Ministry for Primary Industries
Manatū Ahu Matua

Import Health Standard

Pig Semen

PIGSEMEN.GEN

[Document Date]

Draft for Consultation

Issued under the Biosecurity Act 1993

New Zealand Government

TITLE

Import Health Standard: Import Health Standard: Pig Semen

COMMENCEMENT

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

REVOCATION

Import Health Standard Pig Semen 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 .....

Howard Pharo
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Ministry for Primary Industries
(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 import health standard (IHS) specifies the minimum requirements that must be met when importing pig semen into New Zealand

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 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 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 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. 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.

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.

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Part 1: General Requirements

1.1 Application

(1) This IHS applies to all importers of fresh or frozen pig semen from any domesticated species of the family Suidae that has not been genetically modified.

1.2 Outcome

(1) The outcome this IHS is seeking to achieve is the effective management of biosecurity risks associated with eligible consignments of pig semen.

(2) The biosecurity risk organisms associated with pig semen that are managed by this IHS are:

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

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1.3 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 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 material that amends or replaces the above listed standards, guideline or lists has legal effect as part of this IHS.

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 Exporting country systems and certification

(1) Importers may only import eligible pig semen from a country where the Competent Authority has provided evidence to the satisfaction of a CTO of the following:

a) The verifiable animal health status of pig populations in the exporting country, zone or compartment, with respect to biosecurity risk organisms of concern
b) The national systems and/or programmes and standards in the exporting country for regulatory oversight of the pig industry and semen collection
c) The capabilities and preferences of the exporting country's Competent Authority with respect to achieving equivalent outcomes to requirements stated in this IHS.

(2) Once satisfied, MPI and the Competent Authority may commence negotiation of country-specific veterinary certification.

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 semen.

See guidance document for more information about exporting country systems and certification.

1.6 Diagnostic testing, vaccination and treatment

(1) Any laboratory conducting the pre-export or surveillance testing where required in this IHS must be approved by the Competent Authority of a country recognised to export pig semen to New Zealand.

(2) Laboratory samples 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*, the *Manual* or as described in the MPI *Approved Diagnostic Tests, Vaccines, Treatments and Post-Arrival Testing Laboratories for Animal Import Health Standards* (MPI-STD-TVTL).

(3) Diagnostic test(s) and vaccines used must be those that have been approved by MPI and documented in 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 recognised to export to New Zealand. All vaccinations must contain 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.

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.

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(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.

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.

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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 must be 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 current import requirements.

1.10 Transport

(1) Transport containers must be new (or disinfected) and free of contamination. When a 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 the 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 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 approved an equivalent measure prior to import, 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 approved an equivalent measure prior to import, different from that set out in the IHS, in the form of a negotiated veterinary certificate.

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

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1.12 The documentation that must accompany goods

(1) The consignment must arrive in New Zealand with the following documentation:

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

i) A unique consignment identifier
ii) The species, donor animal identification, and quantity of semen
iii) The name of the semen collection centre and approval number
iv) The dates of semen collection
v) The name and address of the importer (consignee) and the exporter (consignor)
vi) The name, signature and contact details of the Official Veterinarian
vii) Certification and endorsement by the Official Veterinarian that the general requirements outlined in Part 1 of this IHS have been met
viii) 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 MPI has agreed during negotiation under clause 1.5(2) as not being required for a country-specific veterinary certificate
ix) All diagnostic tests, including test type and date of sampling. Results must be clearly linked to each donor and in the form of either a tabulated summary or copies of the laboratory reports
x) All products and vaccines administered to meet specific disease import requirements, including generic name, active ingredient, dose rate, and date of treatment.

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 which must include:

i) A unique identification for each animal, consistent with the veterinary certificate
ii) The dates of sample collection

iii) The test type
iv) The test result.

(2) 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.

(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.

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Part 2: Specified Requirements for Identified Risk Organisms

(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 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 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.

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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 have lived their entire lives in a country free from PRRS; or

(2) Donors were sourced from herds that are not vaccinated against PRRS, and were tested using a multivalent serum ELISA for PRRS antibodies that uses both European and American strain antigens listed in MPI-STD-TVTL, with negative results before entering the semen collection centre; and

a) On two occasions, the first occasion at the start of the collection period and the second occasion no less than 30 days subsequent to the first occasion, donors were tested for PRRS virus using a serum PCR test listed in MPI-STD-TVTL, with negative results; and
b) Twenty-one to 50 days after the final semen collection, donors were tested using a multivalent serum ELISA for PRRS antibodies that uses both European and American strain antigens listed in MPI-STD-TVTL, with negative results.

2.9 Transmissible gastroenteritis (TGE) virus

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

2.10 *Brucella suis*

(1) Donors meet the *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.

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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

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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.

CTO direction

Chief Technical Officer (CTO) Direction - equivalent measures recorded by number under section 27(1)(d)(iii) of the Act, to enable border staff to clear the goods and record the number in the MPI database.

Director-General

The chief executive of the Ministry for Primary Industries.

Import permit

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

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.

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