



## Noord-Macedonië varkenssperma

Code: **VRKSU-20** Versie: 1.0.0

Ingangsdatum: 17-08-2026

Eigenaar: NVWA T&I, team Export

| Versie | Datum      | Wijziging ten opzichte van vorige versie                                                                                                                                       |
|--------|------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.0.0  | 17-08-2026 | In mei 2026 zijn met Noord-Macedonië afspraken gemaakt over de export van varkenssperma. Deze instructie en het bijgevoegde certificaat vormen de weerslag van deze afspraken. |

### 1 DOEL EN TOEPASSINGSGEBIED

Deze instructie geldt voor het exporteren van varkenssperma naar Noord-Macedonië. De instructie beschrijft de voorwaarden die gelden voor de invoer in Noord-Macedonië, 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 varkenssperma naar Noord-Macedonië 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 LANDX en Nederland.

### 3 DEFINITIES

| Begrip                     | Definitie                                                                                                                                                                                                                                                                                               |
|----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| varken                     | Een dier dat tot de hoefdiersoort <i>Sus scrofa</i> behoort.                                                                                                                                                                                                                                            |
| spermawinningscentrum      | Een inrichting voor levende producten die door de bevoegde autoriteit is erkend voor de winning, de verwerking, de opslag en het vervoer van sperma van runderen, varkens, schapen, geiten of paardachtigen dat voor verplaatsing naar een andere EU-lidstaat of export naar een derde land bestemd is. |
| sperma                     | Het onbewerkte, bewerkte of verdunde ejaculaat van één of meer dieren.                                                                                                                                                                                                                                  |
| dierenarts van het centrum | De dierenarts die verantwoordelijk is voor de activiteiten in het spermawinningscentrum, de verwerkingsinrichting voor levende producten of het opslagcentrum voor levende producten.                                                                                                                   |

## 4 WERKWIJZE

De export van varkenssperma naar Noord-Macedonië 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.
- Diagnostische laboratoriumtesten dienen te worden uitgevoerd door een laboratorium welk conform het 'Werkvoorschrift toegestane laboratoria dierzieketesten export derde landen' is toegestaan. Dit werkvoorschrift is [hier](#) te vinden.

Certificaat: zie bijlage

Verklaring 1:  
*The Netherlands*

Verklaring 1.1:

*Either<sup>(1)</sup> Has during the past 12 months been free of foot-and-mouth disease, classical swine fever and African swine fever;*  
*And That no vaccinations have been carried out against any of these diseases during the past 12 months;*  
*Or<sup>(1)</sup> Is recognised as free of foot-and-mouth disease without vaccination by the World Organization for Animal Health (WOAH) and free of classical swine fever and African swine fever, in accordance with the recommendations laid down in the WOAH Terrestrial Animal Health Code;*

De niet van toepassing zijnde optie dient te worden doorgehaald.

De eerste optie van deze verklaring dient geheel te worden doorgehaald.

Het eerste deel van de tweede optie van deze verklaring ("... free of foot-and-mouth disease without vaccination ...") kan worden afgegeven op basis van de website van de WOAH (= [Foot and mouth disease - WOAH - World Organisation for Animal Health](#)), alwaar de landen worden aangegeven die door de WOAH worden erkend als vrij van mond-en-klauwzeer zonder vaccinatie.

Het tweede deel van de tweede optie van deze verklaring ("... free of classical swine fever and African swine fever ...") kan worden afgegeven na controle van de dierziektesituatie in Nederland. Klassieke varkenspest en Afrikaanse varkenspest zijn aangifteplichtige dierziekten in Nederland. Informatie over de dierziektesituatie in Nederland is [hier](#) te vinden.

Verklaring 2:  
*The semen collection centre in which the semen in this consignment was collected:*

Verklaring 2.1:

*Is approved for export to the Republic of North Macedonia by the veterinary services of the Netherlands and complies with the conditions for approval and supervision set out in articles 21 and 22 of the Book of Rules on veterinary health requirements for placing on the market of semen for artificial insemination, embryos and ova, manner of keeping records, requirements regarding staff, premises, equipment and instruments, method and requirements for approval of embryo-transfer teams and official controls of semen for artificial insemination, ova and embryos which is equivalent to Chapter I and Chapter II of Annex A to Directive 90/429/EEC (Commission Delegated Regulation (EU) 2020/686);*

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

Verklaring 2.2:

*Was, during the period commencing three months prior to the date of collection of the semen in this consignment until the date of its dispatch, situated in an area not restricted due to an outbreak of foot-and-mouth disease, classical swine fever, African swine fever, swine vesicular disease and vesicular stomatitis;*

Deze verklaring kan worden afgegeven na controle van de dierziektesituatie in Nederland. Mond-en-klauwzeer, klassieke varkenspest en Afrikaanse varkenspest zijn aangifteplichtige dierziekten.

Informatie over de dierziektesituatie in Nederland is [hier](#) te vinden.

Voor wat betreft de niet-aangifteplichtige dierziekte swine vesicular disease (SVD) kan deze verklaring worden afgegeven op basis van het feit dat Nederland vrij is van SVD sinds 1994. Mocht SVD in de toekomst weer worden gediagnosticeerd in Nederland, zal dit middels de basismonitoring worden gerapporteerd.

Voor wat betreft de niet-aangifteplichtige dierziekte vesiculaire stomatitis kan deze verklaring worden afgegeven op basis van het feit dat Nederland als 'historisch vrij' van vesiculaire stomatitis kan worden beschouwd. Mocht vesiculaire stomatitis in de toekomst toch worden gediagnosticeerd in Nederland, zal dit middels de basismonitoring worden gerapporteerd.

#### Verklaring 2.3:

*Was, during the period commencing 30 days prior to the date of collection of the semen in this consignment until the date of its dispatch, free from brucellosis and Aujeszky's disease;*

Deze verklaring kan worden afgegeven na controle van de dierziektesituatie in Nederland. Brucellose en de ziekte van Aujeszky zijn aangifteplichtige dierziekten. Informatie over de dierziektesituatie in Nederland is [hier](#) te vinden.

#### Verklaring 2.4:

Either<sup>(1)</sup> Contains only animals that have not been vaccinated against Aujeszky's disease and meet the requirements of articles 23 and 24 of the Book of Rules on veterinary health requirements for placing on the market of semen for artificial insemination, embryos and ova, manner of keeping records, requirements regarding staff, premises, equipment and instruments, method and requirements for approval of embryo-transfer teams and official controls of semen for artificial insemination, ova and embryos which is equivalent to Annex B to Directive 90/429/EEC (Commission Delegated Regulation (EU) 2020/686);

And/or<sup>(1)(2)</sup> Is a centre in which some or all of the animals have been vaccinated against Aujeszky's disease using a gE deleted vaccine and meet the requirements of articles 23 and 24 of the Book of Rules on veterinary health requirements for placing on the market of semen for artificial insemination, embryos and ova, manner of keeping records, requirements regarding staff, premises, equipment and instruments, method and requirements for approval of embryo-transfer teams and official controls of semen for artificial insemination, ova and embryos which is equivalent to Annex B to Directive 90/429/EEC (Commission Delegated Regulation (EU) 2020/686);

De niet van toepassing zijnde optie dient te worden doorgehaald.

De eerste optie van deze verklaring kan worden afgegeven op basis van EU- en nationale regelgeving.

De tweede optie van deze verklaring dient te worden doorgehaald.

N.B.: Conform voetnoot (2) is de tweede optie van deze verklaring niet van toepassing indien het land van bestemming, of een regio daarvan, vrij is van de ziekte van Aujeszky overeenkomstig EU- en nationale regelgeving.

### **CONDITIONS FOR THE ADMISSION OF ANIMALS TO THE SEMEN COLLECTION CENTRE**

#### Verklaring 3:

*Prior to be admitted to the semen collection centre, all animals:*

#### Verklaring 3.1:

*Were subjected to a period of quarantine of at least 30 days in accommodation specifically approved for the purpose by the competent authority, and where only animals having at least the same health status were present (quarantine accommodation);*

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

#### Verklaring 3.2:

*Prior to entering the quarantine accommodation, were chosen from herds or holdings:*

#### Verklaring 3.2.1:

*Which were free of brucellosis in accordance with the Chapter on porcine brucellosis of the Terrestrial Animal Health Code of the World Organisation for Animal Health (WOAH);*

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

Verklaring 3.2.2:

*In which no animal vaccinated against foot-and-mouth disease was present in the preceding 12 months;*

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

Verklaring 3.2.3:

*Which were not situated in a restricted area defined under the provisions of the national legislation due to an outbreak of foot-and-mouth disease, classical swine fever, African swine fever, swine vesicular disease, vesicular stomatitis and Aujeszky's disease;*

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

Verklaring 3.2.4:

*In which no clinical, serological, virological or pathological evidence of Aujeszky's disease was detected in the preceding 12 months;*

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

Verklaring 3.3:

*Prior to entering the quarantine accommodation, were not previously kept in any herd of a lower health status than described in 3.2.;*

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

Verklaring 3.4:

*Within 30 days prior to entering the quarantine accommodation referred to in point 3.1. were subjected to the following tests, performed in accordance with international standards, with negative results;*

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

Verklaring 3.4.1:

*As regards brucellosis, a buffered Brucella antigen test (rose Bengal test), or a cELISA or an iELISA;*

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

Verklaring 3.4.2:

*As regards Aujeszky's disease;*

Verklaring 3.4.2.1:

*Either<sup>(1)</sup> In the case of non-vaccinated animals, a serum neutralisation test or an ELISA for detecting antibodies to the whole Aujeszky's disease virus or to its glycoprotein B (ADV-gB) or glycoprotein D (ADV-gD);*

*Or<sup>(1)</sup> In the case of animals vaccinated with a gE deleted vaccine, an ELISA for detecting antibodies to glycoprotein E (ADV-gE);*

De niet van toepassing zijnde optie dient te worden doorgehaald.

De eerste optie van deze verklaring kan worden afgegeven op basis van EU- en nationale regelgeving.

De tweede optie van deze verklaring kan worden afgegeven op basis van EU- en nationale regelgeving.

Verklaring 3.5:

*Either<sup>(1)</sup> Were admitted to the centre after all the animals had reacted with negative result to a buffered Brucella antigen test (rose Bengal test), or a cELISA or an iELISA carried out on samples collected the last 15 days of the period of quarantine specified in point 3.1.;*

*Or<sup>(1)</sup> Were admitted to the centre after not all the animals had reacted with negative result to a buffered Brucella antigen test (rose Bengal test), or a cELISA or an iELISA carried out on samples collected the last 15 days of the period of quarantine specified in point 3.1. and the suspicion of brucellosis was ruled out in accordance with article 23 of the Book of Rules on veterinary health requirements for placing on the market of semen for artificial insemination, embryos and ova, manner of keeping records, requirements regarding staff, premises, equipment and instruments, method and requirements for approval of embryo-transfer teams and official controls of semen for artificial insemination, ova and embryos which is equivalent to point 1.5 of Chapter 1 of Annex B to Directive 90/429/EEC (Commission Delegated Regulation (EU) 2020/686);*

De niet van toepassing zijnde optie dient te worden doorgehaald.

De eerste optie van deze verklaring kan worden afgegeven op basis van EU- en nationale regelgeving. De tweede optie van deze verklaring kan worden afgegeven op basis van EU- en nationale regelgeving.

**Verklaring 3.6:**

*Were subjected to the following tests for Aujeszky's disease carried out on samples collected the last 15 days of the period of quarantine specified in point 3.1.:*

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

**Verklaring 3.6.1:**

*Either<sup>(1)</sup> In the case of non-vaccinated animals, a serum neutralisation test or an ELISA for detecting antibodies to the whole Aujeszky's disease virus or to its glycoprotein B (ADV-gB) or glycoprotein D (ADV-gD);*

*Or<sup>(1)</sup> In the case of animals vaccinated with a gE deleted vaccine, an ELISA for detecting antibodies to glycoprotein E (ADV-gE);*

De niet van toepassing zijnde optie dient te worden doorgehaald.

De eerste optie van deze verklaring kan worden afgegeven op basis van EU- en nationale regelgeving.

De tweede optie van deze verklaring kan worden afgegeven op basis van EU- en nationale regelgeving.

**Verklaring 3.6.2:**

*Either<sup>(1)</sup> The tests referred to in point 3.6.1. were carried out with negative result in each case;*

*Or<sup>(1)</sup> The animals that proved positive in a test referred to in point 3.6.1. were removed immediately from the quarantine accommodation and the competent authority took all necessary measures to ensure that the remaining animals had a satisfactory health status before being admitted to the collection centre in accordance with point 3.;*

De niet van toepassing zijnde optie dient te worden doorgehaald.

De eerste optie van deze verklaring kan worden afgegeven op basis van EU- en nationale regelgeving.

De tweede optie van deze verklaring kan worden afgegeven op basis van EU- en nationale regelgeving.

**Verklaring 3.7:**

*All tests were carried out in a laboratory approved by the competent authority;*

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

**Verklaring 3.8:**

*Animals were only admitted to the semen collection centre with the express permission of the centre veterinarian and all animal movements, entering and exiting the semen collection centre, are recorded;*

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

**Verklaring 3.9:**

*No animal admitted to the semen collection centre showed any clinical sign of disease on the day of admission: all animals came directly from the quarantine accommodation which, on the day of consignment and during the period of residency of the animals, officially fulfilled the following conditions:*

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

**Verklaring 3.9.1:**

*It was not situated in a restricted area defined under the provisions of national legislation due to an outbreak of foot-and-mouth disease, classical swine fever, African swine fever, swine vesicular disease, vesicular stomatitis and Aujeszky's disease;*

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

**Verklaring 3.9.2:**

*No clinical, serological, virological or pathological evidence of foot-and-mouth disease, classical swine fever, African swine fever, swine vesicular disease, vesicular stomatitis and Aujeszky's disease had been recorded for the past 30 days;*

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

**COMPULSORY ROUTINE TESTS FOR ANIMALS KEPT AT THE SEMEN COLLECTION CENTRE**

Verklaring 4:

*All animals kept at the semen collection centre are subjected to the following routine tests carried out in a laboratory approved by the competent authority:*

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

Verklaring 4.1:

*As regards brucellosis, a buffered Brucella antigen test (rose Bengal test), or a cELISA or an iELISA;*

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

Verklaring 4.2:

*As regards Aujeszky's disease;*

Verklaring 4.2.1:

*Either<sup>(1)</sup> In the case of non-vaccinated animals, a serum neutralisation test or an ELISA for detecting antibodies to the whole Aujeszky's disease virus or to its glycoprotein B (ADV-gB) or glycoprotein D (ADV-gD);*

*Or<sup>(1)</sup> In the case of animals vaccinated with a gE deleted vaccine, an ELISA for detecting antibodies to glycoprotein E (ADV-gE);*

De niet van toepassing zijnde optie dient te worden doorgehaald.

De eerste optie van deze verklaring kan worden afgegeven op basis van EU- en nationale regelgeving.

De tweede optie van deze verklaring kan worden afgegeven op basis van EU- en nationale regelgeving.

Verklaring 4.3:

*The routine tests referred to in points 4.1. and 4.2. are carried out on samples taken in accordance with article 24 of the Book of Rules on veterinary health requirements for placing on the market of semen for artificial insemination, embryos and ova, manner of keeping records, requirements regarding staff, premises, equipment and instruments, method and requirements for approval of embryo-transfer teams and official controls of semen for artificial insemination, ova and embryos which is equivalent to point 1.2 of Chapter II of Annex B to Directive 90/429/EEC (Commission Delegated Regulation (EU) 2020/686) in order to ensure that all animals in the centre have been tested at least once during their stay at that centre and at least every 12 months from the date of admission, if their stay exceeds 12 months;*

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

Verklaring 4.4:

*Either<sup>(1)</sup> All of the animals have reacted with negative results in the routine tests referred to in points 4.1. and 4.2. carried out on samples referred to in point 4.3.;*

*Or<sup>(1)</sup> Not all of the animals have reacted with negative results in the tests referred to in points 4.1. and 4.2. carried out on samples referred to in point 4.3.:*

*a. The animals which proved positive were isolated;*

*b. The semen collected from each animal at the centre since the date of that animal's last negative test was held in separate storage from semen eligible for export to the Republic of North Macedonia which was collected before the animal's last negative test or after the health status of the centre had been re-established under responsibility of the competent authority of the exporting country;*

De niet van toepassing zijnde optie dient te worden doorgehaald.

De eerste optie van deze verklaring kan worden afgegeven op basis van EU- en nationale regelgeving.

De tweede optie van deze verklaring kan worden afgegeven op basis van EU- en nationale regelgeving.

**CONDITIONS FOR SEMEN COLLECTED AT A SEMEN COLLECTION CENTRE AND INTENDED FOR EXPORT TO THE REPUBLIC OF NORTH MACEDONIA**

Verklaring 5:

*The semen in this consignment was obtained from animals which;*

Verklaring 5.1:

*Have been resident in the Netherlands for a minimum period of three months immediately prior to collection;*

Deze verklaring kan worden afgegeven op basis van een verklaring van de aan het spermawinningscentrum verbonden dierenartspracticus.

Verklaring 5.2:

*Showed no clinical signs of disease on the day the semen was collected;*

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

Verklaring 5.3:

*Had not been vaccinated against foot-and-mouth disease;*

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

Verklaring 5.4:

*Satisfy the requirements referred to in points 3.;*

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

Verklaring 5.5:

*Have not been allowed to serve naturally;*

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

Verklaring 5.6:

*Were kept in semen collection centres which were not situated in a restricted area designated under the provisions of the national legislation relating to foot-and-mouth disease, classical swine fever, swine vesicular disease, vesicular stomatitis and Aujeszky's disease;*

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

Verklaring 5.7:

*Were kept in semen collection centres in which no clinical, serological, virological or pathological evidence of foot-and-mouth disease, classical swine fever, African swine fever, swine vesicular disease, vesicular stomatitis and Aujeszky's disease has been detected in the 30 day period immediately prior to collection;*

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

Verklaring 6:

*An effective combination of antibiotics, in particular against leptospires, was added to the semen in this consignment after final dilution or to the diluent. In the case of frozen semen, antibiotics were added before the semen was frozen;*

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

Verklaring 6.1:

*The combination of antibiotics referred to in point 6. produced an effect at least equivalent to the following concentration in the final diluted semen:*

- a. Not less than 500 µg streptomycin per ml final dilution;*
- b. Not less than 500 IE penicillin per ml final dilution;*
- c. Not less than 150 µg lincomycin per ml final dilution;*
- d. Not less than 300 µg spectinomycin per ml final dilution;*

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

Verklaring 6.2:

*Immediately after the addition of the antibiotics the diluted semen was kept at a temperature of at least 15 °C for a period of not less than 45 minutes;*

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

Verklaring 7:

*The semen in this consignment:*

Verklaring 7.1:

*Has been stored as laid down in article 21 paragraph (1) point 2) subpoint d) and article 22 point 7) subpoints a), b), e) and f) of the Book of Rules on veterinary health requirements for placing on the market of semen for artificial insemination, embryos and ova, manner of keeping records, requirements regarding staff, premises, equipment and instruments, method and requirements for approval of embryo-transfer teams and official controls of semen for artificial insemination, ova and*

*embryos which is equivalent to point 2 (d) of Chapter I and point 6 (a), (b), (e) and (f) of Chapter II of Annex A to Directive 90/429/EEC (Commission Delegated Regulation (EU) 2020/686) prior to dispatch;*

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

Verklaring 7.2:

*Is being transported to the country of destination in flasks which were cleaned and disinfected or sterilised before use and which have been sealed prior to dispatch from the approved storage facilities;*

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

## **5 BEVOEGDHEDEN EN VERANTWOORDELIJKHEDEN**

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

Bijlage 1: certificaat

VETERINARY CERTIFICATE FOR THE EXPORT OF SEMEN OF DOMESTIC ANIMALS OF THE PORCINE SPECIES FROM THE NETHERLANDS TO THE REPUBLIC OF NORTH MACEDONIA

## I. IDENTIFICATION OF THE SEMEN

| Product no. | Product | Donor identity | Species (Scientific name) | Breed |
|-------------|---------|----------------|---------------------------|-------|
|             |         |                |                           |       |

| Batch no. | Date of semen collection | Identification of the straw | Quantity |
|-----------|--------------------------|-----------------------------|----------|
|           |                          |                             |          |

Seal number :

## II. ORIGIN OF THE SEMEN

| Product no. | Approval number of artificial insemination (AI) centre | Name and address of artificial insemination (AI) centre |
|-------------|--------------------------------------------------------|---------------------------------------------------------|
|             |                                                        |                                                         |

Name and address consignor :

Date of shipment :

Place of shipment :

## III. DESTINATION OF THE SEMEN

Means of transport :

Identification of the means of transport :

Name and address consignee :

Name and address destination :

## IV. HEALTH INFORMATION

I, the undersigned, official veterinarian, hereby certify that:

## 1. The Netherlands

1.1. Either<sup>(1)</sup>

Has during the past 12 months been free of foot-and-mouth disease, classical swine fever and African swine fever;

And

That no vaccinations have been carried out against any of these diseases during the past 12 months;

Or<sup>(1)</sup>

Is recognised as free of foot-and-mouth disease without vaccination by the World Organization for Animal Health (WOAH) and free of classical swine fever and African swine fever, in accordance with the recommendations laid down in the WOAH Terrestrial Animal Health Code;

## 2. The semen collection centre in which the semen in this consignment was collected:

- 2.1. Is approved for export to the Republic of North Macedonia by the veterinary services of the Netherlands and complies with the conditions for approval and supervision set out in articles 21 and 22 of the Book of Rules on veterinary health requirements for placing on the market of semen for artificial insemination, embryos and ova, manner of keeping records, requirements regarding staff, premises, equipment and instruments, method and requirements for approval of embryo-transfer teams and official controls of semen for artificial insemination, ova and embryos which is equivalent to Chapter I and Chapter II of Annex A to Directive 90/429/EEC (Commission Delegated Regulation (EU) 2020/686);

- 2.2. Was, during the period commencing three months prior to the date of collection of the semen in this consignment until the date of its dispatch, situated in an area not restricted due to an outbreak of foot-and-mouth disease, classical swine fever, African swine fever, swine vesicular disease and vesicular stomatitis;
- 2.3. Was, during the period commencing 30 days prior to the date of collection of the semen in this consignment until the date of its dispatch, free from brucellosis and Aujeszky's disease;
- 2.4. Either<sup>(1)</sup> Contains only animals that have not been vaccinated against Aujeszky's disease and meet the requirements of articles 23 and 24 of the Book of Rules on veterinary health requirements for placing on the market of semen for artificial insemination, embryos and ova, manner of keeping records, requirements regarding staff, premises, equipment and instruments, method and requirements for approval of embryo-transfer teams and official controls of semen for artificial insemination, ova and embryos which is equivalent to Annex B to Directive 90/429/EEC (Commission Delegated Regulation (EU) 2020/686);  
And/or<sup>(1)(2)</sup> Is a centre in which some or all of the animals have been vaccinated against Aujeszky's disease using a gE deleted vaccine and meet the requirements of articles 23 and 24 of the Book of Rules on veterinary health requirements for placing on the market of semen for artificial insemination, embryos and ova, manner of keeping records, requirements regarding staff, premises, equipment and instruments, method and requirements for approval of embryo-transfer teams and official controls of semen for artificial insemination, ova and embryos which is equivalent to Annex B to Directive 90/429/EEC (Commission Delegated Regulation (EU) 2020/686);

#### CONDITIONS FOR THE ADMISSION OF ANIMALS TO THE SEMEN COLLECTION CENTRE

3. Prior to be admitted to the semen collection centre, all animals:
  - 3.1. Were subjected to a period of quarantine of at least 30 days in accommodation specifically approved for the purpose by the competent authority, and where only animals having at least the same health status were present (quarantine accommodation);
  - 3.2. Prior to entering the quarantine accommodation, were chosen from herds or holdings:
    - 3.2.1. Which were free of brucellosis in accordance with the Chapter on porcine brucellosis of the Terrestrial Animal Health Code of the World Organisation for Animal Health (WOAH);
    - 3.2.2. In which no animal vaccinated against foot-and-mouth disease was present in the preceding 12 months;
    - 3.2.3. Which were not situated in a restricted area defined under the provisions of the national legislation due to an outbreak of foot-and-mouth disease, classical swine fever, African swine fever, swine vesicular disease, vesicular stomatitis and Aujeszky's disease;
    - 3.2.4. In which no clinical, serological, virological or pathological evidence of Aujeszky's disease was detected in the preceding 12 months;
  - 3.3. Prior to entering the quarantine accommodation, were not previously kept in any herd of a lower health status than described in 3.2.;
  - 3.4. Within 30 days prior to entering the quarantine accommodation referred to in point 3.1. were subjected to the following tests, performed in accordance with international standards, with negative results;
    - 3.4.1. As regards brucellosis, a buffered Brucella antigen test (rose Bengal test), or a cELISA or an iELISA;
    - 3.4.2. As regards Aujeszky's disease;
      - 3.4.2.1. Either<sup>(1)</sup> In the case of non-vaccinated animals, a serum neutralisation test or an ELISA for detecting antibodies to the whole Aujeszky's disease virus or to

- its glycoprotein B (ADV-gB) or glycoprotein D (ADV-gD);
- Or<sup>(1)</sup> In the case of animals vaccinated with a gE deleted vaccine, an ELISA for detecting antibodies to glycoprotein E (ADV-gE);
- 3.5. Either<sup>(1)</sup> Were admitted to the centre after all the animals had reacted with negative result to a buffered Brucella antigen test (rose Bengal test), or a cELISA or an iELISA carried out on samples collected the last 15 days of the period of quarantine specified in point 3.1.;
- Or<sup>(1)</sup> Were admitted to the centre after not all the animals had reacted with negative result to a buffered Brucella antigen test (rose Bengal test), or a cELISA or an iELISA carried out on samples collected the last 15 days of the period of quarantine specified in point 3.1. and the suspicion of brucellosis was ruled out in accordance with article 23 of the Book of Rules on veterinary health requirements for placing on the market of semen for artificial insemination, embryos and ova, manner of keeping records, requirements regarding staff, premises, equipment and instruments, method and requirements for approval of embryo-transfer teams and official controls of semen for artificial insemination, ova and embryos which is equivalent to point 1.5 of Chapter 1 of Annex B to Directive 90/429/EEC (Commission Delegated Regulation (EU) 2020/686);
- 3.6. Were subjected to the following tests for Aujeszky's disease carried out on samples collected the last 15 days of the period of quarantine specified in point 3.1.:
- 3.6.1. Either<sup>(1)</sup> In the case of non-vaccinated animals, a serum neutralisation test or an ELISA for detecting antibodies to the whole Aujeszky's disease virus or to its glycoprotein B (ADV-gB) or glycoprotein D (ADV-gD);
- Or<sup>(1)</sup> In the case of animals vaccinated with a gE deleted vaccine, an ELISA for detecting antibodies to glycoprotein E (ADV-gE);
- 3.6.2. Either<sup>(1)</sup> The tests referred to in point 3.6.1. were carried out with negative result in each case;
- Or<sup>(1)</sup> The animals that proved positive in a test referred to in point 3.6.1. were removed immediately from the quarantine accommodation and the competent authority took all necessary measures to ensure that the remaining animals had a satisfactory health status before being admitted to the collection centre in accordance with point 3.;
- 3.7. All tests were carried out in a laboratory approved by the competent authority;
- 3.8. Animals were only admitted to the semen collection centre with the express permission of the centre veterinarian and all animal movements, entering and exiting the semen collection centre, are recorded;
- 3.9. No animal admitted to the semen collection centre showed any clinical sign of disease on the day of admission: all animals came directly from the quarantine accommodation which, on the day of consignment and during the period of residency of the animals, officially fulfilled the following conditions:
- 3.9.1. It was not situated in a restricted area defined under the provisions of national legislation due to an outbreak of foot-and-mouth disease, classical swine fever, African swine fever, swine vesicular disease, vesicular stomatitis and Aujeszky's disease;
- 3.9.2. No clinical, serological, virological or pathological evidence of foot-and-mouth disease, classical swine fever, African swine fever, swine vesicular disease, vesicular stomatitis and Aujeszky's disease had been recorded for the past 30 days;

#### COMPULSORY ROUTINE TESTS FOR ANIMALS KEPT AT THE SEMEN COLLECTION CENTRE

4. All animals kept at the semen collection centre are subjected to the following routine tests carried out in a laboratory approved by the competent authority:

- 4.1. As regards brucellosis, a buffered Brucella antigen test (rose Bengal test), or a cELISA or an iELISA;
- 4.2. As regards Aujeszky's disease;
  - 4.2.1. Either<sup>(1)</sup> In the case of non-vaccinated animals, a serum neutralisation test or an ELISA for detecting antibodies to the whole Aujeszky's disease virus or to its glycoprotein B (ADV-gB) or glycoprotein D (ADV-gD);
  - Or<sup>(1)</sup> In the case of animals vaccinated with a gE deleted vaccine, an ELISA for detecting antibodies to glycoprotein E (ADV-gE);
- 4.3. The routine tests referred to in points 4.1. and 4.2. are carried out on samples taken in accordance with article 24 of the Book of Rules on veterinary health requirements for placing on the market of semen for artificial insemination, embryos and ova, manner of keeping records, requirements regarding staff, premises, equipment and instruments, method and requirements for approval of embryo-transfer teams and official controls of semen for artificial insemination, ova and embryos which is equivalent to point 1.2 of Chapter II of Annex B to Directive 90/429/EEC (Commission Delegated Regulation (EU) 2020/686) in order to ensure that all animals in the centre have been tested at least once during their stay at that centre and at least every 12 months from the date of admission, if their stay exceeds 12 months;
- 4.4. Either<sup>(1)</sup> All of the animals have reacted with negative results in the routine tests referred to in points 4.1. and 4.2. carried out on samples referred to in point 4.3.;
  - Or<sup>(1)</sup> Not all of the animals have reacted with negative results in the tests referred to in points 4.1. and 4.2. carried out on samples referred to in point 4.3.:
    - a. The animals which proved positive were isolated;
    - b. The semen collected from each animal at the centre since the date of that animal's last negative test was held in separate storage from semen eligible for export to the Republic of North Macedonia which was collected before the animal's last negative test or after the health status of the centre had been re-established under responsibility of the competent authority of the exporting country;

#### CONDITIONS FOR SEMEN COLLECTED AT A SEMEN COLLECTION CENTRE AND INTENDED FOR EXPORT TO THE REPUBLIC OF NORTH MACEDONIA

5. The semen in this consignment was obtained from animals which;
  - 5.1. Have been resident in the Netherlands for a minimum period of three months immediately prior to collection;
  - 5.2. Showed no clinical signs of disease on the day the semen was collected;
  - 5.3. Had not been vaccinated against foot-and-mouth disease;
  - 5.4. Satisfy the requirements referred to in points 3.;
  - 5.5. Have not been allowed to serve naturally;
  - 5.6. Were kept in semen collection centres which were not situated in a restricted area designated under the provisions of the national legislation relating to foot-and-mouth disease, classical swine fever, swine vesicular disease, vesicular stomatitis and Aujeszky's disease;
  - 5.7. Were kept in semen collection centres in which no clinical, serological, virological or pathological evidence of foot-and-mouth disease, classical swine fever, African swine fever, swine vesicular disease, vesicular stomatitis and Aujeszky's disease has been detected in the 30 day period immediately prior to collection;
6. An effective combination of antibiotics, in particular against leptospires, was added to the semen in this consignment after final dilution or to the diluent. In the case of frozen semen, antibiotics were added before the semen was frozen;
  - 6.1. The combination of antibiotics referred to in point 6. produced an effect at least equivalent to the following concentration in the final diluted semen:
    - a. Not less than 500 µg streptomycin per ml final dilution;

- b. Not less than 500 IE penicillin per ml final dilution;
  - c. Not less than 150 µg lincomycin per ml final dilution;
  - d. Not less than 300 µg spectinomycin per ml final dilution;
- 6.2. Immediately after the addition of the antibiotics the diluted semen was kept at a temperature of at least 15 °C for a period of not less than 45 minutes;
- 7. The semen in this consignment:
  - 7.1. Has been stored as laid down in article 21 paragraph (1) point 2) subpoint d) and article 22 point 7) subpoints a), b), e) and f) of the Book of Rules on veterinary health requirements for placing on the market of semen for artificial insemination, embryos and ova, manner of keeping records, requirements regarding staff, premises, equipment and instruments, method and requirements for approval of embryo-transfer teams and official controls of semen for artificial insemination, ova and embryos which is equivalent to point 2 (d) of Chapter I and point 6 (a), (b), (e) and (f) of Chapter II of Annex A to Directive 90/429/EEC (Commission Delegated Regulation (EU) 2020/686) prior to dispatch;
  - 7.2. Is being transported to the country of destination in flasks which were cleaned and disinfected or sterilised before use and which have been sealed prior to dispatch from the approved storage facilities.

Notes

- <sup>(1)</sup> Delete as necessary.
- <sup>(2)</sup> This option shall be deleted in case the region of destination is free of Aujeszky's disease in accordance with Article 10 of Directive 64/432/EEC (Regulation (EU) 2016/429).

The signature and the stamp must be in a different color to that of the printing.