



Import Health Standard

Pig Semen

PIGSEMEN.GEN

[Document Date]

Provisional

TITLE

Import Health Standard: Pig Semen

COMMENCEMENT

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

REVOCATION

This Import Health Standard revokes and replaces the following:

- a) *Import Health Standard for Pig Semen, PIGSEMIC.GEN, dated 18 June 2013.*

ISSUING AUTHORITY

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

Dated at Wellington, this day of 2017

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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 import health standard (IHS) specifies the minimum requirements that must be met when importing pig semen into New Zealand.

The identified risk organisms associated with pig semen that are managed by this IHS are:

- a) African swine fever virus
- b) Aujeszky's disease virus
- c) Blue eye disease virus
- d) Classical swine fever virus
- e) Foot and mouth disease virus
- f) Japanese encephalitis virus
- g) Porcine myocarditis (Bungowannah) virus
- h) Porcine reproductive and respiratory syndrome virus
- i) Transmissible gastroenteritis virus
- j) *Brucella suis*
- k) *Leptospira* spp

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 accompanies this IHS and provides information on how the requirements may be met.

Who should read this Import Health Standard?

This IHS applies to importers of pig semen.

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 or treated in accordance with this IHS prior to biosecurity clearance. Importers are liable for all associated expenses.

The costs to MPI in performing functions relating to the importation of pig semen 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.

See guidance document for more information about importer responsibilities.

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.

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

See guidance document for more information about equivalence and permits.

Biosecurity clearance

A biosecurity clearance, under section 26 of the Act, may be issued when the pig semen meets all the requirements of this IHS, provided the applicable requirements of section 27 in the Act are met.

Restricted organisms will not be given biosecurity clearance. On authorisation from the biosecurity inspector, they may be moved from quarantine but must remain in the containment facility.

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.

All equipment entering New Zealand with the pig semen must comply with the [Import Health Standard for the Importation into New Zealand of Used Equipment Associated with Animals or Water](#).

Part 1: General Requirements

1.1 Application

- (1) This IHS applies to all importers of fresh or frozen pig semen from domesticated pigs of the species *Sus scrofa* that has not been genetically modified.

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) Animal identification and recording devices certified by the *International Committee for Animal Recording*, available at the ICAR website: www.icar.org.
- (2) The following 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).
- (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 any amendments to or replacements of the material incorporated in clauses 1.2(1) and 1.2(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.
- See guidance document for more information about incorporation by reference and section 142O(1).

1.3 Definitions

- (1) For the purposes of this IHS, 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.

1.4 Requirements for clearance

- (1) In order to obtain biosecurity clearance pig semen must:
 - a) Meet the requirements of clauses 1.6 – 1.10 of Part 1 and Part 2 of this IHS; and
 - b) Be imported from a country that the CTO is satisfied meets the export country systems and certification requirements of clause 1.5; and

- c) Be accompanied by a veterinary certificate that meets the requirements of clause 1.12, has been agreed by the CTO, and details the measures in Part 2 that the importing country will meet; and
- d) Be accompanied by an import permit where required by clause 1.11.

1.5 Exporting country systems and certification

- (1) Importers may import pig semen only if a CTO is satisfied, on the basis of evidence, that the Veterinary Services of the exporting country are capable of ensuring that commodity imported from that country can meet the requirements of this IHS.
- (2) The evidence must include details about all of the following, that the CTO considers applicable to the commodity from that exporting country:
 - a) The ability of the exporting country's Competent Authority to verify the animal health status of pig semen in the exporting country, zone or compartment, with respect to the risk organisms identified in Part 2
 - b) The adequacy of the national systems and/or programmes and standards in the exporting country for regulatory oversight of the pig industry and semen collection centres
 - c) The capability of the exporting country's Competent Authority to support the issue of veterinary certificates as required by this IHS.
- (3) Importers may not import from a country where a CTO has determined that the Veterinary Services of the exporting country are no longer capable of ensuring that pig semen imported from that country can meet the requirements of this IHS.

Guidance

- The evidence will be obtained during evaluation of the Veterinary Services of the Competent Authority of the exporting country in accordance with section 3 of the *Code*.
- Once the CTO is satisfied with the exporting country's evidence for exporting systems and certification, MPI and the Competent Authority may commence negotiation of the country-specific veterinary certificate.
- In order to be satisfied with the evidence provided an in-country or desk-top audit may be carried out at any time, including prior to the first shipment of commodity.
- See guidance document for more information about exporting country systems and certification, and for a list of currently approved countries and country-specific veterinary certificates.

1.6 Diagnostic testing, vaccination and treatment

- (1) All pre-export and/or surveillance testing required by this IHS must be conducted by a laboratory approved by the Competent Authority of:
 - a) the exporting country; or
 - b) any other country approved under this IHS to export pig semen to New Zealand.
- (2) All laboratory samples required by this IHS must be collected, processed and stored in accordance with the recommendations in the *Code* chapter *Collection and Processing of Bovine, Small Ruminant and Porcine Semen* and/or the *Manual* or as described in the 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) Where the herd monitoring testing option is used to satisfy the porcine reproductive and respiratory syndrome virus requirements in Part 2, sampling of pigs for diagnostic testing must be randomised, and representative of the herd from which the semen is derived. The sample size selected must be

sufficiently large to give at least a 95% confidence of detecting infection at a prevalence of 5% or less in the herd.

- (5) All products and vaccinations required by this IHS to be administered to meet the specific disease requirements in Part 2 must be administered according to the manufacturer's instruction in a country that the CTO agrees meets the requirements of clause 1.5 for export to New Zealand.
- (6) 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.
- (7) Where products required by this IHS have been administered, the product name, manufacturer, active ingredients (where applicable) and the dose and date of the treatment must be recorded on the veterinary certificate.
- (8) Where vaccines required by this IHS have been administered, 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.

Guidance

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

1.7 Semen collection centre requirements

- (1) Semen collection must be carried out in a semen collection centre that complies with the requirements for centres in the *Code* chapter *General Hygiene in Semen Collection and Processing Centres* and *Collection and Processing of Bovine, Small Ruminant and Porcine Semen*.
- (2) The semen collection centre must be:
 - a) Approved for export by the Competent Authority
 - b) Subjected to regular inspection, at least every 12 months, by an Official Veterinarian
 - c) Under the supervision of a semen collection centre veterinarian approved by the Competent Authority.
- (3) The name and approval number of the semen collection centre must be recorded on the veterinary certificate.
- (4) Semen donors may be transferred from one approved semen collection centre to another approved centre of equal health status without isolation or testing if the Competent Authority ensures that all of the following requirements are met:
 - a) Donors have been examined by the approved semen collection centre veterinarian and show no evidence of infectious disease transmissible in semen on the day of entry into the centre
 - b) Transfer is direct
 - c) Donors are protected from insect attack during transit
 - d) Donors do not come into direct or indirect contact with animals of lower health status
 - e) The means of transport is disinfected before use.

1.8 Semen donor requirements

- (1) Semen donors must meet the requirements in the *Code* chapter *Collection and Processing of Bovine, Small Ruminant and Porcine Semen*, and any additional requirements in Part 2 of this IHS.

- (2) During the 28 days in which boars are held in pre-entry isolation prior to entering the semen collection centre (as prescribed in the *Code*), they must not be used for natural mating and must be isolated from animals not of equivalent health status.
- (3) The approved semen collection centre veterinarian must ensure that the donor is free from clinical evidence of infectious disease transmissible in semen on the day of semen collection.
- (4) Where a specific requirement of this IHS for a risk organism is met by monitoring the donor for clinical signs for a specified time after collection, the semen must be stored for that amount of time prior to export.

Guidance

- See guidance document for the model veterinary certification which includes the most current *Code* requirements and the measures for additional risk organisms listed in Part 2 of this IHS.

1.9 Semen collection, processing and storage

- (1) Semen collection, processing and storage must comply with the sections relevant for boars and semen 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 and transport must not have been used previously in association with any other product of animal origin.
- (3) Semen must be in straws or sanitised containers which are sealed and tamper-evident, and clearly and permanently marked to identify the donor and the date(s) of collection. The markings must conform to international standards of the *International Committee for Animal Recording (ICAR)*. If a code is used for this information, its decipher instructions must accompany the consignment.
- (4) Semen may only be stored with germplasm that has been collected and processed in accordance with the *Code*. Semen must be held in a storage place approved by the Competent Authority of the exporting country until the time of export.
- (5) Semen may be stored in a third country (a country other than the country of origin) if the third country and the country of origin have met the requirements of clause 1.5 of this IHS, and the consignment of semen is accompanied by:
 - a) A declaration from the Competent Authority of the third country, linking the semen from the country of origin to the semen being exported to New Zealand and confirming that the semen has been stored as required by this IHS, at a facility approved by the Competent Authority; and accompanied by 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 the semen meets New Zealand's import requirements.

1.10 Transport

- (1) All transport containers in which semen is transported to New Zealand must be new (or disinfected) and must be free of contamination. When a transport container is disinfected, the disinfectant, its active chemical and the date of disinfection must be recorded on the veterinary certificate.
- (2) All transport containers in which semen is transported to New Zealand must be sealed, by either the semen collection centre veterinarian or an Official Veterinarian, using tamper-evident seals. The seal number must be recorded on the veterinary certificate.

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

1.11 Import permit

- (1) An import permit under section 24D of the Act is required if a CTO has issued a direction under section 27(1)(d) of the Act prior to import for a measure that is different from that set in the 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) of the Act for a measure that is different from that set out in the IHS during negotiation of a country-specific veterinary certificate and the equivalent measure is incorporated into that certificate.

Guidance

- See the guidance document for more information on equivalence and permits.

1.12 The documentation that must accompany goods

- (1) The consignment must arrive in New Zealand with documentation that is specified in and meets the requirements of clauses 1.12.1 to 1.12.3 below.
- (2) All documentation that is required by this clause 1.12 to accompany the pig semen 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 based alternative security features.

1.12.1 Import Permit

- (1) An import permit (copy acceptable) as required by clause 1.11.

1.12.2 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) The description, species, donor animal identification and quantity of semen
 - c) The name of the semen collection centre and approval number
 - d) The dates of semen collection
 - e) The name and address of the importer (consignee) and the exporter (consignor)
 - f) The name, signature and contact details of the Official Veterinarian
 - g) Certification and endorsement by the Official Veterinarian that the general requirements outlined in Part 1 of this IHS have been met
 - h) Certification and endorsement by the Official Veterinarian that the specified requirements outlined in Part 2 of this IHS have been met, excepting for those requirements that a CTO has agreed during negotiation under clause 1.5 as not being required for a country-specific veterinary certificate.

Guidance

- Where equivalent measures have been negotiated and agreed with MPI, and a CTO has, prior to import, approved an equivalent measure under section 27(1)(d) of the Act that is different from those in this IHS 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.

1.12.3 Laboratory reports

- (1) The 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 of this IHS, which must include:
 - a) A unique identification for each animal, consistent with the veterinary certificate
 - b) The dates of sample collection
 - c) The test type.
 - d) The test result.

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Part 2: Specified Requirements for Identified Risk Organisms

- (1) Pig semen must comply with the following measures for identified risk organisms, where required:

2.1 African swine fever (ASF) virus

- (1) Donors meet the *Code* recommendations for importation from ASF free countries, zones or compartments; or
- (2) Donors meet the *Code* recommendations for importation from countries or zones considered infected with ASF.

2.2 Aujeszky's disease (AD) virus

- (1) Donors meet the *Code* recommendations for importation from one of the following:
 - a) AD free countries or zones
 - b) AD provisionally free countries or zones
 - c) AD infected countries or zones.

2.3 Blue eye disease virus

- (1) Donors have lived their entire lives in a country free from blue eye disease; or
- (2) Donors have been subjected to a serological test for blue eye disease listed in MPI-STD-TVTL, with negative results.

2.4 Classical swine fever (CSF) virus

- (1) Donors meet the *Code* recommendations for importation from countries, zones or compartments free from CSF; or
- (2) Donors meet the *Code* recommendations for importation from countries or zones considered infected with CSF.

2.5 Foot and mouth disease (FMD) virus

- (1) For fresh semen, donors meet the *Code* recommendations for importation from FMD free countries or zones where vaccination is not practised, or FMD free compartments; or
- (2) For frozen semen, donors meet the *Code* recommendations for importation from one of the following:
 - a) FMD free countries or zones where vaccination is not practised, or FMD free compartments
 - b) FMD free countries or zones where vaccination is practised
 - c) FMD infected countries or zones.

2.6 Japanese encephalitis (JE) virus

- (1) Donors have lived their entire lives in a country or zone that is free from JE virus.

2.7 Porcine myocarditis (Bungowannah) virus

- (1) Donors have lived their entire lives in a country, zone or compartment that is free from porcine myocarditis virus; or
- (2) Donors originating from properties where porcine myocarditis has been diagnosed were isolated and subjected to tests listed in MPI-STD-TVTL to demonstrate they were seropositive for porcine myocarditis virus and negative for porcine myocarditis virus RNA before entering the semen collection centre; and
 - a) An aliquot of each batch of semen for export was subjected to a RT-PCR test listed in MPI-STD-TVTL, with negative results.

2.8 Porcine reproductive and respiratory syndrome (PRRS) virus

- (1) Donors meet the *Code* recommendations for importation from PRRS free countries, zones or compartments; or
- (2) Donors meet the *Code* recommendations for importation from countries or zones considered infected with PRRS.

2.9 Transmissible gastroenteritis (TGE) virus

- (1) Donors meet the TGE virus *Code* recommendations for the importation of semen.

2.10 *Brucella suis*

- (1) Donors meet the *Brucella suis* *Code* recommendations for the importation of semen.

2.11 *Leptospira* spp.

- (1) Antibiotics effective against *Leptospira* spp. as listed in MPI-STD-TVTL, were added to the semen.

Schedule 1 – Document History

Date First Issued	Title	Shortcode
18 June 2013	Pig Semen	PIGSEMIC.GEN
Date of Issued Amendments	Title	Shortcode
TBA	Pig Semen	PIGSEMEN.GEN

Provisional

Schedule 2 – Definitions

Compartment

An animal subpopulation contained in one or more establishments under a common biosecurity management system with a distinct health status with respect to a specific disease or specific diseases for which required surveillance, control and biosecurity measures have been applied for the purpose of international trade.

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.

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.

Semen collection 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.

The *Code*

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

The *Manual*

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