

Semen and Embryos from **Equids**

EQUIGERM.SPE Consultation

[Document Date]

TITLE

Import Health Standard: Semen and Embryos from Equids

COMMENCEMENT

This Import Health Standard comes into force on [Effective Date]

REVOCATION

This Import Health Standard revokes and replaces the following:

a) Semen and Embryos from Horses (Equidae), HORSSEMB.SPE, 18 July 2017

ISSUING AUTHORITY

This Import Health Standard is issued under section 24A of the Biosecurity Act 1993.

Dated at Wellington, [Document Date]

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Introduction

This introduction is not part of the Import Health Standard (IHS), but is intended to indicate its general effect.

Purpose

This IHS specifies the minimum requirements that must be met when importing equine semen and embryos into New Zealand.

The identified risk organisms associated with equine semen and embryos that are managed by this IHS are:

- Equine arteritis virus (equine viral arteritis)
- Equine herpesvirus-1 (abortigenic and paralytic forms)
- Equine infectious anaemia virus
- Taylorella equigenitalis and Taylorella asinigenitalis (contagious equine metritis)
- Trypanosoma equiperdum (dourine)

Background

The Biosecurity Act 1993 (the Act) provides the legal basis for excluding, eradicating and effectively managing pests and unwanted organisms.

Import health standards issued under the Act set out requirements to be met to effectively manage biosecurity risks associated with importing goods. They include requirements that must be met in the exporting country, during transit, and before biosecurity clearance can be given.

Guidance boxes are included within this IHS for explanatory purposes. The guidance included in these boxes is for information only and has no legal effect.

A guidance document also accompanies this IHS providing information on how requirements may be met.

Who should read this Import Health Standard?

This IHS should be read by importers of equine semen and embryos.

Why is this important?

It is the importer's responsibility to ensure the requirements of this IHS are met. Consignments that do not comply with the requirements of this IHS may not be cleared for entry into New Zealand and/or further information may be sought from importers. Consignments that do not comply with the requirements of this IHS may be re-shipped or destroyed under the Act or tested/treated in accordance with this IHS prior to release or equivalence determined. Importers are liable for all associated expenses.

The costs to MPI in performing functions relating to the importation of equine semen and embryos will be recovered in accordance with the Act and any regulations made under the Act. All costs involved with documentation, transport, storage and obtaining a biosecurity clearance must be covered by the importer or agent.

Equivalence

The Chief Technical Officer (CTO) may issue a direction under section 27(1)(d) of the Act that measures different from those set out in this IHS may be applied to effectively manage risks associated with the importation of these goods.

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If an equivalent measure is approved, an import permit may be issued under section 24D(2) of the Act if the CTO considers it appropriate to do so. The details of the CTO direction on equivalence will be included as notes in the special conditions section of the permit to inform the inspector's assessment of the commodity.

MPI's preference is that the exporting country's Competent Authority makes equivalence requests. Equivalence requests can be lodged with animal.imports@mpi.qovt.nz.

Inspection

On arrival, all documentation accompanying the consignment will be verified by an inspector. The consignment may also be subject to inspection.

Document History

Refer to Schedule 1.

Other information

This is not an exhaustive list of compliance requirements and it is the importer's responsibility to be familiar with and comply with all New Zealand laws.

Trade Single Window (TSW)

All goods imported into New Zealand need to be cleared by the New Zealand Customs Service (Customs) and the Ministry for Primary Industries (MPI). This is achieved by lodging required documentation in through the Trade Single Window (TSW) portal.

For more information about TSW please visit https://www.customs.govt.nz/business/trade-single-window/.

Environmental Protection Authority (EPA) and new organisms

Importers of new organisms must meet all requirements of the Hazardous Substances and New Organisms (HSNO) Act 1996. See guidance for more information.

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Part 1: Requirements

1.1 Application

(1) This IHS applies to all imports of semen and embryos from horses (*Equus caballus*) and donkeys (*Equus asinus*) from Australia, Canada, European Union Member States, Norway, Switzerland or the United States of America.

1.2 Incorporation by reference

- (1) The following international standards are incorporated by reference in this IHS under section 142M of the Act:
 - a) The World Organisation for Animal Health (OIE) *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (the *Manual*), available at the OIE website: http://www.oie.int/international-standard-setting/terrestrial-manual/access-online/.
 - b) The OIE *Terrestrial Animal Health Code* (the *Code*), available at the OIE Website: http://www.oie.int/international-standard-setting/terrestrial-code/access-online/.
 - c) The *International Embryo Transfer Society Manual* (the IETS Manual), available at the IETS website: http://www.iets.org/.
- (2) The following material is incorporated by reference in this IHS under section 142M of the Act:
 - a) MPI <u>Approved Diagnostic Tests, Vaccines, Treatments and Post-arrival Testing Laboratories for Animal Import Health Standards, MPI-STD-TVTL</u>.
- (3) Under section 142O(3) of the Act it is declared that section 142O(1) does not apply. That is, a notice under section 142O(2) of the Act is not required to be published before material that amends or replaces the standards, guideline or lists incorporated under clauses 1.2(1) and (2) above has legal effect as part of this IHS.

Guidance

 Incorporation by reference means that standards, guidelines or lists are incorporated into the IHS and they form part of the requirements.

1.3 Definitions

- (1) For the purposes of this IHS and the associated guidance, terms used that are defined in the Act have the meanings set out there. The Act is available at http://www.legislation.govt.nz/.
- (2) See Schedule 2 for additional definitions that apply.

1.4 Requirements for clearance

- (1) In order to obtain biosecurity clearance, equine semen and embryos must:
 - a) Meet the requirements of clauses 1.5-1.8 of *Part 1*, and *Part 2*; and
 - b) Be accompanied by a veterinary certificate that meets the requirements of clause 1.10.1, has been agreed by the CTO, and details the measures in *Part 1* and *Part 2* that the importing country will meet; and
 - c) Be accompanied by an import permit where required by clause 1.9.

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1.5 Diagnostic tests, vaccines and treatment

- (1) All pre-export and/or surveillance testing required by this IHS must be:
 - a) Conducted by a laboratory approved by the Competent Authority of the exporting country; or
 - b) Conducted by a laboratory approved by the Competent Authority of any other country listed in clause 1.1.
- (2) All laboratory samples required by this IHS must be collected, processed, and stored in accordance with the recommendations in the *Code* and/or the *Manual* or as described in *MPI-STD-TVTL*.
- (3) All diagnostic test(s) and vaccines that are required to be used or undertaken by this IHS must be those that have been approved by MPI for that purpose and documented in MPI-STD-TVTL.
- (4) All vaccinations required by this IHS to be administered to meet the specific disease requirements in Part 2 must have been administered according to the manufacturer's instruction in a country listed in clause 1.1.
- (5) All requirements in this IHS for the administration of a vaccine require that either the final dose of a primary vaccination course has been administered or the recommended booster to complement the primary course has been administered.
- (6) Where vaccines required by this IHS have been administered all vaccine names, virus types and strains included in the vaccine (where applicable), and the date(s) of vaccination must be recorded on the veterinary certificate.

1.6 Semen requirements

1.6.1 Semen collection centre requirements

- (1) Semen collection and processing centres must meet the recommendations of the relevant articles of the *Code* chapter *General Hygiene in Semen Collection and Processing Centres*.
- (2) The semen must be collected in a semen collection centre that is approved by the Competent Authority prior to the start of each period of collection of semen for export, or where the centre is used continuously, on an annual basis.
- (3) Semen may only be imported if it has been collected at a semen collection centre approved by the Competent Authority no more than 12 months before the last date of collection of semen in the consignment.

1.6.2 Semen donor requirements

- (1) Semen must only be collected from donors that meet the following requirements:
 - a) While resident at the semen collection centre, donors must only have contact with other equids of equivalent health status.
 - b) Where *Part 2* requires pre-collection testing, donors must be isolated from other equids not of an equivalent health status from the time of sample collection for the pre-collection test until completion of germplasm collection for export to New Zealand.
 - c) The approved veterinarian must perform an examination of the donor, including inspection of the external reproductive organs, to ensure the donor is free from clinical evidence of infectious disease transmissible in semen on the day of semen collection.
 - d) Donors must not be naturally mated after entry into the semen collection centre unless required by *Part 2*.
 - e) Semen donors may be transferred from one approved semen collection centre to another approved centre of equal health status without repeating the testing required by *Part 2*, if the Competent Authority ensures that all of the following requirements are met:

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- i) Donors have been examined by the approved veterinarian on the day of entry into the centre and show no evidence of infectious disease transmissible in semen
- ii) Transfer is direct
- iii) Donors do not come into direct or indirect contact with animals of lower health status
- iv) The means of transport is disinfected before use.

1.6.3 Teaser animal requirements

- (1) If teaser animals are used in the collection of semen, the teaser animal:
 - a) Must be of equivalent health status to the donor; and
 - b) Must be examined by an approved veterinarian, including the external reproductive organs, to ensure the teaser animal is free from clinical evidence of infectious disease transmissible in semen on the day of semen collection.

1.6.4 Semen collection, processing and storage

- (1) Semen collection, processing, and storage must be conducted at a standard equivalent to the general considerations for hygienic collection and handling of semen that is specified in the *Code* chapter *Collection and Processing of Bovine, Small Ruminant and Porcine Semen.*
- (2) The cryogenic or cooling agent used in the freezing process, storage or transport of semen must not have been used previously in association with any other product of animal origin.
- (3) Semen must be in straws or new or disinfected containers which are sealed and tamper-evident, and clearly and permanently marked to identify the donor and the date(s) of collection. If a code is used for this information, its decipher instructions must accompany the consignment.
- (4) Semen must only be stored with germplasm that was collected and processed in accordance with the *Code* and/or the *IETS Manual*, and is of equivalent health status.
- (5) Semen must be held in a storage place approved by the Competent Authority until the time of export.
- (6) Semen can only be imported into New Zealand if the semen is imported directly from the country in which it was collected.
- (7) Notwithstanding (6), if semen is collected in a country listed in clause 1.1 (origin country) and stored in another country listed in clause 1.1 (exporting country), that semen may be imported into New Zealand if the consignment is accompanied by:
 - a) A declaration from the Competent Authority of the exporting country identifying the semen from the origin country as the semen being exported to New Zealand; and
 - A veterinary certificate from the Competent Authority of the exporting country that certifies that the semen has been stored and transported in the exporting country in accordance with the requirements of this IHS; and
 - c) Evidence that the semen was collected, processed, and stored in the origin country in accordance with the requirements of this IHS in the form of either:
 - A veterinary certificate issued by the Competent Authority of the origin country certifying that the semen meets the requirements of this IHS; or
 - ii) A letter from the Competent Authority of the origin country confirming the semen meets the requirements of this IHS.

1.7 Embryo requirements

(1) Embryos must be *in vivo*-derived and frozen.

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1.7.1 Embryo collection team requirements.

(1) Embryos must be collected by an embryo collection team that complies with the recommendations of the Code chapter Collection and Processing of In Vivo Derived Embryos from Livestock and Equids.

1.7.2 Embryo donor requirements

- (1) Embryos must only be collected from donors that comply with the following requirements:
 - a) Embryo donors must not be situated on premises or with other equids that are subject to veterinary restrictions for the identified risk organisms managed in *Part 2* of this IHS for at least 28 days prior to the first embryo collection until completion of donor testing, where required by this IHS.
 - b) Where *Part 2* requires pre-collection testing, donors must be isolated from other equids not of an equivalent health status from the time of sample collection for the pre-collection test until completion of germplasm collection for export to New Zealand.
 - c) The approved veterinarian must perform an examination of the donor, including inspection of the external reproductive organs, to ensure the donor is free from clinical evidence of infectious disease transmissible in embryos on the day of embryo collection.
- (2) All semen used for artificial insemination of embryo donors must meet the requirements of this IHS.

1.7.3 Embryo collection, processing and storage

- (1) Embryo collection, processing, and storage must meet the recommendations of the *Code* chapter *Collection and Processing of In Vivo Derived Embryos from Livestock and Equids.*
- (2) The cryogenic or cooling agent used in the freezing process, storage, and transport of embryos must not have been used previously in association with any other product of animal origin.
- (3) Embryos must have an intact zona pellucida and be free of adherent material after the final wash when examined over its entire surface at not less than 50X magnification. If any micro-manipulation is done that causes a breach of the zona pellucida, it must be done according to the procedures described in the *Code* and *IETS Manual*. The cryogenic or cooling agent used in the freezing process, storage and transport must not have been used previously in association with any other product of animal origin.
- (4) Embryos must be in new or cleaned and disinfected containers which are sealed and tamper-evident, and clearly and permanently marked to identify the donor and the date(s) of collection. The marking must conform to the international standards of the IETS. If a code is used for this information, its decipher instructions must accompany the consignment.
- (5) Embryos must only be stored with germplasm that was collected and processed in accordance with the *Code* and/or the *IETS Manual*, and is of equal health status.
- (6) Embryos must be held in a storage place approved by the Competent Authority until the time of export.
- (7) Embryos can only be imported into New Zealand if the embryos are imported directly from the country in which it was collected.
- (8) Notwithstanding (7), if embryos are collected in a country listed in clause 1.1 (origin country) and stored in another country listed in clause 1.1 (exporting country), the embryos may be imported into New Zealand if the consignment is accompanied by:
 - a) A declaration from the Competent Authority of the exporting country identifying the embryos from the origin country as the embryos being imported into New Zealand; and
 - A veterinary certificate from the Competent Authority of the exporting country that certifies that the embryos has been stored and transported in the exporting country in accordance with the requirements of this IHS; and
 - c) Evidence that the embryos were been collected, processed and (if applicable) stored in the origin country in accordance with the requirements of this IHS in the form of either:

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- i) A veterinary certificate issued by the Competent Authority of the origin country certifying that the embryos meet the requirements of this IHS; or
- ii) A letter from the Competent Authority of the origin country confirming that the embryos meet the requirements of this IHS.

1.8 Transport

- (1) All transport containers in which semen or embryos are transported to New Zealand must be new or cleaned and disinfected, and must be free of contamination.
- (2) All transport containers in which semen or embryos are transported to New Zealand must be sealed, by either the approved veterinarian or an Official Veterinarian, using tamper-evident seals. The seal number must be recorded on the veterinary certificate.
- Where semen or embryos are transferred from one transport container to another, the date of transfer, approved collection centre or storage facility, reason for transfer, and the name of veterinarian involved in the transfer must be recorded on the veterinary certificate.

1.9 Import permit

- (1) An import permit under section 24D of the Act issued by the Director-General is required if a CTO has approved an equivalent measure prior to import, different from that set in this IHS that may be applied to effectively manage risks.
- (2) An import permit is not required where a CTO has issued a direction under section 27(1)(d) for a measure that is different from that set in this IHS during negotiation of a country-specific veterinary certificate and the equivalent measure is incorporated into that certificate.

Guidance

• Completed applications can be submitted to Animal Imports animal.imports@mpi.govt.nz
Application forms can be found on the MPI website at: Application form for Semen and Embryos

1.10 The documentation that must accompany goods

- (1) The consignment must arrive in New Zealand with the documentation that is specified in, and meets the requirements of, clauses 1.10.1 to 1.10.2 below.
- (2) All documentation that is required by this clause 1.10 to accompany equine semen and embryos must, unless otherwise stated:
 - a) Be original
 - b) Accompany the imported goods.
 - c) Be in English or have an English translation that is clear and legible.
 - d) Be endorsed on every page by the Official Veterinarian with their original stamp, signature and date or be endorsed in the space allocated and all pages have paper or electronic based alternative security features.

Guidance

 A Trade Single Window (TSW) lodgement is required to meet both MPI and Customs requirements. For more information about TSW please visit: https://www.customs.govt.nz/business/trade-single-window/.

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1.10.1 Veterinary certificate

- (1) A veterinary certificate from the exporting country's Official Veterinarian. The veterinary certificate must include the following:
 - a) A unique consignment identifier;
 - b) Species, donor identification, quantity (semen/embryos);
 - c) Dates of collection;
 - d) For semen, the name, address, and approval number of the semen collection centre, and date of donor entry;
 - e) For embryos, the approval number of the embryo collection team, and the date of entry into the embryo collection herd/centre, and address of the embryo collection herd/centre;
 - f) Name of the approved veterinarian:
 - g) Name and address of the importer (consignee) and exporter (consignor);
 - h) Transport container number seal number and disinfection information;
 - i) All diagnostic tests, including test type, date of sampling, and results which must be clearly linked to each donor and accompanied by copies of laboratory reports. A tabulated summary of laboratory results endorsed by the Official Veterinarian is also acceptable;
 - j) All vaccines administered to meet specific disease import requirements, including vaccine name, the virus types and strains included in the vaccine (where applicable), and vaccination date(s).
 - k) Name, signature and contact details of the Official Veterinarian.
 - Where semen and embryos are transferred from one transport container to another, the date of transfer, approved collection centre or storage facility, reason for transfer and name of the veterinarian involved in the transfer
 - m) Certification and endorsement by the Official Veterinarian that the general requirements outlined in *Part 1* of this IHS have been met.
 - n) Certification and endorsement by the Official Veterinarian that the relevant requirements outlined in *Part 2* of this IHS have been met.

Guidance

- Where equivalent measures have been negotiated and agreed and a CTO has, prior to import, issued a direction under section 27(1)(d) of the Act that is different from those in this standard in the form of a negotiated veterinary certificate, a country-specific veterinary certificate must accompany the consignment.
- See guidance document for more information about equivalence and country-specific veterinary certificates.

1.10.2 Laboratory and vaccination reports

- (1) Original laboratory reports; copies of laboratory reports endorsed by the Official Veterinarian; or a tabulated summary of laboratory results endorsed by the Official Veterinarian of all tests required by Part 2: Specified Requirements for Identified Risk Organisms of this IHS, which must include:
 - a) Unique identification for each animal, consistent with the veterinary certificate.
 - b) Dates of sample collection or vaccination.
 - c) Test/vaccine type.
 - d) Test result.

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Part 2: Specified Requirements for Identified Risk Organisms

(1) Semen and embryos must comply with the following measures for identified risk organisms, where required.

2.1 Equine arteritis virus (EVA)

- (1) Semen donors:
 - a) Must meet the recommendations for managing equine semen in the *Code* chapter *Infection with Equine Arteritis Virus*; or
 - Must be kept for the 28 days prior to semen collection on premises where no equid has shown any clinical sign of EVA during that period and show no clinical sign of EVA on the day of semen collection; and
 - i) Must be subjected to a test for EVA carried out on a single blood sample, collected not less than 21 days after entry into the semen collection centre, with negative results.
- (2) Embryo donors must meet the recommendations for managing *in vivo-*derived embryos in the *Code* chapter *Infection with Equine Arteritis Virus*.

2.2 Equine herpesvirus-1 (abortigenic and paralytic forms) (EHV-1)

- (1) Semen and embryos donors:
 - a) Must be kept on premises where no case of EHV-1 (abortigenic and paralytic forms) has been reported in the 21 days prior to each collection; and
 - b) Must show no clinical signs of EHV-1 infection on the day of collection and during the 21 days prior to collection.

2.3 Equine infectious anaemia virus (EIA)

- (1) Donors must:
 - a) Be kept on premises where no case of EIA has been reported during the 90 days prior to each collection; and
 - b) Show no clinical sign of EIA on the day of each collection; and
 - Be tested for EIA not less than 21 days after entry into the collection centre for semen, or in the 21 days prior to collection for embryos, with a negative result.

2.4 *Taylorella equigenitalis and Taylorella asinigenitalis* (contagious equine metritis [CEM])

- (1) Semen and embryos donors must comply with (2), (3) or (4) below, and must comply with (5):
- Donors must be kept, since birth or for at least the 60 days prior to collection, in a country recognised by the CTO as free from CEM, where no case of CEM has been reported in the 2 years prior to export.
- (3) Donors must be kept, since birth or for at least 60 days prior to collection, on premises where no case of CEM has been reported during that time; and
 - a) Must have no direct or indirect contact with CEM during the 60 days prior to collection; and
 - b) Must not show no clinical sign of CEM on the day of each collection; and
 - c) Must be subjected to a test for CEM not less than 7 days after entry into the collection centre for semen, or in the 30 days prior to collection for embryos, with negative results;

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- i) Stallions must be sampled two times at intervals of 4-7 days. Swab sampling sites are the urethra; urethral fossa and its sinus; and the penile sheath.
- ii) Mares must be sampled two times at intervals of 4-7 days. Swab sampling sites are the clitoral fossa and sinuses; and
- d) Must not receive antibiotics in the 7 days (systemic treatment) or 21 days (local treatment) before the first sample collection or during the CEM sampling period.
- (4) Donors that have previously shown signs of CEM or have been in direct or indirect contact with CEM during the two months prior to collection:
 - a) Must be treated for CEM; and
 - b) After treatment, must be subjected to a test for CEM listed in *MPI-STD-TVTL*, with negative results:
 - i) Stallions must be sampled three times at intervals of at least 7 days (sampling sites are the urethra, urethral fossa and its sinus, and the penile sheath). Thereafter, the first three mares mated or inseminated by the stallion are tested on clitoral swabs taken 3 times at intervals of at least 7 days, starting 2 days after mating or insemination.
 - ii) Mares must be sampled three times at intervals of at least 7 days (sampling sites are the clitoral fossa and sinuses), and 3 endometrial swabs taken during the next 3 oestrus periods. Maiden mares only require 1 endometrial swab; and
- (5) Must be protected against any possibility of infection with CEM since the beginning of the tests.

2.5 *Trypanosoma equiperdum* (dourine)

- (1) Semen donors must meet the recommendations for managing equine semen in the *Code* chapter *Dourine*.
- (2) Embryo donors must:
 - a) Be kept since birth, or for the 180 days prior to collection of the embryos in a country which has been free from dourine for not less than the past 180 days; or
 - b) Be kept for the 180 days prior to collection of the embryos on premises where no case of dourine was reported during that period and subjected to a diagnostic test for dourine with negative results.

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Schedule 1 – Document History

Date First Issued	Title	Shortcode
3 December 2015	Import Health Standard: Semen and Embryos from Horses (<i>Equidae</i>)	HORSSEMB.SPE
Date of Issued Amendments	Title	Shortcode
18 July 2017	Import Health Standard: Semen and Embryos from Horses (<i>Equidae</i>)	HORSSEMB.SPE
ТВА	Import Health Standard: Semen and Embryos from Equids	EQUIGERM.SPE

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Schedule 2 – Definitions

Approved Veterinarian

A veterinarian approved by the relevant Competent Authority to collect semen or embryos for export to New Zealand.

Competent Authority

The Veterinary or other Governmental Authority of an OIE Member, that has the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations in the *Code* in the whole territory.

Director-General

The chief executive of the Ministry for Primary Industries.

Donor

Female animal from which embryos were collected, or male animal from which semen was collected.

Germplasm

Ova, semen or embryos collected from animals that are eligible for importation under this import health standard.

IETS

International Embryo Transfer Society

IETS Manual

Manual for embryo collection, processing and transfer as written by the IETS. Any references to this Manual are to the most current version.

In vivo-derived embryos

Embryos recovered after incubation occurred in the reproductive tract of the female donor.

MPI

Ministry for Primary Industries, New Zealand.

Official Veterinarian

A veterinarian authorised by the Competent Authority of the country to perform certain designated official tasks associated with animal health and/or public health and inspections of commodities and, when appropriate, to certify in conformity with the provisions of the OIE *Code* Chapter for certification procedures.

OIE

The World Organisation for Animal Health.

The Code

The OIE Terrestrial Animal Health Code as found on the OIE website.

The Manual

The World Organisation for Animal Health (OIE) Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.

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Veterinary Certificate

A certificate, issued in conformity with the provisions of the *Code* Chapter for certification procedures, describing the animal health and/or public health requirements which are fulfilled by the exported commodities.

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