met een landeninstructie dan is de informatie vermeld in de TMDL-01 leidend.
- Section A dient, in aanwezigheid van de certificerende NVWA-dierenarts, te worden ingevuld en ondertekend door de aan het spermawinningscentrum verbonden bevoegde dierenarts. Deze getekende Section A geldt als basis waarop de certificerende NVWA-dierenarts Section B van het certificaat kan ondertekenen.
- Diagnostische laboratoriumtesten dienen te worden uitgevoerd door een laboratorium welk conform het werkvoorschrift K-O&O-IE-WV05 is toegestaan.

Certificaat: zie bijlage

Sectie B (to be signed by the Official Veterinarian after the Center Veterinarian has signed)

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

Verklaring 1:
The Member State where the semen was collected is considered by the USDA to be free of foot-and-mouth disease, as listed in 9 CFR Part 94 and other official publications, and was free of this disease at the time of semen collection;
De EU-lidstaat waar het sperma is gewonnen moet door de USDA worden beschouwd als vrij van mond-en-klauwzeer, zoals vermeld in de Code of Federal Regulations, hoofdstuk 9, paragraaf 94.1(a)(1) en andere officiële publicaties.
Deze verklaring kan worden afgegeven na controle van de lijst met landen die door de USDA vrij van mond- en klauwzeer zijn verklaard. Deze lijst is te vinden op de website van APHIS: www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-status-of-regions.
Het tweede deel van deze verklaring ("*… and was free of this diseases at the time of semen collection.*") kan worden afgegeven na controle van de dierziektesituatie op het moment van spermawinning. Informatie over de dierziektesituatie is hier te vinden.

Verklaring 2:
The Member State where the semen was collected is free of contagious bovine pleuropneumonia;
Deze verklaring kan worden afgegeven na controle van de dierziektesituatie. Besmettelijke runderperipneumonie is een aangifteplichtige dierziekte. E-CertNL controleert automatisch op aangifteplichtige dierziekten. Informatie over de dierziektesituatie is hier te vinden.

Verklaring 3:
The donor animals for the semen to be exported to the United States have been part of the national herd of the Member State where the semen was collected for a minimum of 60 days and are free from any movement or quarantine restrictions;
Het eerste deel van deze verklaring ("*The donor animals … for a minimum of 60 days …*") kan worden afgegeven op basis van een handmatige controle van de I&R-gegevens van de donorstieren.
Het tweede deel van deze verklaring ("*… and are free from any movement or quarantine restrictions.*") kan worden afgegeven op basis van EU- en nationale regelgeving.

Verklaring 4:
The semen collection center, hereinafter "SCC", was approved by the competent authority of the Member State where the semen was collected;
Deze verklaring kan worden afgegeven na controle van het bedrijvenregistratiesysteem van de NVWA.

Verklaring 5:
Health tests required for export to the United States of bovid semen were performed by testing methods recognized by the World Organization for Animal Health (WOAH, formerly OIE) Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, as acceptable for international trade;
Deze verklaring kan worden afgegeven op basis van een controle of de testmethoden voldoen aan de WOAH-voorschriften.

Verklaring 6:
The laboratory tests mentioned in IV. 4.2. to IV. 4.6. were carried out with negative results in a laboratory approved by the competent veterinary services;
Deze verklaring kan worden afgegeven op basis van een controle. Belanghebbende dient, ten behoeve van de exportcertificering, de relevante testresultaten te overleggen. De diagnostische testen dienen te zijn uitgevoerd door erkende laboratoria.

Verklaring 7:
Ruminant products used in commercial semen extenders in the Member State where the semen was collected were sourced from countries considered by USDA to be free from foot-and-mouth disease as listed in 9 CFR Part 94 and other official publications;
Hiervoor moet door belanghebbende worden aangetoond uit welke landen de herkauwerproducten, die worden gebruikt in de commerciële toevoegingsmiddelen, afkomstig zijn. Deze landen moeten door de USDA worden beschouwd als vrij van mond-en-klauwzeer, zoals vermeld in de Code of Federal Regulations, hoofdstuk 9, paragraaf 94.1(a)(1) en andere officiële publicaties.
Deze verklaring kan worden afgegeven na controle van de lijst met landen die door de USDA vrij van mond- en klauwzeer zijn verklaard. Deze lijst is te vinden op de website van APHIS: www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-status-of-regions.

Verklaring 8:
The semen to be exported to the United States was maintained under lock and key or in the custody of the SCC veterinarian, and segregated from other semen of lesser health status, until it was placed in the shipping container and sealed with official seals of the Member State where the semen was collected;
Deze verklaring kan worden afgegeven op basis van een verklaring met gelijke strekking van de aan het spermawinningscentrum verbonden dierenartspracticus.

Verklaring 9:
None of the semen for export to the USA has been stored or transported in containers with semen produced under less than equivalent animal health conditions;
Deze verklaring kan worden afgegeven op basis van een verklaring met gelijke strekking van de aan het spermawinningscentrum verbonden dierenartspracticus.

Verklaring 10:
The integrity of the total shipment and continuity of storage conditions for semen produced in different approved SCC units and collected in the Member State are listed on this health certificate(*);
Indien deze verklaring niet van toepassing is, dient deze verklaring te worden doorgehaald.
Deze verklaring is uitsluitend van toepassing in het geval van doorcertificeren van sperma, afkomstig van een ander erkend spermawinningscentrum. Op basis van de gegevens beschreven in de "USA import permit", controle van de gegevens en op basis van een verklaring van gelijke strekking van belanghebbende kan deze verklaring worden afgegeven.

Verklaring 11:
The shipping containers were sealed with an approved seal from the competent authority of the exporting Member State, and the seal number is recorded on the health certificate
Deze verklaring kan worden afgegeven nadat verzegeling heeft plaatsgevonden. De zegelnummers dienen op het certificaat te worden vermeld.

Verklaring 12:
The semen is routed directly to the United States from the Member State in which it was collected with no stops en route other than those provided on the USDA import permit; and
Deze verklaring kan worden afgegeven op basis van een controle van het vluchtschema, of indien wordt voldaan aan hetgeen hierover in de import permit is aangegeven. Belanghebbende dient dit aan te tonen.

Verklaring 13:
The Center Veterinarian that completed Section A of this certificate is authorized by the National Veterinary Service to perform this service;

Deze verklaring kan worden afgegeven op basis van een controle van de bevoegdheid van de aan het spermawinningscentrum verbonden dierenartspracticus. De bevoegdheid van de aan het spermawinningscentrum verbonden dierenartspracticus kan worden gecontroleerd in het diergeneeskunderegister. Het diergeneeskunderegister is te vinden op de website van het CIBG (Centraal Informatiepunt Beroepen Gezondheidszorg), een uitvoeringsorganisatie van het ministerie van Volksgezondheid, Welzijn en Sport: www.diergeneeskunderegister.nl.

Verklaring 14:
For sexed semen:

Verklaring 14.1:
The semen sexing laboratory used to sex the semen for export to the United States is located in the EU Member State where the semen was collected or was imported from the United States meeting all EU import requirements. 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 and updated in Regulation (EU) 2016/429 or updated in Regulation (EU) 2016/429 (Commission Delegated Regulation (EU) 2020/686). The sexing facility followed a United States Department of Agriculture approved "Cleaning and Disinfection Standard Operating Protocol" while processing this semen for export to the United States;
Het eerste deel van deze verklaring ("*The semen … Regulation (EU) 2016/429.*") kan worden afgegeven op basis van EU- en nationale regelgeving. Het te exporteren rundersperma mag afkomstig zijn uit Nederland of zijn geïmporteerd vanuit de Verenigde Staten.
Het tweede deel van deze verklaring ("*The sexing facility … for export to the United States;*") kan worden afgegeven op basis van een verklaring van gelijke strekking van de aan het spermawinningscentrum verbonden dierenartspracticus.

Verklaring 14.2:
The integrity of this shipment was maintained through the semen sexing process and no semen from other donors was mixed with semen that originated from the animals listed in Part I;
Deze verklaring kan worden afgegeven op basis van een verklaring met gelijke strekking van de aan het spermawinningscentrum verbonden dierenarts.

5 BEVOEGDHEDEN EN VERANTWOORDELIJKHEDEN

De certificerende NVWA-dierenarts is bevoegd en verantwoordelijk voor het afgeven van het certificaat.

Bijlage 1: certificaat

HEALTH CERTIFICATE FOR EXPORT OF BOVID SEMEN (SPECIFICALLY BOVINE (BOS TAURUS, BOS INDICUS, BISON BISON), WATER BUFFALO (BUBALUS BUBALIS), YAK (BOS GRUNNIENS)) FROM FOOT-AND-MOUTH DISEASE-FREE MEMBER STATES OF THE EUROPEAN UNION TO THE UNITED STATES OF AMERICA

I. IDENTIFICATION OF THE SEMEN

Product no.	Product (Name of the donor bull)	Breed	Age	Identification number

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

Seal number of container(s) :

II.ORIGIN OF THE SEMEN

Product no.	Approval no. of the semen collection center	Name and address of the semen collection center

Product no.	Name and address of the semen sexing facility, if applicable

Name and address of the consignor :
Place of loading :
Country of loading :

III. DESTINATION OF THE SEMEN
Means of conveyance :
Name and address of the consignee :

IV. HEALTH INFORMATION
Section A (to be signed by the Center Veterinarian)
I, the undersigned Center Veterinarian of the described semen collection center, hereinafter "SCC", certify that:

1. All bovid animals in the above SCC were:
   - 1.1. Established as residents only if admitted by a formal process of quarantine, observation, and testing as required by legislation in force, Annex B to Council Directive 88/407/EEC, as amended by Directive 2003/43/EC or in Regulation (EU) 2016/429 (Commission Delegated Regulation (EU) 2020/686);
   - 1.2. Admitted to the SCC herd only after having been proven free of brucellosis, tuberculosis, bovine genital campylobacteriosis and trichomoniasis;
   - 1.3. Admitted to the SCC herd only after having been proven free of viremia from persistent bovine viral diarrhea virus infection before entry into the SCC resident herd; and
   - 1.4. Were tested annually for brucellosis, tuberculosis, bovine genital campylobacteriosis, and trichomoniasis;
   - 1.5. The semen for export to the United States was (select one):
     Either(*) Collected prior to June 1, 2011;
     Or(*) The semen in the consignment was collected after June 1, 2011, from donors that were negative to two serum neutralization tests (using a 1:8 cutoff titer) for Schmallenberg virus, 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;

2. In the SCC:
   2.1. The SCC is certified as clinically free of paratuberculosis;
   2.2. The herd was tested for brucellosis, tuberculosis, bovine genital campylobacteriosis, and trichomoniasis in its entirety with negative results at the most recent herd test prior to the period of semen collection for export to the United States of America (USA);
   2.3. No clinical or other evidence of brucellosis, tuberculosis, bovine genital campylobacteriosis, trichomoniasis or leptospirosis was found since the most recent herd test and prior to the embarkation of semen to the United States;
   2.4. There was no evidence to indicate that the donors have been affected with tuberculosis or brucellosis during the 12 months prior to the collection of semen for export to the United States;
   2.5. There was no clinical evidence of infection by bovine viral diarrhea virus, bluetongue virus, enzootic hemorrhagic disease (EHD) or infectious bovine rhinotracheitis virus during the 60 days prior to and during the period of collection of semen for export to the United States; and
   2.6. All bulls passed a testing program with negative result consistent with the World Organization for Animal Health (WOAH, formerly OIE) Terrestrial Animal Health Code (Article 4.5.5) or as outlined in Council Directive 88/407/EEC, as amended in Regulation (EU) 2016/429 or in Regulation (EU) 2016/429 (Commission Delegated Regulation (EU) 2020/686) to detect persistent testicular bovine viral diarrhea virus infection prior to semen release;
3. Each donor bull for the semen described above:
   3.1. Originated from a tuberculosis-free herd;
   3.2. Was not corralled, pastured, or held with animals of lesser health status or under any restrictions which would make them ineligible to export semen to the United States during the 60 days prior to and during the period of collection of semen for export to the United States;
   3.3. Was subjected with negative results to the test described in IV. 4.1 to IV. 4.4 within six months prior to collection or six months after collection of the semen described above;
   3.4. Was subjected with negative results to the tests for bluetongue virus group (BTV) described in IV. 4.6;
   3.5. Was inspected on the date of semen collection and found to be free of clinical signs of diseases transmissible in semen;
4. Where reference is made to health tests, the following tests were carried out:
   4.1. The cervical test for bovine tuberculosis described in the World Organization for Animal Health (WOAH, formerly OIE) Manual for Diagnostic Tests and Vaccines for Terrestrial Animals;
   4.2. For brucellosis testing (select one):
   Buffered brucella antigen card test;
   Or(*) Rose bengal test;
   Or(*) Buffered plate agglutination test;
   Or(*) Indirect ELISA test for bovine brucellosis;
   Or(*) Competitive ELISA test for bovine brucellosis;
   Or(*) In accordance with the WOAH Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, under the condition that samples that react positively were retested with negative results using a suitable confirmatory test such as the complement fixation test;
   4.3. For bovine genital campylobacteriosis (Campylobacter fetus ssp. venerealis) with negative testing results (select one):
   Polymerase chain reaction (PCR) test;
   Or(*) Culture of preputial smegma;
   Note: The immunofluorescent antibody test may be used only as a screening test under the condition that samples that react positively must be retested using a suitable confirmatory test such as a PCR or culture of preputial smegma with negative results;
   4.4. For trichomoniasis (Trichomonas foetus) with negative results (select one):

PCR test;

Or(*) Microscopic examination;

Or(*) Culture of preputial smegma;

4.5. For epizootic hemorrhagic disease (EHD) (select one):

The animals were collected or originate from the Member State or region of the State where no cases of EHD have been reported within the previous 12 months in the region or zone, and where no serological evidence of EHD infection exists;

Or(*) The following serotypes of EHD exist: …… and animals were tested on two occasions by an agar gel immunodiffusion test (AGID) with negative results;

Or(*) Testing was by competitive enzyme-linked immunosorbent assay (C-ELISA) and a whole-blood PCR test for all the above-listed serotypes of EHD, with negative results using blood samples taken prior to, and not less than 21 days following collection of the semen (the two samples may not be taken more than 12 months apart);

Or(*) Testing was by competitive enzyme-linked immunosorbent assay (C-ELISA) and a virus neutralization test (VNT) for all the above-listed serotypes of EHD, with negative results using blood samples taken prior to, and not less than 21 days following collection of the semen (the two samples may not be taken more than 12 months apart);

4.6. The donor bull (select one):

4.6.1. Was tested for the bluetongue virus (BTV) group on blood serum performed prior to the first day of semen collection, at least every 60 days during the collection period, and between 21 and 60 days after semen collection, with negative results;

AGID test;

Or(*) ELISA test;

Or(*) 4.6.2. Was tested with a whole blood PCR test for BTV group with one negative test at the beginning and conclusion of the collection period, and at least every 28 days during the period of semen collection;

Or(*) Was tested with a whole-blood virus isolation test for BTV group with one negative test at the beginning and conclusion of the collection period, and at least every 7 days during the period of semen collection;

5. The semen was collected and processed under my supervision and placed in individual ampules or straws which were permanently marked with the name of the donor, his registration number, or the collection code;
6. Semen collection equipment which came into contact with bulls, or their secretions and excretions was thoroughly disinfected after each use, and good laboratory practices were followed during collection and processing of semen in order to minimize the possible introduction of microbial contamination;
7. Antibiotics were added to the semen and semen extender in amounts and combinations consistent with the standards described in "Certified Semen Services (CSS) Minimum Requirements for Disease Control of Semen Produced for AI," Appendix I, website: 202112136CSSMinReq%20Jan2021-ENG_FINAL_v_4.pdf (naab-css.org);
8. No biological products other than frozen semen or embryos qualified for shipment to the United States were present in the containers prior to use for export of semen to the United States;
9. The storage and shipping containers are either new or cleaned and disinfected; and
10. Only virgin liquid nitrogen was used to export semen to the United States;
11. For sexed semen:

11.1. The semen collected and processed under my supervision was shipped to the semen sexing facility within the Member State of collection under seal or was maintained under the oversight of a center or official veterinarian;

11.2. Note: the semen sexing facility used to sex the semen is located in the Member State where the semen was collected. The facility has submitted a "Cleaning and Disinfection Standard Operating Protocol" reviewed and approved by the USDA, Approved EU, Great Britain and Northern Ireland Bovine Semen Sex Sorting Facilities.

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Name and qualification of the Center Veterinarian

Signature and stamp of the Center Veterinarian

Section B (to be signed by the Official Veterinarian after the Center Veterinarian has signed)
I, the undersigned Official Veterinarian of the Netherlands, certify that:

1. The Member State where the semen was collected is considered by the USDA to be free of foot-and- mouth disease, as listed in 9 CFR Part 94 and other official publications, and was free of this disease at the time of semen collection;
2. The Member State where the semen was collected is free of contagious bovine pleuropneumonia;
3. The donor animals for the semen to be exported to the United States have been part of the national herd of the Member State where the semen was collected for a minimum of 60 days and are free from any movement or quarantine restrictions;
4. The semen collection center, hereinafter "SCC", was approved by the competent authority of the Member State where the semen was collected;
5. Health tests required for export to the United States of bovid semen were performed by testing methods recognized by the World Organization for Animal Health (WOAH, formerly OIE) Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, as acceptable for international trade;
6. The laboratory tests mentioned in IV. 4.2. to IV. 4.6. were carried out with negative results in a laboratory approved by the competent veterinary services;
7. Ruminant products used in commercial semen extenders in the Member State where the semen was collected were sourced from countries considered by USDA to be free from foot-and-mouth disease as listed in 9 CFR Part 94 and other official publications;
8. The semen to be exported to the United States was maintained under lock and key or in the custody of the SCC veterinarian, and segregated from other semen of lesser health status, until it was placed in the shipping container and sealed with official seals of the Member State where the semen was collected;
9. None of the semen for export to the USA has been stored or transported in containers with semen produced under less than equivalent animal health conditions;
10. The integrity of the total shipment and continuity of storage conditions for semen produced in different approved SCC units and collected in the Member State are listed on this health certificate(*);
11. The shipping containers were sealed with an approved seal from the competent authority of the exporting Member State, and the seal number is recorded on the health certificate;
12. The semen is routed directly to the United States from the Member State in which it was collected with no stops en route other than those provided on the USDA import permit; and
13. The Center Veterinarian that completed Section A of this certificate is authorized by the National Veterinary Service to perform this service;
14. For sexed semen:
    14.1. The semen sexing laboratory used to sex the semen for export to the United States is located in the EU Member State where the semen was collected or was imported from

the United States meeting all EU import requirements. 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 and updated in Regulation (EU) 2016/429 or updated in Regulation (EU) 2016/429 (Commission Delegated Regulation (EU) 2020/686). The sexing facility followed a United States Department of Agriculture approved "Cleaning and Disinfection Standard Operating Protocol" while processing this semen for export to the United States;

14.2. The integrity of this shipment was maintained through the semen sexing process and no semen from other donors was mixed with semen that originated from the animals listed in Part I.

(*)Delete as appropriate.

This certificate is valid for 30 days.