Japan, runderembryo's

Code: **RNDEU-11** Versie: 1.1.3

Ingangsdatum: 01-04-2024

Eigenaar: NVWA O&O, Team Export

Versie	Datum	Wijziging ten opzichte van vorige versie
1.1.1	27-07-2021	De toelichting bij verklaring 1 is aangepast, verklaring 3 is aangepast en een 'additional certification' (bijlage 3) is toegevoegd. Daarnaast is de verwijzing naar EU-regelgeving geactualiseerd.
1.1.2	21-10-2021	Verwijderd is dat de certificerende NVWA-dierenarts na iedere export een kopie (scan) van het certificaat dient te verzenden naar NVWA Utrecht via: export@nvwa.nl.
1.1.3	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 Japan. De instructie beschrijft de voorwaarden die worden gesteld aan de invoer in Japan, 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 Japan zijn officiële bilaterale afspraken gemaakt. Deze afspraken zijn bindend, van deze afspraken kan dus niet worden afgeweken.

2 WETTELIJKE BASIS

2.1 EU-regelgeving

- Gedelegeerde verordening (EU) 2020/686
- Uitvoeringsverordening (EU) 2020/999

2.2 Nationale wetgeving

- Wet dieren

2.3 Overige

- Bilaterale afspraken tussen Japan en Nederland.

3 DEFINITIES

Begrip	**Definitie**
embryowinningsteam	een inrichting voor levende producten bestaande uit een groep beroepsbeoefenaars of een structuur die door de bevoegde autoriteit is erkend voor de winning, de verwerking, de opslag en het vervoer van in vivo verkregen embryo's van runderen, varkens, schapen, geiten of paardachtigen.

4 WERKWIJZE

Export van runderembryo's naar Japan is toegestaan. Ten behoeve van de export zijn er twee documenten noodzakelijk: het exportcertificaat (zie paragraaf 4.1 + bijlage 1) en een aanvraag voor de import (zie paragraaf 4.2).

4.1 Exportcertificaat

- *Certificaat: zie bijlage 1*

Toelichting bij het certificaat:

Algemeen:

- Onder "Health Authorities of The Netherlands" wordt verstaan het Ministerie van Landbouw, Natuur en Voedselkwaliteit.
- In verband met het Schmallenbergvirus zijn met Japan extra verklaringen afgesproken (bijlage 2). De verklaringen zijn na controle af te geven en hierin moet(en) de niet van toepassing zijnde optie(s) worden doorgehaald. De tekst van de bijlage moet worden geprint op NVWA-waardepapier.
- 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 K-O&O-IE-WV05 is toegestaan.

Verklaring 1:
The Netherlands are free from Rinderpest, Contagious bovine pleuropneumonia, Foot and Mouth disease (FMD), Vesicular stomatitis, Rift Valley fever, bovine tuberculosis and Lumpy skin disease;
Deze verklaring kan worden afgegeven na controle van de dierziektesituatie in Nederland. Runderpest, besmettelijke bovine pleuropneumonie, mond-en-klauwzeer, Rift Valley koorts, tuberculose ten gevolge van Mycobacterium tuberculosis complex en nodulaire dermatose (lumpy skin disease) zijn aangifteplichtige dierziekten in Nederland. E-CertNL controleert automatisch op aangifteplichtige dierziekten. Informatie over de dierziektesituatie in Nederland is hier te vinden.
Voor wat betreft vesiculaire stomatitis kan deze verklaring worden afgegeven op basis van het feit dat Nederland als 'historisch vrij' van vesiculaire stomatitis kan worden beschouwd. De OIE World Animal Health Information System (WAHIS) geeft aan dat vesiculaire stomatitis nooit is gerapporteerd in Nederland. Mocht vesiculaire stomatitis in de toekomst toch worden gediagnosticeerd in Nederland, zal dit middels de basismonitoring worden gerapporteerd.

Verklaring 2:
In the Netherlands Akabane disease, Chuzan disease and Aino virus infection have never been diagnosed;
Deze verklaring kan worden afgegeven op basis van een overheidsverklaring. De dierziekten 'Akabane disease', 'Chuzan disease' en 'Aino virus infectie' zijn nog nooit gediagnosticeerd in Nederland.

Verklaring 3:
Rinderpest, Contagious bovine pleuropneumonia, FMD, ~~Vesicular stomatitis,~~ Rift Valley fever, Bovine brucellosis, Bovine tuberculosis, Transmissible spongiform encephalopathy (TSE), Bluetongue, Lumpy skin disease, Enzootic bovine leukosis and Bovine genital campylobacteriosis are designated as notifiable diseases in the Netherlands;
Deze verklaring kan worden afgegeven. De dierziekten runderpest, besmettelijke bovine pleuropneumonie, mond-en-klauwzeer, Rift Valley koorts, brucellose, tuberculose ten gevolge van Mycobacterium tuberculosis complex, alle overdraagbare spongiforme encefalopathieën (TSE's),

blauwtong, nodulaire dermatose (lumpy skin disease), endemische leukose bij runderen en campylobacteriose zijn aangifteplichtig.
Voor wat betreft vesiculaire stomatitis is een 'additional certification' toegevoegd aan het certificaat. Deze 'additional certification' dient te worden ondertekend door de certificerende NVWA-dierenarts.

Verklaring 4:
The premises on which each donor female for the exported embryos (herinafter referred to as "the embryo donor") was present for the 60 days prior to embryo collection (including the embryo collection facility) were clinically free of the following diseases for the 12 months prior to embryo collection; bovine brucellosis, bovine tuberculosis, paratuberculosis, Bluetongue, Enzootic bovine leucosis, Bovine viral diarrhea-mucosal disease (BVD-MD), Infectious bovine rhinotracheitis/infectious postular vulvovaginitis (IBR/IPV), Leptospirosis, Bovine genital campylobacteriosis and Trichomonosis;
Deze verklaring kan worden afgegeven op basis van een verklaring met gelijke strekking van de aan het bedrijf verbonden dierenartspracticus.

Verklaring 5:
The embryo donor stayed only in the Netherlands for at least 60 days at the time of embryo collection;
Deze verklaring kan worden afgegeven op basis van een verklaring met gelijke strekking van de aan het bedrijf verbonden dierenartspracticus.

Verklaring 6:
Each embryo donor was healthy and free of signs of infectious disease at the time of embryo collection, as were all other animals at the facility at that time;
Deze verklaring kan worden afgegeven op basis van een verklaring met gelijke strekking van de aan het bedrijf verbonden dierenartspracticus.

Verklaring 7:
Each embryo donor was tested by virus isolation, PCR or antigen capture ELISA for BVD-MD virus, with negative result, see annex I;
Deze verklaring kan worden afgegeven op basis van negatieve laboratoriumuitslagen van de donordieren, aan te leveren door belanghebbende.
Verklaring 8:
Each embryo donor was tested by intradermal test using bovine PPD for bovine tuberculosis at least 30 days after embryo collection, with negative results, see annex;
Deze verklaring kan worden afgegeven op basis van negatieve testresultaten van de donordieren, aan te leveren door belanghebbende.

Verklaring 9:
Each embryo donor was tested, see annex I:
(1) by agar gel immunodiffusion test or ELISA test to detect antibody to bluetongue virus between 21 and 60 days after collection, with negative result,
OR
(2) by virus isolation test or PCR test on a blood sample taken on the day of collection, with negative results;
Deze verklaring kan worden afgegeven op basis van negatieve laboratoriumuitslagen van de donordieren, aan te leveren door belanghebbende.

Verklaring 10:
Concerning bovine spongiform encephalopathy (BSE):
(1) BSE is a notifiable disease in the Netherlands;
AND
(2) The embryo donor is not BSE infected cattle or BSE cohort;
Deze verklaring kan worden afgegeven op basis van EU- en nationale regelgeving.

Verklaring 11:

The exported embryos were collected and handled in accordance with the recommendations of the International Embryo Transfer Society (IETS);
Deze verklaring kan worden afgegeven op basis van EU- en nationale regelgeving voor erkende embryowinningsteams.

Verklaring 12:
The semen used in fertilizing ova came from donor bulls, which met the animal health requirements for bovine semen to be exported to Japan from the Netherlands. In case the Netherlands is not the country of origin of the semen, a copy of the inspection certificate, issued by the Animal Health Authorities of the country of origin stating that the semen met the animal health requirements established between the Animal Health authorities of Japan and the country of origin, has been attached to this inspection certificate;
Deze verklaring kan worden afgegeven op basis van een verklaring met gelijke strekking van de teamdierenarts of op basis van een document/kopie certificaat van de autoriteiten van het land van herkomst van het gebruikte sperma.
Indien voor het bevruchten van de eicellen gebruik is gemaakt van sperma afkomstig uit een ander land dan Nederland moet een kopie van het certificaat van de autoriteiten van het land van herkomst van het gebruikte sperma worden toegevoegd aan dit certificaat. Dit is de verantwoordelijkheid van belanghebbende.

Verklaring 13:
The exported embryos were collected, processed and stored in conformance with "Conditions applicable to the embryo collection team", "Conditions applicable to processing laboratories" and "Conditions applicable to collection and storage of embryos" of the OIE Terrestrial Animal Health Code (hereinafter referred to as "the OIE Code");
Deze verklaring kan worden afgegeven indien de te exporteren runderembryo's afkomstig zijn van een erkend embryowinningsteam, op grond van het vereiste in Gedelegeerde verordening (EU) 2020/686.

Verklaring 14:
The exported embryos were consecutively washed at least 10 times with each washing diluted 1:100 and were washed twice with 0.25% sterile trypsin for a total trypsin exposure time of 60-90 seconds, in accordance with the procedures recommended by the IETS under the supervision of a veterinarian accredited by the Animal Health Authorities of the Netherlands;
Deze verklaring kan worden afgegeven indien de te exporteren runderembryo's afkomstig zijn van een erkend embryowinningsteam, op grond van het vereiste in Gedelegeerde verordening (EU) 2020/686.
Verklaring 15:
The exported embryos were examined microscopically according to the procedures recommended by the IETS under the supervision of a government veterinarian or a veterinarian accredited by the Animal Health Authorities of the Netherlands, and only embryos, which have an intact zona pellucida and freedom from adherent materials are eligible to export to Japan;
Deze verklaring kan worden afgegeven indien de te exporteren runderembryo's afkomstig zijn van een erkend embryowinningsteam, op grond van het vereiste in Gedelegeerde verordening (EU) 2020/686.

Verklaring 16:
The exported embryos are packed individually in the ampoules/straws that are permanently marked with collection date and identity (including breed) of the semen and embryo donors, in accordance with the IETS recommendations. Only one embryo per ampoule or straw is permitted;
Deze verklaring kan worden afgegeven indien de te exporteren runderembryo's afkomstig zijn van een erkend embryowinningsteam, op grond van het vereiste in Gedelegeerde verordening (EU) 2020/686.

Verklaring 17:
The exported embryos are maintained in a basket used only for them in the storage tank at a storage facility designated by the Animal Health Authorities of the Netherlands under the supervision of a government veterinarian or a veterinarian accredited by the Animal Health Authorities of the

Netherlands until being placed in the shipping tank which will be sealed by the Animal Health Authorities of the Netherlands;
Deze verklaring kan worden afgegeven indien de te exporteren runderembryo's afkomstig zijn van een erkend embryowinningsteam, op grond van het vereiste in Gedelegeerde verordening (EU) 2020/686.

Verklaring 18:
The shipping tank is either new or cleaned and disinfected under the supervision of a veterinarian accredited by the Animal Health Authorities of the Netherlands, and only fresh liquid nitrogen was used to charge the tank.
Deze verklaring kan worden afgegeven indien de te exporteren runderembryo's afkomstig zijn van een erkend embryowinningsteam, op grond van het vereiste in Gedelegeerde verordening (EU) 2020/686.

4.2 Aanvraag voor de import

Naast het exportcertificaat is ten behoeve van de export een document noodzakelijk in overeenstemming met bijlage 4 bij deze instructie. Dit document wordt niet afgegeven op NVWA-waardepapier. Het document moet door de certificerende ambtenaar van de NVWA worden ondertekend. De volgende toelichting is hierbij van belang:

Het onderdeel "genetic defects & reproductive disorders" (voor spermadonor) en "genetic defects" (voor de embryodonor) kan worden afgegeven op basis van een achterliggende verklaring, overeenkomstig bijlage 8, door de aan het bedrijf verbonden dierenartspracticus.

Daarnaast wordt er bij de ondertekening een relatie gelegd met Japanse wetgeving. De relevante delen van deze wetgeving zijn als bijlage 5, 6 en 7 bij deze instructie gevoegd zodat hier eventueel kennis van kan worden genomen.

5 BEVOEGDHEDEN EN VERANTWOORDELIJKHEDEN

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

Bijlage 1: certificaat

HEALTH CERTIFICATE
FOR BOVINE EMBRYOS TO BE EXPORTED FROM THE NETHERLANDS TO JAPAN

I. IDENTIFICATION OF THE PRODUCTS

Product no.	Product	Name of the donor bull	Breed of the donor bull	Identification of the donor bull

Product no.	Name of the embryo donor	Breed of the embryo donor	Identification of the embryo donor	Name and address of the premises of residence of the embryo donor for the 60 days prior to embryo collection

Batch no.		Dates of embryo collection	Dates of semen collection	Date of insemination of the donor female	Quantity of embryos

Container number :
Seal number :

II.ORIGIN OF THE PRODUCTS (EMBRYO COLLECTION FACILITY)

Product no.	Approval no.	Name and address

ORIGIN OF THE PRODUCTS (OTHER FACILITY)

Product no.	Additional approvals	Approval no.	Name and address
	Semen collection center		
	Semen storage center		

Name and address of exporter :
Place of loading :

III. DESTINATION OF THE PRODUCTS

Means of conveyance :
Identification of the means of conveyance :
Place of destination :
Name and address consignee :

IV. HEALTH INFORMATION

I, the undersigned, official veterinarian, certify that:

1. The Netherlands are free from Rinderpest, Contagious bovine pleuropneumonia, Foot and Mouth disease (FMD), Vesicular stomatitis, Rift Valley fever, bovine tuberculosis and Lumpy skin disease;
2. In the Netherlands Akabane disease, Chuzan disease and Aino virus infection have never been diagnosed;

3. Rinderpest, Contagious bovine pleuropneumonia, FMD, ~~Vesicular stomatitis,~~ Rift Valley fever, Bovine brucellosis, Bovine tuberculosis, Transmissible spongiform encephalopathy (TSE), Bluetongue, Lumpy skin disease, Enzootic bovine leukosis and Bovine genital campylobacteriosis are designated as notifiable diseases in the Netherlands;
4. The premises on which each donor female for the exported embryos (herinafter referred to as "the embryo donor") was present for the 60 days prior to embryo collection (including the embryo collection facility) were clinically free of the following diseases for the 12 months prior to embryo collection; bovine brucellosis, bovine tuberculosis, paratuberculosis, Bluetongue, Enzootic bovine leucosis, Bovine viral diarrhea-mucosal disease (BVD-MD), Infectious bovine rhinotracheitis/infectious postular vulvovaginitis (IBR/IPV), Leptospirosis, Bovine genital campylobacteriosis and Trichomonosis;
5. The embryo donor stayed only in the Netherlands for at least 60 days at the time of embryo collection;
6. Each embryo donor was healthy and free of signs of infectious disease at the time of embryo collection, as were all other animals at the facility at that time;
7. Each embryo donor was tested by virus isolation, PCR or antigen capture ELISA for BVD-MD virus, with negative result, see annex I;

Disease	Date	Method	Result	Name and address laboratory
BVD-MD				

8. Each embryo donor was tested by intradermal test using bovine PPD for bovine tuberculosis at least 30 days after embryo collection, with negative results, see annex;

Disease	Date	Method	Result	Name and address laboratory
Tuberculosis				

9. Each embryo donor was tested, see annex I:
   (1) by agar gel immunodiffusion test or ELISA test to detect antibody to bluetongue virus between 21 and 60 days after collection, with negative result,
   or (2) by virus isolation test or PCR test on a blood sample taken on the day of collection, with negative results;

Disease	Date	Method	Result	Name and address laboratory
Bluetongue				

10. Concerning bovine spongiform encephalopathy (BSE):
    (1) BSE is a notifiable disease in the Netherlands;
    and (2) The embryo donor is not BSE infected cattle or BSE cohort;
11. The exported embryos were collected and handled in accordance with the recommendations of the International Embryo Transfer Society (IETS);
12. The semen used in fertilizing ova came from donor bulls, which met the animal health requirements for bovine semen to be exported to Japan from the Netherlands. In case the Netherlands is not the country of origin of the semen, a copy of the inspection certificate, issued by the Animal Health Authorities of the country of origin stating that the semen met the animal health requirements established between the Animal Health authorities of Japan and the country of origin, has been attached to this inspection certificate;
13. The exported embryos were collected, processed and stored in conformance with "Conditions applicable to the embryo collection team", "Conditions applicable to processing laboratories" and "Conditions applicable to collection and storage of embryos" of the OIE Terrestrial Animal Health Code (hereinafter referred to as "the OIE Code");

14. The exported embryos were consecutively washed at least 10 times with each washing diluted 1:100 and were washed twice with 0.25% sterile trypsin for a total trypsin exposure time of 60-90 seconds, in accordance with the procedures recommended by the IETS under the supervision of a veterinarian accredited by the Animal Health Authorities of the Netherlands;
15. The exported embryos were examined microscopically according to the procedures recommended by the IETS under the supervision of a government veterinarian or a veterinarian accredited by the Animal Health Authorities of the Netherlands, and only embryos, which have an intact zona pellucida and freedom from adherent materials are eligible to export to Japan;
16. The exported embryos are packed individually in the ampoules/straws that are permanently marked with collection date and identity (including breed) of the semen and embryo donors, in accordance with the IETS recommendations. Only one embryo per ampoule or straw is permitted;
17. The exported embryos are maintained in a basket used only for them in the storage tank at a storage facility designated by the Animal Health Authorities of the Netherlands under the supervision of a government veterinarian or a veterinarian accredited by the Animal Health Authorities of the Netherlands until being placed in the shipping tank which will be sealed by the Animal Health Authorities of the Netherlands;
18. The shipping tank is either new or cleaned and disinfected under the supervision of a veterinarian accredited by the Animal Health Authorities of the Netherlands, and only fresh liquid nitrogen was used to charge the tank.

Bijlage 2: Schmallenbergverklaring

Annex to embryo certificate

ADDITIONAL DECLARATION FOR THE EXPORT OF BOVINE EMBRYOS TO JAPAN IN REGARD TO SCHMALLENBERG VIRUS (SBV) INFECTION.

1. The embryos in this consignment were collected before 01-04-2011;

OR* 2. The PCR test or virus isolation of the embryo donor, using serum collected on each collection day of the embryos for this consignment, was negative;

OR* 3. The virus neutralization test, ELISA or IFA, of the embryo donor, using serum collected between 21 – 60 days after collection of the embryos, was negative;

OR* 4. The virus neutralization test, ELISA or IFA, of the embryo donor, using serum collected between 21 – 60 days before embryo collection, was positive.

* Delete as appropriate

Name of embryo donor	Date of embryo collection	Date of serum sampling	Method(s) of testing (delete if appropriate)	Results of examinations (delete if appropriate)
			Virus neutralization test ELISA IFA PCR test / Virus isolation	Negative / positive Negative / positive Negative / positive Negative
			Virus neutralization test ELISA IFA PCR test / Virus isolation	Negative / positive Negative / positive Negative / positive Negative

Tested by:
Wageningen Bioveterinary Research (WBVR)
Houtribweg 39
8221 RA Lelystad
The Netherlands

Bijlage 3:

Annex to embryo certificate

ADDITIONAL CERTIFICATION
FOR BOVINE EMBRYOS TO BE EXPORTED TO JAPAN FROM THE NETHERLANDS

In the Netherlands, vesicular stomatitis is not designated as notifiable disease, however, the disease is able to be detected by the national Animal Health Surveillance System (AHSS).

Bijlage 4:

Issue no.

Issue date:

IMPORT CERTIFICATE FOR BOVINE EMBRYO TO JAPAN

Country of export: The Netherlands

DONOR BULL	Grade
Name	
Species & breed	
Registry organization & Registration no.	
Genetic defects & reproductive disorders	None
DONOR COW	
Name	
Species & breed	
Registry organization & Registration no.	
Mated or inseminated date	
Date of embryo collection	
Name and address of breeder of donor cow	
Qualification, name and address of person collecting / processing embryo	
Name and address of facility collecting / processing embryo	
Method of embryo collecting / processing	Acceptable

Certified above as confirmed and / or as believed trustworthy as provided for in the Japanese Law for Improvement Increased Production of Livestock (Law no. 209 enacted in 1950) by:

Official veterinarian of the Netherlands Food and Consumer Product Safety Authority, Ministry of Agriculture, Nature and Food Quality, The Netherlands.

(Signature)

Bijlage 5:

Enforcement Regulations of the Law for Improvement and Increased Production of Livestock (Ministerial Ordinance of the Ministry of Agriculture, Forestry and Fisheries No.96 of August 19, 1950)

Article 1 - Article 5 [omitted]

(Types of diseases concerning inspection)
Article 6 "Diseases specified by ministerial ordinance" mentioned in Article 4, paragraph 2 of the LAW for Improvement and Increased Production of Livestock (hereinafter referred to as the LAW) refers to the following:
(1) Infectious diseases
[omitted]
(2) Genetic defects
A. [omitted (same as those listed in the import quality requirements of the certificate for bovine embryo to be exported from Netherlands to Japan)]
B. [omitted (genetic defects for horses)]
C. [omitted (genetic defects for pigs)]
(3) Reproductive disorders
[omitted (same as those listed in the import quality requirements of the certificate for bovine embryo to be exported from Netherlands to Japan)]

Article 7- Article 13 [omitted]

(Types of diseases concerning diagnosis)
Article 13-2 "Infectious diseases and genetic defects" mentioned in Article 9-2, paragraph 1 of the LAW are listed below. However, in case ovary is collected from a slaughtered female animal and if an inspection has been carried out by prefecture on the said animal based on Abattoirs Law, Article 10, paragraph 1 - paragraph 3, diseases covered by the said inspection may be excluded.
(1) Infectious diseases [omitted]
(2) Genetic defects
Same as those listed in Article 6, (2)

(Veterinarian's diagnosis)
Article 13-3 "Veterinarian's diagnosis" mentioned in Article 9-2, paragraph 1 of the LAW must be made within 30 days before the date of collection of in vivo fertilised embryo from a female animal or the date of collection of ovary from a female animal (live or slaughtered).

(Exceptions to restriction on collection of embryos)
Article 13-4 "Any other cases specified by ministerial ordinance" mentioned in the proviso of Article 9-2, paragraph 1 of the LAW refers to the cases where a breeder collects an embryo from a female animal kept by himself in order to transplant it into another female animal kept by himself.

Article 14 - Article 16 [omitted]

(Method of inspection of in vivo fertilised embryos)
Article 16-2 "Inspection" mentioned in Article 13, paragraph 2 of the LAW must be carried out by using the following methods:
(1) Inspection of in vivo fertilised embryo must be carried out after the said embryo has been washed properly.
(2) Naked eye inspection must be carried out for items listed in A below and microscopic examination must be carried out for items listed in B below:
A. colour of suspension fluids, etc.
B. Shape of embryo; whether filiform matters and other impurities exist or not

(Method of collection of unfertilised eggs, etc.)
Article 16-3 "Collection and processing of unfertilised egg from ovary, performing of in vitro artificial insemination and inspection of in vitro fertilised embryo" mentioned in Article 13, paragraph 3 of the LAW must be carried out by using the following methods:
(1) In vitro insemination must be carried out after the said unfertilised egg has been washed properly.
(2) Naked eye inspection must be carried out for items listed in A below and microscopic examination must be carried out for items listed in B below:
A. colour of suspension fluids, etc.
B. Shape of embryo; whether filiform matters and other impurities exist or not

(Handling of semen, in vivo fertilised embryos and in vitro fertilised embryos)
Article 16-4 "Methods specified by ministerial ordinance" mentioned in Article 13, paragraph 4 of the LAW refers to the following:
(1) Containers, which are unlikely to cause adverse effects on semen or embryo must be used during storage or transport.
(2) Semen and embryos must be handled in a hygienic manner.

Article 17 [omitted]

(Issuer of certificate concerning imported semen)
Article 17-2 "Any other party designated by ministerial ordinance" mentioned in Article 14, paragraph 1, (1) of the Law, except those mentioned from A to D, refers to a non-profit corporation duly established under the laws of a foreign country and that have been designated by the Minister for Agriculture, Forestry and Fisheries as being capable of carrying out the task of issuing certificates.

(Types of genetic defects and reproductive disorders)
Article 17-3 "Genetic defects and reproductive disorders" mentioned in Article 14, paragraph 1, (1), A of the LAW are the same as those stated in Article 6, (2) and (3).

(Collector of imported seamen)
Article 17-4 "Any other party designated by ministerial ordinance" mentioned in Article 14, paragraph 1, (1) B of the LAW refers to a person who meets either of the following conditions:
(1) A veterinarian or artificial inseminator
(2) A person who has at least the equivalent knowledge and skill as an artificial inseminator and is deemed to be capable of performing artificial insemination properly and in a hygienic manner.

(Method of inspection concerning imported seamen, etc.)
Article 17-5"Methods specified by ministerial ordinance" mentioned in Article 14-1, paragraph 1, (1), B of the LAW is the same as those stated in Article 16 and 16-4.

(Matters to be indicated on certificate concerning imported semen)
Article 17-6 "Any other matters specified by ministerial ordinance" mentioned in Article 14, paragraph 1, (1) D of the LAW refers to the following:
(1) Name of the donor male
(2) Species and breed of the donor male
(3) Date of semen collection
(4) Name and address of the breeder of the donor male
(5) Name and address of the person who collected and processed semen

(Issuer of certificate concerning imported embryo)
Article 17-7 "Any other party designated by ministerial ordinance" mentioned in Article 14, paragraph 2, (1) of the LAW, except those mentioned from A to E, refers to a non-profit corporation duly established under the laws of a foreign country and that have been designated by the Minister for Agriculture, Forestry and Fisheries as being capable of carrying out the task of issuing certificates.

(Types of genetic defects)
Article 17-8 "Genetic defects designated by ministerial ordinance" referred to in Article 14, paragraph 2, (1), A of the LAW are the same as those stated in Article 6, (2), A.

(Collector of imported embryo)
Article 17-9 "Any other party designated by ministerial ordinance" mentioned in Article 14, paragraph 2, (1), C of the LAW refers to a veterinarian.

(Method of inspection concerning imported embryo, etc.)
Article 17-10 "Methods specified by ministerial ordinance" mentioned in Article 14, paragraph 2, (1), C of the LAW are the same as those stated in Article 16-2 and 16-4.

Article 17-11 "Any other party designated by ministerial ordinance" mentioned in Article 14, paragraph 2, (1), D of the LAW refers to a person who meets either of the following conditions:
(1) A veterinarian or artificial inseminator
(2) A person who has at least equivalent knowledge and skill as an artificial inseminator and is deemed to be capable of performing transplantation of in vitro fertilized embryo properly and in a hygienic manner.

Article 17-12 "Methods specified by ministerial ordinance" mentioned in Article 14, paragraph 2, (1), D of the LAW are the same as those stated in Article 16-3 and 16-4.

(Matters to be indicated on certificate concerning imported embryo)
Article 17-13 In the case of in vivo fertilised embryo, "any other matters specified by ministerial ordinance" mentioned in Article 14, paragraph 2, (1), F of the LAW refers to the following:
(1) Name of the donor male
(2) Species and breed of the donor male
(3) Name of the donor female
(4) Species and breed of the donor female
(5) Date of breeding or insemination of semen
(6) Date of collection of in vivo fertilised embryo
(7) Name and address of the breeder of the donor female
(8) Name and address of the person who collected and processed in vivo fertilised embryo

2. In the case of in vitro fertilised embryo, "any other matters specified by ministerial ordinance" mentioned in Article 14, paragraph 2, (1), F of the LAW refers to the following:
(1) Name of the donor male
(2) Species and breed of the donor male
(3) Name of the donor female
(4) Species and breed of the donor female
(5) Date of in vitro insemination
(6) Date of inspection of in vitro fertilised embryo
(7) Name and address of the breeder of the donor female
(8) Name and address of the person who collected the ovary, collected and processed the unfertilised egg, performed in vitro insemination and processed the embryo

(Low quality semen and embryos)
Article 18 "Low quality semen or embryo defined by ministerial ordinance" mentioned in Article 14, paragraph 3 of the LAW refers to the following:
(1) Low quality semen
   A. Semen contaminated with large numbers of bacteria
   B. Semen with filiform matters and other impurities
   C. Semen with a pH value indicating extreme acidity or alkalinity
(2) Low quality embryo

A. Embryo with egg cells degenerated or disappeared, or embryo extremely deformed
B. Embryo in a development stage, which differs remarkably from what is expected from the date of breeding or insemination
C. Embryo with large numbers of bacteria, filiform matters or other impurities

Article 19: Deleted

Article 20 – end of document [omitted]

Bijlage 6:

Law for Improvement and Increased Production of Livestock (Law No 209 of May 27 1950)

Latest Amendments: Law No. 150 of December 1, 2004

Article 1 - Article 3-5 [omitted]

(Restriction on breeding, etc.)

Article 4 To use male animals of cattle, horses and any other domestic animals designated by cabinet order for the purpose of collection of semen shall be prohibited, unless the animal has received an inspection carried out on an annual basis by National Livestock Breeding Centre and a breeding stock certificate has been issued by the Minister for Agriculture, Forestry and Fisheries. However, this does not apply to the following cases:

(1) – (3) [omitted]

2. "Inspection" mentioned in Article 4, paragraph 1 shall be carried out to determine if the animal has infectious diseases, genetic defects and reproductive disorders specified by ministerial ordinance (hereinafter referred to as "diseases") [see Article 6 of ministerial ordinance].

3. Grade of donor male based on breed, performance and form must be indicated on breeding stock certificate.

Paragraph 4 [omitted]

Article 5 – Article 9 [omitted]

(Restriction of collection of embryos)

Article 9-2 To use female animals of cattle and any other domestic animals designated by cabinet order for the purpose of collection of embryo shall be prohibited, unless the animal has been diagnosed by a veterinarian and a health certificate stating that the animal does not have infectious diseases and genetic defects specified by ministerial ordinance [see Article 13-2 of ministerial ordinance] has been issued. However, this does not apply in case of academic research and in any other cases specified by ministerial ordinance [Article 13-4 of ministerial ordinance].

Article 9-3 - Article 10 [omitted]

(Restriction on artificial insemination and embryo transplantation for livestock)

Article 11 Those who are not veterinarians or artificial inseminators are not allowed to collect or process semen and inseminate it into female animals. However, this does not apply in case of academic research, where a breeder collects or processes semen from male animals kept by him and inseminates it into female animals kept by him, or in any other cases specified by ministerial ordinance [Article 15 of ministerial ordinance].

Article 11-2 paragraph 1 - paragraph 3 [omitted]

4. Those who are not veterinarians or artificial inseminators are not allowed to collect or process unfertilised eggs for in vitro embryo transplantation, perform in vitro insemination, or process embryos for in vitro embryo transplantation. However, this does not apply in case of academic research or in any other cases specified by ministerial ordinance [Article 15-2 of ministerial ordinance].

5. Those who are not veterinarians or artificial inseminators are not allowed to transplant embryos to female animals. However, this does not apply in case of academic research or in any other cases specified by ministerial ordinance.

Article 12 [omitted]

(Inspection of semen and embryos for artificial insemination for livestock)

Article 13:

1. When a veterinarian or artificial inseminator collects semen, he must inspect it, without delay, by using the methods specified by ministerial ordinance [Article 16 of ministerial ordinance].

2. When a veterinarian collects in vivo fertilised embryo, he must inspect it, without delay, by using the methods specified by ministerial ordinance [Article 16-2 of ministerial ordinance].

3. When a veterinarian or artificial inseminator collects ovary, he must collect unfertilised egg from the ovary, process it, perform in vitro artificial insemination and inspect in vitro fertilised embryo that has been produced as a result of artificial insemination, by using the methods specified by ministerial ordinance [Article 16-3 of ministerial ordinance]. (In case the ovary is collected from a female animal, only a veterinarian is allowed to perform these procedures; same applies to the following paragraph and Article 14, paragraph 2, (1), D).

4. After the inspection mentioned in paragraph 3 of this article, a veterinarian or artificial inseminator must package and seal semen or embryo and append a semen certificate or in vivo/ in vitro fertilised embryo certificate, without delay, by using the methods specified by ministerial ordinance [see Article 16-4 of ministerial ordinance]. However, this does not apply in the case where the semen or embryo is used for artificial insemination or embryo transplantation at the same place after inspection.
Paragraph 5 - paragraph 8 [omitted]

(Restriction on transfer, etc. of semen and embryos for artificial insemination for livestock)

Article 14 Any semen, which is not sealed in accordance with Article 13 paragraph 4, or not accompanied by a semen certificate may not be transferred or used for artificial insemination. However, the following cases are excepted.

(1) When imported semen is accompanied by a certificate issued by a foreign government or any other party designated by ministerial ordinance [See Article 17-2 of ministerial ordinance], stating that the following matters are confirmed or believed to be trustworthy:

A. In the case of semen of cattle, horses and any other domestic animals designated by cabinet order, the donor male is free from genetic defects and reproductive disorders specified by ministerial ordinance [See Article 17-3 of ministerial ordinance] and clearly belong to one of the grades mentioned in Article 4, paragraph 3.

B. The semen was collected by a veterinarian or artificial inseminator duly authorised under the laws of a foreign country or any other party designated by ministerial ordinance [see Article 17-4 of ministerial ordinance]; the semen was inspected, packaged and sealed by using the methods specified by ministerial ordinance [see Article 17-5 of ministerial ordinance].

C. The semen was collected and processed at a facility which is deemed appropriate for hygienic operation.

D. Any other matters specified by ministerial ordinance [see Article 17-6 of ministerial ordinance].

(2) In cases specified in the provisos to Article 11, Article 11-2, paragraph 4 or Article 13, paragraph 4.

2. Any embryo which is not sealed in accordance with Article 13, paragraph 4 or not accompanied by an embryo certificate may not be transferred or used for artificial insemination. However, the following cases are excepted.

(1) When imported embryo is accompanied by a certificate issued by a foreign government or any other party designated by ministerial ordinance [see Article 17-7 of ministerial ordinance], stating that the following matters are confirmed or believed to be trustworthy:

A. The donor female is free from genetic defects specified by ministerial ordinance [see Article 17-8 of ministerial ordinance].

B. The donor male satisfies the conditions specified in paragraph 1, (1), A of this article.

C. In the case of in vivo fertilised embryo, the embryo was collected by a veterinarian duly authorised under the laws of a foreign country or any other party designated by ministerial ordinance [see Article 17-9 of ministerial ordinance]; the embryo was inspected, packaged and sealed by using the methods specified by ministerial ordinance [see Article 17-10 of ministerial ordinance].

D. In the case of in vitro fertilised embryo, ovary was collected from a donor female (live or slaughtered) by a veterinarian or artificial inseminator duly authorised under the laws of a foreign country or any other party designated by ministerial ordinance [see Article 17-11 of ministerial ordinance]; unfertilised egg was collected from the ovary and processed; after performing artificial insemination, the embryo was inspected, packaged and sealed by using the methods specified by ministerial ordinance [see Article 17-12 of ministerial ordinance].

E. The embryo was processed at a facility which is deemed appropriate for hygienic operation.

F. Any other matters specified by ministerial ordinance [see Article 17-13 of ministerial ordinance].

(2) In cases specified in the provisos to Article 11-2, paragraph 5 or Article 13, paragraph 4.

3. Low quality semen or embryo defined by ministerial ordinance [see Article 18 of ministerial ordinance] may not be transferred or used for in vivo or in vitro insemination. However, cases specified in the provisos to Article 11-2, paragraph 5 or Article 13, paragraph 4 are excepted.

Article 15 – end of document [omitted]

Bijlage 7:

IMPORT QUALITY REQUIREMENTS OF THE CERTIFICATE FOR BOVINE EMBRYO TO BE EXPORTED FROM NETHERLANDS TO JAPAN

The import quality requirements for bovine embryo (except embryo fertilized in vitro) to be exported from Netherlands to Japan (hereinafter referred to as "Embryo") shall be set forth as described hereunder:

1. The certificate for the Embryo to be imported into Japan (hereinafter referred to as "Import Embryo Certificate") referred to in Article 14, Section 2-(1) of the Law for Improvement and Increased Production of Livestock (Law No. 209 enacted in 1950) shall be issued by the Ministry of Agriculture, Nature and Food Quality, Netherlands (hereinafter referred to as "MANF-N").
2. The Import Embryo Certificate to be issued by MANF-N shall be prepared in the format shown in Appendix 1, and this certificate shall be appended to each embryo container, such as an ampule or a straw. (zie bijlage 1 van deze instructie.)
3. The following conditions shall be adhered to, in collecting and processing the embryo, and in preparing the Import Embryo Certificate,
   (1) The grading method of donor bull is referred to as follows:
      (i) The grading method of donor bull resident in the Netherlands conforms to the article 3- (1) of "IMPORT QUALITY REQUIREMENTS OF THE CERTIFICATE FOR BOVINE SEMEN TO BE EXPORTED FROM THE NETHERLANDS TO JAPAN (March 9, 2004; Ref.No. 15 Seichiku 4899) which was agreed between Japanese authority and the MANF-N.
      (ii)The grading method of donor bull resident in other country conforms to the "IMPORT QUALITY REQUIREMENTS OF THE CERTIFICATE FOR BOVINE SEMEN TO BE EXPORTED TO JAPAN" which was agreed between Japanese authority and the corporation of the country.
   (2)It shall be clearly stated in the Import Embryo Certificate that the donor bull is free from genetic defects and reproductive disorders as stated below. Freedom from the above mentioned defects and disturbances shall be confirmed by an authorised veterinarian.
      (i) Genetic defects;
         Friesian
         Inherited Congenital Porphyria, Inherited Idiopathic Epilepsy, Inherited Spastic Paresis, Inherited Congenital Achondroplasia with Hydrocephalus, Inherited Prolonged Gestation, Inherited abnormality, Bovine Leukocyte Adhesion Deficiency, Complex Vertebral Malformation, Brachyspina, and other inheritable diseases that cause these defects in the progeny.

         Other breeds
         Inherited Congenital Porphyria, Inherited Idiopathic Epilepsy, Inherited Spastic Paresis, Inherited Congenital Achondroplasia with Hydrocephalus, Inherited Prolonged Gestation, Inherited abnormality, and other inheritable diseases that cause these defects in the progeny.
      (ii) Reproductive disorders;
         Orchitis, Testicular insufficiency. Testicular atrophy, Cryptorchidism, Inflammation of scrotum, Impotentia erigendi, Prolapse of penis, Phallocampsis, Balanoposthitis, Phimosis, Seminal vesiculitis, Prostatitis, Testicular hypoplasia and Hypoplasia of accessory sex glands, Fracture of Penis and Prepuce.
   (3)It shall be clearly stated in the Import Embryo Certificate that the donor cow is free from genetic defects as stated in (2) - (i).
      Freedom from the above mentioned defects shall be confirmed by an authorised veterinarian.
   (4)The Embryo shall be collected and processed in a hygienic facility and by an authorised veterinarian.
   (5)Inspection of the Embryo at collection stage shall be done as stated below items.
      (i) whether colour of suspension fluids is normal or not.
      (ii) whether suspension fluids have filiform matters and other impurities or not.
      (iii) whether shape of the Embryo is normal or not.

(6) Storage medium and containers such as ampules or straws shall be of a quality that does not have adverse effects on the Embryo.
(7)The authorised signer of the Import Embryo Certificate shall be the official veterinarian of the National Inspection Service for Livestock and Meat, MANF-N.
(8)The Import Embryo Certificate shall be described in Japanese or English language and shall be issued to each ampule or straw.

4. To each container, such as an ampule or straw, the breed of donor cow and bull, the individual identification number of donor cow and bull, the name of donor cow and bull, the date of the Embryo collected or freezed shall be attached to check the information on each Import Embryo Certificate.
5. MANF-N should send to the Director, Livestock Production and Feed Division, Livestock Industry Department, Agricultural Production Bureau, Ministry of Agriculture, Forestry and Fisheries, Japan by the end of March every year an annual report of the actual number of Import Embryo Certificate issued during January 1 to December 31 of the previous year (the report shall be prepared in the format shown in Appendix 2).
6. MANF-N should inform the Director, Livestock Production and Feed Division, Livestock Industry Department, Agricultural Production Bureau, Ministry of Agriculture. Forestry and Fisheries, Japan each time of any change in the Laws and regulations of The Netherlands, which concern the collection, processing or export of bovine embryo.

Bijlage 8:

DECLARATION FOR EXPORT OF BOVINE EMBRYOS TO JAPAN

ISSUE NO: ISSUE DATE:
COUNTRY OF EXPORT: NETHERLANDS

DONOR BULL GRADE:
NAME:
SPECIES & BREED:
REGISTRY ORGANIZATION & REGISTRATION NO.:

DONOR COW

NAME:
SPECIES & BREED:
REGISTRY ORGANIZATION & REGISTRATION NO.:

MATED or INSEMINATED DATE:
DATE OF EMBRYO COLLECTION
NAME & ADDRESS OF BREEDER OF DONOR COW:

QUALIFICATION, NAME & ADDRESS OF PERSON COLLECTING / PROCESSING EMBRYO:

NAME & ADDRESS OF FACILITY COLLECTING / PROCESSING EMBRYO:

METHOD OF EMBRYO COLLECTING / PROCESSING:

EMBRYO COLLECTION

Number of Units to be Exported	Collection Code	Date of Collection

All embryo's from the above identified donor bulls and donor cows, collected on the above date, have been identified in accordance with the requirements of EU Directive 89/556/EEC and the Collection Code specified above. The embryos were collected and processed in an Embryo Collection and Processing Centre approved in accordance with EU Directive 89/556/EEG for collection and processing of embryos for export. Collection and processing of the embryos was according to the procedures uniformly applied by the embryo collection and processing centre laboratory, including inspection:

i. whether colour of suspension fluids is normal or not
ii. whether suspension fluids have filiform matters and other impurities or not
iii. whether shape of the embryo's is normal or not.

All of the embryos meet or exceeds the minimum requirements of the embryo collecting and processing laboratory for sale to users. The equipment, materials and diluents used in the collection and processing of the embryos will not cause any adverse effects on the embryos.

It is hereby certified that the embryos, identified above, have been collected and processed by me and all of the information reported herein has been confirmed by me to be true and correct or believed to be trustworthy in accordance with the Japanese law on Livestock Improvement and Increased Production of Livestock (Law No. 209, enacted May 27, 1950 and as amended).

Name :
Title :
Company :
Address :

Signature :

GENETIC DEFECTS AND REPRODUCTION COMPLICATIONS

The above-identified donor bulls (if resident in the Netherlands) and donor cows have been inspected by me and I hereby certify that they do not display any evidence of being affected by any of the genetic defects (donor bulls and donor cows) and reproductive disorders (donor bulls) listed below. I also certify that I have no knowledge that any progeny of the donor bulls and cows are known to have been affected by any of the below listed genetic defects (donor bulls and donor cows) and reproductive disorders (donor bulls).
Genetic Defects:
Friesian
Inherited Congenital Porphyria, Inherited Idiopathic Epilepsy, Inherited Spastic Paresis, In-herited Congenital Achondroplasia with Hydrocephalus, Inherited Prolonged Gestation, Inherited abnormality, Bovine Leukocyte Adhesion Deficiency, Complex Vertebral Malformation, Brachyspina, and other inheritable diseases that cause these defects in the progeny.
Other breeds
Inherited Congenital Porphyria, Inherited Idiopathic Epilepsy, Inherited Spastic Paresis, In-herited Congenital Achondroplasia with Hydrocephalus, Inherited Prolonged Gestation, Inherited abnormality, and other inheritable diseases that cause these defects in the progeny.
Reproductive disorders: Orchitis, Testicular Insufficiency, Testicular Atrophy, Cryptorchidism, Inflammation of Scrotum, Improtentia Erigendi, Prolapse of penis, Phallocampsis, Balanoposthitis, Phimosis, Seminalvesiculitis, Prostatitis, Testicular hypoplasia and Hypoplasia of accessory sex glands, Fracture of penis and Prepuce.
It is further certified that I have no knowledge of any evidence of genetic defects and reproductive disorders listed above of donor bulls resident in other countries.

Veterinarian Name :

Address :

Signature