Ministry for Primary Industries
Manatū Ahu Matua

Import Health Standard

Semen and Embryos from Horses (*Equidae*)

HORSSEMB.SPE

18 July 2017

Issued under the Biosecurity Act 1993

New Zealand Government

TITLE

Import Health Standard: *Semen and Embryos from Horses (Equidae)*

COMMENCEMENT

This Import Health Standard comes into force on 18 July 2017

ISSUING AUTHORITY

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

Dated at Wellington this 18th day of July 2017.

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(acting under delegated authority of the Director-General)

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Introduction

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

Purpose

This IHS specifies the minimum requirements that must be met when importing semen and embryos from domestic horses (*Equidae*) from specified countries.

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 during importation, before biosecurity clearance can be given.

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

Who should read this Import Health Standard?

This IHS applies to importers of semen and embryos from horses (*Equidae*) from specified countries.

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 treated in accordance with this IHS prior to release or equivalence determined. Importers are liable for all associated expenses.

See guidance document for more information about importer responsibilities.

Equivalence

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

See guidance document for more information about equivalence and permits.

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.

See guidance document for more information about inspection and verification of consignments.

Part 1: General Requirements

1.1 Application

(1) This import health standard (IHS) applies to:

a) semen from domestic horses (*Equidae*) that is not genetically modified; and

i) fresh/chilled in screw top containers; or
ii) frozen, in straws, ampoules or pellets; and

b) embryos from domestic horses (*Equidae*) that are frozen, not genetically modified, *in vivo* derived and non-cloned.

(2) This IHS applies to imports of semen and embryos from domestic horses (*Equidae*) from the following countries:

a) Australia.
b) Canada.
c) European Union member countries.
d) Norway.
e) Switzerland.
f) USA.

See the guidance document for more information about specified countries.

1.2 Outcome

(3) The outcome this IHS is seeking to achieve is the effective management of biosecurity risks associated with eligible consignments of semen and embryos from domestic horses (*Equidae*) from specified countries.

(4) The biosecurity risk organisms associated with semen and embryos from domestic horses (*Equidae*) from specified countries that are managed by the requirements of this IHS are:

a) Equine herpesvirus-1 (EHV-1)
b) Equine infectious anaemia virus (EIA)
c) Equine viral arteritis (EVA)
d) *Leptospira* spp.
e) *Taylorella* spp. (contagious equine metritis, CEM).

1.3 Incorporation by reference

(5) 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 OIE *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 from the IETS website: http://www.iets.org/).

(6) The following MPI material is incorporated by reference in this IHS under section 142M of the Act:

a) MPI Approved Diagnostic Tests, Vaccines, Treatments and Post-Arrival Testing Laboratories for Animal Import Health Standards (*MPI-STD-TVTL*) (available at the MPI website)

(7) 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 above listed standards, guideline or lists has legal effect as part of these documents.

See guidance document for more information about incorporation by reference and section 142O(1)

1.4 Definitions

(1) For the purposes of this IHS and the attached guidance document, terms used that are defined in the Act have the meanings set out there. The Act is available at the following website: http://www.legislation.govt.nz/.

(2) See Schedule 2 for additional definitions that apply.

1.5 Diagnostic testing, vaccination and treatment

(1) Any laboratory conducting the pre-export or surveillance testing where required by this IHS must be approved by the Competent Authority of a country that is one of the countries listed in section 1.1(2) of this IHS.

(2) Laboratory samples 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) Diagnostic test(s) and vaccines used must be listed in and carried out in accordance with *MPI-STD-TVTL*.

(4) All products and vaccinations administered to meet the specific disease requirements in Part 2 must be administered according to the manufacturer's instruction in a country that is one of the countries listed in Section 1.1(2) of this IHS. All vaccinations must be either the final dose of a primary course or the recommended booster to complement the primary course.

(5) All product names, manufacturers, active ingredients (where applicable), dose and date of treatment must be recorded on the veterinary certificate.

(6) All vaccine names, whether they are inactivated or modified live virus, and the virus types and strains included in the vaccine must be recorded on the veterinary certificate.

See guidance document for more information about diagnostic tests and vaccination.

1.6 Embryo requirements

1.6.1 Embryo collection team requirements

(1) At the time of collection of embryos for export to New Zealand, the embryo collection team must be approved by and registered with the Competent Authority to collect, process, and store embryos for export according to the *Code*.

(2) The approved embryo collection team veterinarian must ensure donors are free from clinical evidence of infectious diseases transmissible in embryos on the day of collection.

1.6.2 Embryo donor requirements

(1) The embryo collection team must have knowledge of and authority over the embryo donor(s) until completion of collection and testing required by this IHS.

(2) Embryo donors must not be situated on premises or with other horses that are subject to veterinary restrictions for the identified risk organisms managed in Part 2 of this IHS for at least 28 days before the first embryo collection until completion of donor testing, where required by this IHS.

(3) Where a specific requirement for a risk organism is met by pre-collection testing, embryo donors must be isolated from other horses not of an equivalent tested health status, from the time of the pre-collection test until completion of embryo collection for export to New Zealand.

(4) Where a specific requirement of this IHS for a risk organism is met by monitoring for clinical signs for a specified time after collection, the embryos must be stored for that amount of time prior to export.

1.7 Semen requirements

1.7.1 Semen centre requirements

(1) The semen centre must meet the conditions specified in the *Code* Chapter on general hygiene in semen collection and processing centres.

(2) The semen centre must be:

a) Approved for export by the Competent Authority.
b) Subject to regular inspection, at least every 12 months, by an Official Veterinarian.
c) Under the supervision of a semen centre veterinarian approved by the Competent Authority.

(3) The name and approval numbers of the semen centre(s) must be recorded on the veterinary certificate.

(4) Donors may be transferred from one approved centre to another of equal health status without isolation or testing if all of the following requirements are met:

a) Donors must be examined by the semen centre veterinarian, and show no clinical sign of disease on the day of entry into the facility.
b) Transfer must be direct.
c) Donors must not come into direct or indirect contact with animals of a lower health status.
d) The means of transport must be disinfected before use.

1.7.2 Semen donor requirements

(1) Semen donors must be resident for at least 28 consecutive days at the semen collection centre prior to collection of the semen for export. During this time semen donors must not be used for natural mating and must be isolated from animals not of equivalent health status.

(2) The semen centre veterinarian must ensure by clinical examination including that of the external reproductive organs that on the day of collection the donor is free from clinical evidence of infectious diseases transmissible in semen.

(3) Where a specific requirement of this IHS for a risk organism is met by monitoring for clinical signs for a specified time after collection, the semen must be stored for that amount of time prior to export.

1.8 Collection and processing

(1) Embryos must be collected and processed in accordance with the recommendations in the *Code* Chapter on collection and processing of *in vivo* derived embryos from equids.

(2) 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*.

(3) All media and solutions used to produce embryos must be either sterilised by approved methods in accordance with the IETS *Manual* or commercially prepared. They must be handled in such a manner as to ensure that sterility is maintained. All biological products of animal origin used in the media and solutions must be free from pathogenic organisms.

(4) Semen must be collected and processed in accordance with the recommendations of the *Code* Article 4.6.6. for the conditions applicable to the collection of semen.

See guidance document for more information about semen collection and processing.

(5) Antibiotics recommended in the *Code* and IETS *Manual* and listed in *MPI-STD-TVTL* must be added to embryo collection, processing, washing and storage media and to the semen diluent in accordance with the *Code*. The names of antibiotics added and their concentration must be stated on the veterinary certificate.

1.9 Storage

(1) 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.

(2) Dry ice and associated equipment used to process semen pellets must be managed to prevent contamination with semen of donors not of equivalent tested health status.

(3) Semen and embryos must be in straws, ampoules, pellets, 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. For embryos the marking must, in accordance with the *Code*, conform to the international standards of the IETS.

See guidance document for more information about semen containers.

(4) Semen and embryos may only be stored with semen or embryos that have been collected and processed in compliance with the *Code*. Containers must be held in a storage place approved by the Competent Authority of the exporting country until the time of export.

(5) Storage of semen and embryos in a third country (other than the country of origin) is permitted if the third country is a specified country listed in this IHS. The consignment of semen and embryos must be accompanied by:

a) a declaration from the Competent Authority of the third country, linking the semen and embryos from the country of origin to the semen and embryos being exported to New Zealand and confirming that the semen and embryos have been stored as required by this IHS, at a facility approved by the Competent Authority; and either

i) the veterinary certificate (current version) certified by the Competent Authority of the country of origin to export to New Zealand; or
ii) a letter from the country of origin's Competent Authority indicating that the semen and embryos meets New Zealand's current import requirements.

1.10 Transport

(1) Transport containers must be new or disinfected and free of contamination. When the transport container is not new, the disinfectant, its active chemical and date of disinfection must be recorded on the veterinary certificate.

(2) The transport container in which semen and embryos are transported to New Zealand must be sealed, by either the semen centre or embryo collection team veterinarian or an Official Veterinarian, using tamper-evident seals. The seal number must be recorded on the veterinary certificate.

(3) Where semen or embryos are transferred from one transport container to another, the date of transfer, name and number of the approved collection facility, reason for transfer, and name of veterinarian involved in the transfer must be recorded on the veterinary certificate.

1.11 Permit to import

(1) A permit to import under section 24D(2) of the Act is required if a CTO has approved an equivalent measure prior to import under section 27(1)(d) of the Act, that is different from those set out in this IHS that may be applied to effectively manage biosecurity risks.

(2) A permit to import is not required where a CTO has approved an equivalent measure prior to import under section 27(1)(d) of the Act, that is different from those set out in this IHS in the form of a negotiated veterinary certificate.

See the guidance document for more information about equivalence and permits.

1.12 The documentation that must accompany goods

(1) The semen and embryos must arrive in New Zealand with:

a) A veterinary certificate, that must include all of the following:

i) a unique consignment identifier;
ii) species, donor animal identification, quantity (semen/embryos);
iii) dates of collection;
iv) collection centre name and date of donor entry;
v) Name and address of importer (consignee) and exporter (consignor);
vi) certification and endorsements that the requirements set out in Part 1 and Part 2 of this IHS have been met;
vii) transport container seal number and disinfection information;
viii) name, signature, and contact details of the Official Veterinarian;
ix) all diagnostic tests, including test type, date of sampling, and results which must be clearly linked to each donor and in the form of either a tabulated summary or copies of laboratory reports;
x) all products and vaccines administered to meet specific disease import requirements, including the generic name, active ingredient, dose rate, and date of treatment;
xi) the name of the antibiotics and their concentration used to meet the requirements of this IHS;
xii) where semen and embryos are transferred from one transport container to another, the date of transfer, approved collection facility, reason for transfer and name of the veterinarian involved in the transfer.

b) Original laboratory reports; copies of laboratory reports endorsed by the Official Veterinarian; or a tabulated summary of laboratory results endorsed by the Official Veterinarian must include:

i) unique identification for each animal, consistent with the veterinary certificate;
ii) dates of sample collection;
iii) test type;
iv) test result.

(2) A country-specific veterinary certificate must accompany the consignment where equivalent measures have been negotiated and approved by a CTO under section 27(1)(d) of the Act.

See guidance document for more information about equivalence and country-specific veterinary certificates.

(3) All documents must:

a) be original, unless otherwise stated;
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 based alternative security features.

(4) Documentation copies must be sent to the Biosecurity Inspector at the airport/port of arrival at least one working day in advance of importation. For fresh semen only, the documentation must be emailed to MPI within 24 hours prior to arrival.

1.13 Biosecurity clearance

(1) A biosecurity clearance, under section 26 of the Act 1993, may be issued when the semen and embryos from horses meet all the requirements of this IHS, provided the applicable requirements of section 27 in the Act are met.

Part 2: Specified Requirements for Identified Risk Organisms

Note: requirements are for semen and embryo donors unless otherwise specified.

(1) The Competent Authority of the exporting country is required to issue a signed, stamped and dated veterinary certificate containing declarations regarding the following diseases:

2.1 Equine herpesvirus-1 (EHV-1) [abortigenic and paralytic forms]

(1) Donors must meet the *Code* recommendations for managing EHV-1 in horses.

2.2 Equine infectious anaemia virus (EIA)

(1) Donors showed no clinical sign of EIA on the day of each collection; and

a) Donors were kept on premises where no case of EIA has been reported during the 90 days prior to each collection; and
b) Donors were subjected to a test listed in the MPI document*: MPI Approved Diagnostic Tests, Vaccines, Treatments and Post-arrival Testing Laboratories for Animal Import Health Standards* (MPI-STD-TVTL), not less than 21 days after entry into the collection centre with a negative result.

2.3 Equine viral arteritis (EVA)

2.3.1 Semen

(1) Donors must meet the *Code* recommendations for managing EVA in equine semen.

2.3.2 Embryos

(1) Donors must meet the *Code* recommendations for managing EVA in *in vivo* derived embryos.

2.4 *Leptospira* species

(1) Semen and embryos must be prepared with antibiotics effective against *Leptospira* species as listed in the document MPI-TVTL-STD.

See guidance document for more information about antibiotics effective against Leptospirosis.

2.5 Taylorella species (contagious equine metritis, CEM)

(1) Donors must meet the *Code* recommendations for managing CEM in horses.

Schedule 1 – Document History

Date First Issued	Title	Shortcode
3 December 2015	Import Health Standard: Semen and Embryos from Horses *(Equidae)*	HORSSEMB.SPE
Date of Issued Amendments	**Title**	**Shortcode**
18 July 2017	Import Health Standard: Semen and Embryos from Horses (*Equidae*)	HORSSEMB.SPE

Schedule 2 – Definitions

Artificial Insemination Centre (semen centre)

A facility approved by the Competent Authority and which meets the conditions set out in the *Code* for the collection, processing and/or storage of semen.

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.

Domestic Horse

Equidae including horses (*Equus caballus*) and donkeys (*Equus asinus*), but excluding zebras (*Equus quagga*, *Equus grevyi* and *Equus zebra*) and other zoo equidae (for example *Equus przewalskii)*.

Donor

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

Genetically Modified

As defined by the Hazardous Substances and New Organisms (HSNO) Act 1996: any organism in which any of the genes or other genetic material have been modified by in vitro techniques; or are inherited or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by in vitro techniques.

IETS

The International Embryo Transfer Society

***In vivo* Derived Embryo**

Embryo recovered after fertilisation and development occurred in the reproductive tract of the donor female.

The *Manual*

The OIE *Manual* of Diagnostic Tests and Vaccines for Terrestrial Animals.

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 *Code* Chapter for certification procedures.

OIE

The World Organisation for Animal Health.

Permit to Import

A permit issued by the Director General of MPI under section 24D(2) of the Act.

Premises

Area surrounding and including the facility.

The *Code*

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

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.