



## Verenigde Staten, schapen- en geitensperma

Code: **SGSU-01** Versie: 1.0.1

Ingangsdatum: 01-04-2024

Eigenaar: NVWA O&O, Team Export

Versie	Datum	Wijziging ten opzichte van vorige versie
1.0.0	01-04-2021	Met de Verenigde Staten zijn afspraken gemaakt over de export van schapen- en geitensperma. Deze instructie en het bijgevoegde certificaat vormen de weerslag van deze afspraken.
1.0.1	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 schapen- en geitensperma 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 schapen- en geitensperma 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

- Beschikking 2010/470/EU (sperma, eicellen en embryo's van paardachtigen, schapen en geiten en eicellen en embryo's van varkens)

#### 2.2 Nationale wetgeving

- Gezondheid- en welzijnswet voor dieren, artikel 79
- Wet dieren

#### 2.3 Overige

- Bilaterale afspraken tussen de Verenigde Staten en Nederland.

### 3 DEFINITIES

n.v.t.

### 4 WERKWIJZE

De export van schapen- en geitensperma naar de Verenigde Staten is toegestaan.

- *Certificaat: zie bijlage*

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.
- Export van schapen- en geitensperma naar de USA kan alleen plaatsvinden vanaf het spermacentrum waar het sperma is gewonnen.
- Sectie A van het certificaat moet, in aanwezigheid van de NVWA-dierenarts, worden ingevuld en ondertekend door de aan het spermacentrum verbonden bevoegde dierenarts. Dit houdt in dat de aan het spermacentrum verbonden bevoegde dierenarts aanwezig moet zijn op het moment van certificeren. De getekende Sectie A geldt als basis waarop de officiële NVWA-dierenarts Sectie B van het certificaat kan ondertekenen.
- De naam en functie van de aan het spermacentrum verbonden dierenarts moet ook in e-CertNL worden aangegeven. Zie tabblad "Afgifte" en kies vervolgens "Af te drukken keuzevelden".
- Diagnostische laboratoriumtesten dienen te worden uitgevoerd door een laboratorium welk conform het [werkvoorschrift K-O&O-IE-WV05](#) is toegestaan.

##### Verklaring 1:

*The semen collection center, hereinafter "SCC", was approved by the competent authority of the Netherlands and has no outstanding violations under the provisions of Council Directive 92/65/EEC;*  
Deze verklaring kan worden afgegeven voor een erkend spermacentrum.

##### Verklaring 2:

*The center veterinarian that completed Section A of this certificate is authorized by the national veterinary service of the Netherlands to perform this service;*  
Deze verklaring kan worden afgegeven na controle.

##### Verklaring 3:

*The center veterinarian is not subject to any past or current disciplinary actions that would result in ineligibility to certify the health of the animals at the SCC, and meets all other applicable requirements of Regulation (EU) 2017/625 or of the competent authority, as applicable;*

Het eerste deel van deze verklaring ("...not subject to any past or current disciplinary...") kan worden afgegeven na controle.

Het tweede deel van deze verklaring kan worden afgegeven op basis van EU- en nationale regelgeving.

##### Verklaring 4:

*The donor animals for the semen to be exported to the United States have been part of the national flock/herd of the Netherlands and are free from any movement or quarantine restrictions, according to point A1. to A17. above;*

Het eerste deel van deze verklaring kan worden afgegeven na controle van de I&R-gegevens van de donordieren.

Het tweede deel van de verklaring kan worden afgegeven op basis van EU- en nationale regelgeving.

##### Verklaring 5:

*Any tests required under Section A. above for ovine or caprine semen exported to the United States 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;*

Deze verklaring kan worden afgegeven indien alle laboratoriumuitslagen afkomstig zijn van een erkend laboratorium. Belanghebbende dient, ten behoeve van de exportcertificering, de relevante testresultaten te overleggen.

Verklaring 6:

*The laboratory tests mentioned in point A8. to point A9. were carried out with negative results in a laboratory approved by the competent veterinary services;*

Het eerste deel van deze verklaring kan worden afgegeven op basis van negatieve laboratoriumuitslagen van de donordieren, aan te leveren door belanghebbende. De donordieren moeten worden getest op bovine tuberculose en brucellose (*Brucella abortus/melitensis* en (in geval van schapen) *Brucella ovis*) en eventueel op Schmallenberg, blauwtong en Epizootic hemorrhagic disease (EHD) (zie Sectie A, verklaring 8 en verklaring 9). Voor de te gebruiken testen: zie voetnoot (2) en voetnoot (3).

Het tweede deel van deze verklaring kan worden afgegeven indien alle laboratoriumuitslagen afkomstig zijn van een erkend laboratorium.

Verklaring 7:

*The Netherlands is free of foot-and-mouth disease (FMD), rinderpest, contagious caprine pleuropneumonia and Rift Valley Fever;*

Voor wat betreft mond-en-klauwzeer (MKZ), runderpest en Rift Valley koorts kan deze verklaring worden afgegeven na controle van de dierziektesituatie in Nederland. Mond-en-klauwzeer (MKZ), runderpest en Rift Valley koorts zijn aangifteplichtige dierziekten in Nederland. E-CertNL controleert automatisch op aangifteplichtige dierziekten. Informatie over de dierziektesituatie in Nederland is [hier](#) te vinden.

Contagious caprine pleuropneumonia (CCPP) is een besmettelijke dierziekte bij geiten die, volgens de website van de OIE, nog nooit is gerapporteerd in Nederland. Voor wat betreft contagious caprine pleuropneumonia (CCPP) kan deze verklaring worden afgegeven na controle van de dierziektesituatie in Nederland met behulp van de website van de OIE (=

[https://www.oie.int/wahis\\_2/public/wahid.php/Countryinformation/Animalsituation](https://www.oie.int/wahis_2/public/wahid.php/Countryinformation/Animalsituation)).

Verklaring 8:

*In the Netherlands:*

- a. *Scrapie is a compulsorily notifiable disease and an effective surveillance and monitoring system for scrapie is in place.*
- b. *Sheep and goats affected with scrapie are maintained under quarantine in a manner that will prevent disease spread until the animal is no longer living and the remains have been disposed of in a way that prevents disease spread;*
- c. *The feeding of sheep and goats with meat-and-bone meal or greaves derived from ruminants has been banned and the ban is effectively enforced in the whole region for the entire life of the animal; and the donors have not been in any other country/region with a less restrictive feeding policy prior to the collection of semen for export;*

Deze verklaring kan, voor sperma gewonnen van donordieren die na 1 juli 2001 zijn geboren, worden afgegeven op basis van EU- en nationale regelgeving.

Voor sperma gewonnen van donordieren die vóór 1 juli 2001 zijn geboren kan deze verklaring NIET worden afgegeven.

Verklaring 9:

*Ruminant products used in commercial semen extenders in the Netherlands were sourced from countries considered by USDA to be free from foot-and mouth disease and rinderpest as listed in 9 CFR Part 94 and other official publications;*

Belanghebbende moet aantonen dat aan deze voorwaarde is voldaan door de herkomst van de toevoegingen aan te tonen.

Deze verklaring kan na controle worden afgegeven. Nederland is op grond van de Code of Federal Regulations, hoofdstuk 9, paragraaf 94 vrij verklaard van runderpest en mond-en-Klauwzeer (MKZ). Runderpest is in mei en juni 2011 door de OIE en de FAO uitgeroepen als wereldwijd uitgeroeid. De gezondheidsstatus van andere landen dan Nederland ten aanzien van mond-en-klauwzeer (MKZ) is te controleren via de volgende website:

<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-status-of-regions>.

Verklaring 10:

*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 Netherlands;*

Deze verklaring kan worden afgegeven op basis van een verklaring met gelijke strekking van de aan het spermacentrum verbonden dierenartspracticus.

Verklaring 11:

*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 spermacentrum verbonden dierenartspracticus.

Verklaring 12:

*The entire shipment exported under this certificate (including semen that might have been collected in more than one approved semen collection center by the same SCC veterinarian) has been maintained under continuous oversight of the official veterinarian until the conveyance is scheduled to depart for the United States;*

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

Verklaring 13:

*The shipping containers were sealed with an approved seal from the competent authority of the Netherlands, and the seal number(s) is (are) recorded in point I;*

Deze verklaring kan worden afgegeven nadat de containers zijn verzegeld door of onder toezicht van de certificerende NVWA-dierenarts. Hierbij moet gebruik worden gemaakt van officiële NVWA-zegels.

Verklaring 14:

*The semen is routed directly to the United States from the Netherlands with no stops en route other than those provided on the USDA import permit.*

Deze verklaring kan worden afgegeven na controle van het vluchtschema, of als voldaan wordt aan hetgeen hierover in de permit is aangegeven. Belanghebbende moet dit aantonen.

## **5 BEVOEGDHEDEN EN VERANTWOORDELIJKHEDEN**

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

Bijlage 1: certificaat

VETERINARY CERTIFICATE FOR THE EXPORT OF OVINE AND CAPRINE SEMEN  
FROM THE NETHERLANDS TO THE UNITED STATES OF AMERICA

I. IDENTIFICATION OF THE SEMEN

Product no.	Name donor ram/buck	Identification of donor	Species	Breed	Date of birth

Batch no.	Date(s) of semen collection	Number of straws	Straw identification

Seal number : \_\_\_\_\_

II. ORIGIN OF THE SEMEN

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

Name and address consignor : \_\_\_\_\_

III. DESTINATION OF THE SEMEN

Means of conveyance : \_\_\_\_\_  
 Identification of the means of conveyance : \_\_\_\_\_  
 Name and address consignee : \_\_\_\_\_

IV. HEALTH INFORMATION

Section A (to be signed by the semen collection center veterinarian)

I, the undersigned center veterinarian of the described semen collection center, hereinafter 'SCC,' certify that:

1. The SCC where the donor(s) represented in this consignment was (were) collected are currently approved in accordance with Chapters I and II of Annex D of Council Directive 92/65/EEC;
2. The ovine or caprine semen donors, and any teaser animals, were established as residents of the SCC in accordance with Chapter II of Annex D, Council Directive 92/65/EEC, as amended (including any related applicable requirements under Council Directive 91/68/EEC); and in accordance with any additional U.S. import requirements as specified in this certificate;
3. During the period of semen collection involved, the SCC has continuously been under my supervision, or that of another veterinarian designated by the national government of the Netherlands; and whose information has been verified by me;
4. The premises where the semen is collected, and the flocks/herds of origin of the donors and all contact animals, are located in an area at least 50 kilometers from any known occurrence of FMD or rinderpest, and have remained within the area for at least 90 days prior to and 30 days following collection of the semen for export to the United States;
5. The donor and teaser animals have been part of the national flock/herd of the Netherlands for at least 60 days prior to collection of semen for export to the United States, and are not otherwise subject to movement restrictions or quarantines due to disease. If imported from any country considered by APHIS as affected with foot-and-mouth disease or rinderpest, the donor animals have been part of the national flock/herd for at least 90 days prior to collection of semen for export to the United States, and are not otherwise subject to any movement restrictions or quarantines due to

- disease; The following certifications are made with respect to any sheep or goats resident in the SCC;
6. The following certifications are made with respect to any sheep or goats resident in the SCC:
    - a. The animals are permanently identified to enable traceback to their flock/herd of origin;
    - b. The animals have been isolated as a group, without further additions, for a period of at least 30 days prior to the first collection of semen for export to the United States (hereafter 30-day pre-entry quarantine). During this time, there were no clinical signs of communicable diseases;
    - c. Immediately prior to the first collection of semen for export to the United States, the donors were inspected by the SCC veterinarian and found to be clinically free of contagious diseases;
    - d. There was no clinical evidence of infection of the animals by bluetongue virus during the 60 days prior to and during the period of collection of semen for export to the United States;
  7. Scrapie:
    - a. Insofar as can be determined after due inquiry, the dams or sires of the semen donors have never been affected with scrapie;
    - b. The animals have been kept since birth in flocks/herds in which no case of scrapie had been confirmed during their residency;
    - c. The animals showed no clinical signs of scrapie at the time of semen collection, or prior to the export of semen to the United States;
  8. The following certifications are made with respect to bovine tuberculosis and brucellosis:

Either<sup>(1)</sup> The animals have been resident in the SCC for less than one year, and come from a flock/herd of origin that was tested negative for bovine tuberculosis<sup>(2)</sup> and brucellosis<sup>(3)</sup> on two occasions, at least 60 days apart. The first test was within one year prior to entry into the SCC; with the second test occurring during the 30-day pre-entry quarantine period before their admission into the SCC; and no clinical, microbiological, or serological evidence of these diseases was found during the 24 months prior to export of the semen to the United States;

Or<sup>(1)</sup> The animals have been resident in the SCC for more than one year, and were tested negative for bovine tuberculosis<sup>(2)</sup> and brucellosis<sup>(3)</sup> during annual herd tests at the SCC;
  9. The animals are certified as stipulated below, or were tested using the following technical criteria for other specific tests
    - a. Schmallenberg virus: the semen for export to the United States was:

Either<sup>(1)</sup> Collected prior to June 1, 2011;

Or<sup>(1)</sup> The semen in the consignment was collected after June 1, 2011 from donors that were negative to two serum neutralization tests (using a 1:16 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;
    - b. Bluetongue virus: the donor animal was:

Either<sup>(1)</sup> Kept in a BTV free country or zone, as recognized by USDA APHIS, since birth or for at least 60 days prior to shipment to the United States;

Or<sup>(1)</sup> Tested negative by an ELISA test for the BTV group on blood serum during the pre-entry quarantine period, and at least every 60 days after, with one test occurring 21-60 days after semen collection;

Or<sup>(1)</sup> 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<sup>(1)</sup> 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;
    - c. Epizootic hemorrhagic disease (EHD):

Either<sup>(1)</sup> The animals originate from the Netherlands where no cases of EHD have been reported within the previous 12 months, and where no serological evidence of EHD infection exists;

Or<sup>(1)</sup> The following serotypes of EHD exist: ..... and animals were tested on two occasions by an agar gel immunodiffusion test (AGID); OR by competitive enzyme-linked immunosorbent assay (C-ELISA) AND by either a whole-blood PCR test or 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).

COLLECTION AND PROCESSING CERTIFICATIONS<sup>(4)</sup>

10. The SCC veterinarian supervised the collection and processing of the semen for shipment to the United States;
11. Semen collection equipment which came into contact with rams or bucks 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;
12. The semen was packaged in ampules or straws which are permanently marked with the name, breed, and individual identification number of the donor and the date of collection;
13. Any antibiotics that were added to each ml of the semen and semen extender were limited to 100 µg of tylosin, 500 µg of gentamicin, or 300/600 µg of linco-spectin (lincomycin and spectinomycin), as diluted by 0.02 ml of double-distilled sterile water;
14. Ruminant products used in commercial semen extenders in the Netherlands were sourced from countries considered by USDA to be free from foot-and mouth disease and rinderpest as listed in 9 CFR Part 94 and other official publications;
15. 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;
16. The shipping tank is new or has been cleaned and sanitized, and only fresh liquid nitrogen has been used to charge the tank;
17. After processing, the ampules/straws of ovine or caprine semen to be exported to the United States were segregated in locked containers at a storage facility (or facilities) designated by the national government of the Netherlands; and were maintained under supervision until such time as the ampules/straws were placed in the shipping tank and sealed under official veterinary supervision.

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

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 semen collection center, hereinafter "SCC", was approved by the competent authority of the Netherlands and has no outstanding violations under the provisions of Council Directive 92/65/EEC;
2. The center veterinarian that completed Section A of this certificate is authorized by the national veterinary service of the Netherlands to perform this service;
3. The center veterinarian is not subject to any past or current disciplinary actions that would result in ineligibility to certify the health of the animals at the SCC, and meets all other applicable requirements of Regulation (EU) 2017/625 or of the competent authority, as applicable;

4. The donor animals for the semen to be exported to the United States have been part of the national flock/herd of the Netherlands and are free from any movement or quarantine restrictions, according to point A1. to A17. above;
5. Any tests required under Section A. above for ovine or caprine semen exported to the United States 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;
6. The laboratory tests mentioned in point A8. to point A9. were carried out with negative results in a laboratory approved by the competent veterinary services;
7. The Netherlands is free of foot-and-mouth disease (FMD), rinderpest, contagious caprine pleuropneumonia and Rift Valley Fever;
8. In the Netherlands:
  - a. Scrapie is a compulsorily notifiable disease and an effective surveillance and monitoring system for scrapie is in place.
  - b. Sheep and goats affected with scrapie are maintained under quarantine in a manner that will prevent disease spread until the animal is no longer living and the remains have been disposed of in a way that prevents disease spread;
  - c. The feeding of sheep and goats with meat-and-bone meal or greaves derived from ruminants has been banned and the ban is effectively enforced in the whole region for the entire life of the animal; and the donors have not been in any other country/region with a less restrictive feeding policy prior to the collection of semen for export;
9. Ruminant products used in commercial semen extenders in the Netherlands were sourced from countries considered by USDA to be free from foot-and mouth disease and rinderpest as listed in 9 CFR Part 94 and other official publications;
10. 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 Netherlands;
11. 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;
12. The entire shipment exported under this certificate (including semen that might have been collected in more than one approved semen collection center by the same SCC veterinarian) has been maintained under continuous oversight of the official veterinarian until the conveyance is scheduled to depart for the United States;
13. The shipping containers were sealed with an approved seal from the competent authority of the Netherlands, and the seal number(s) is (are) recorded in point I;
14. The semen is routed directly to the United States from the Netherlands with no stops en route other than those provided on the USDA import permit.

**Note:**

- (1) Delete as appropriate.
- (2) Animals must be individually tested negative for bovine TB by an intradermal TB test using purified protein derivative Mycobacterium bovis tuberculin. A negative test means no detectable response using both visual and manual palpation when read 72 hours following injection with intradermal tuberculin.
- (3) For brucellosis, the following tests are acceptable:  
Brucella abortus/melitensis:
  - The FPA (a negative result is considered anything less than 20 millipolar above the negative control value);
  - Or The complement fixation test (Note: ewes that have been vaccinated with Brucella abortus S19 vaccine between 3 and 6 months of age are considered negative if the sera have no fixation reaction up to a titer of 30 ICFTU/ml when the animals are tested at an age of 18 months or older);
  - Or The buffered plate antigen agglutination test (read for agglutination immediately after the 8-minute period is completed; a negative result is the absence of any visible reaction.Brucella ovis (in the case of sheep): acceptable tests include either:
  - The enzyme- linked immunosorbent assay (ELISA), (using the International Standard standards for anti-Brucella ovis S serum referenced in the OIE Terrestrial Manual);



Or The complement fixation test, (Sera with no fixation reaction for a titer less than 50 ICFTU/ml are considered to be negative).

- (4) Semen collected in an EU Member State at different approved locations that are under the supervision of the same SCC veterinarian may be qualified for exportation to the United States and included in a single shipment, provided that the SCC veterinarian can certify the integrity of the total shipment under relevant sections above, and that none of the semen was transported in a container with semen which was collected under less than equivalent health standards. This information must be provided to the Official Veterinarian for semen collected by the same SCC Veterinarian at each different SCC.