Ministry for Primary Industries
Manatū Ahu Matua

Guidance Document

# Pig Semen

PIGSEMEN.GEN

[Document Date]



A guidance document issued by the Ministry for Primary Industries

New Zealand Government

# Title

Guidance Document: Guidance Document: Pig Semen

# About this document

This guidance document contains information about acceptable ways of ensuring compliance with the requirements in the *Import Health Standard (IHS): Pig Semen.*

Any guidance on how to comply with the applicable requirements may not be the only way to achieve compliance. Stakeholders are encouraged to discuss departures from the approaches outlined in this guidance document with the Ministry for Primary Industries (MPI) to avoid expending resources on the development of alternative approaches which may later be considered unsuitable.

The term "must" is not typically used in guidance. In this particular document if the term "must" is used, it is used in the context of quoting or paraphrasing the requirements set out in the related *IHS: Pig Semen.*

# Related Requirements

*Import Health Standard: Pig Semen*

# Document history

Refer to Appendix 1.



# Contact Details

For further information and questions about this guidance document, please contact:

Ministry for Primary Industries
Regulation & Assurance
Animal Imports
PO Box 2526
Wellington 6140
Email: animalimports@mpi.govt.nz

# Disclaimer

This guidance does not constitute, and should not be regarded as, legal advice. While every effort has been made to ensure the information in this guidance is accurate, the Ministry for Primary Industries does not accept any responsibility or liability whatsoever for any error of fact, omission, interpretation or opinion that may be present, however it may have occurred.

# Copyright

# Contents

Page

**1 Purpose** 3

**2 Background** 3

**3 Definitions** 3

**4 Importer Responsibilities** 3

**5 Guidance** 3
5.1 Equivalence 3
5.2 Incorporation of material by reference 4
5.3 Inspection and verification 4
5.4 Biosecurity clearance 4
5.5 Exporting country systems and certification 4
5.6 Diagnostic tests and vaccines for international trade 5

**6 Specified Requirements for Identified Risk Organisms** 5

**7 Model Veterinary Certificate** 6

**Appendix 1 – Document History** 13

# 1 Purpose

(1) This guidance document has been issued to accompany the *IHS: Pig Semen*. This guidance document should be read in conjunction with that IHS.

(2) This document includes:

a) Countries with MPI recognised exporting systems to import pig semen into New Zealand
b) A model veterinary certificate
c) Negotiated country-specific veterinary certificates.

# 2 Background

(1) The *IHS: Pig Semen*, which this guidance document accompanies, contains generic import requirements. These are the rules to manage the biosecurity risk of importing pig semen from all countries that can meet the requirements of the IHS and in doing so meet New Zealand's appropriate level of protection. The generic IHS serves as the basis for country-to-country (bilateral) negotiations. This guidance document contains a model veterinary certificate and the bilaterally-agreed veterinary certification for trade in pig semen. This country-specific veterinary certificate represents what will be certified prior to exporting consignments of pig semen from the country specified.

(2) General information about importing pig semen can be found here: http://mpi.govt.nz/importing/live-animals/semen-and-embryos/.

# 3 Definitions

(1) Refer to Schedule 2 of the *IHS: Pig Semen.*

# 4 Importer Responsibilities

(1) The costs to MPI in performing functions relating to the importation of pig semen will be recovered in accordance with the Biosecurity Act 1993 (the Act) and any regulations made under that Act. All costs involved with documentation, transport, storage and obtaining a biosecurity clearance must be covered by the importer or agent.

(2) Consignments that do not comply with the requirements of the IHS may be re-shipped or destroyed.

# 5 Guidance

## 5.1 Equivalence

(1) MPI may accept an alternative method, system or process that can be shown to achieve the biosecurity requirements of the IHS (i.e. equivalence).

(2) MPI's preference is that the exporting country's Competent Authority makes equivalence requests. Equivalence requests can be lodged with animalimports@mpi.govt.nz.

(3) An import permit is not required to import pig semen into New Zealand if the requirements of the IHS are met.

(4) A permit may be required where specific equivalence measures are approved by MPI. An import permit serves as evidence of equivalence decisions and will be written as specific notes in the special conditions section of the permit.

(5) Import permit application forms can be found on the MPI website at: http://www.mpi.govt.nz/importing/live-animals/semen-and-embryos/forms-and-templates/.

(6) Completed applications are lodged with animalimports@mpi.govt.nz.

## 5.2 Incorporation of material by reference

(1) Incorporation by reference means that standards, guidelines or lists are incorporated into the IHS and they form part of the requirements. This is done because technical documents are too large or impractical to include in the IHS.

(2) Where the IHS states that section 142O(1) of the Act does not apply, this means that importers need to refer to the most recent version of any standards, guidelines or lists that are incorporated by reference in the IHS.

## 5.3 Inspection and verification

(1) On arrival, all documentation accompanying the consignment will be verified by an inspector. The inspector may also inspect the consignment, or a sample of the consignment on arrival.

(2) Inspectors are able to inspect and verify due to their authorised powers under the Act.

(3) These requirements are independent of the IHS requirements.

## 5.4 Biosecurity clearance

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



## 5.5 Exporting country systems and certification

### 5.5.1 Recognition of export and certification systems

(1) MPI recommends Competent Authorities that request recognition of their export and certification systems refer to Section 3 of the *Code* chapter *Quality of Veterinary Services* and the MPI guidance document: *Recognition of Export Controls and Certification Systems for Animals and Animal Products*, to prepare evidence for MPI regarding capabilities and preferences of the exporting country's Competent Authority.

(2) The table below lists those exporting countries recognised by MPI as meeting the requirements set out in clause 1.5 of the *IHS: Pig Semen*:

| Countries with recognised export and certification systems | Date agreed |
|---|---|
| **Australia** | Trade ongoing |
| **Canada** | Trade ongoing |
| **New Caledonia** | Trade ongoing |
| **Norway** | Trade ongoing |
| **USA** | Trade ongoing |

### 5.5.2 Agreed country-specific veterinary certificates

(1) Requests from exporting countries to negotiate veterinary certification for the import of pig semen into New Zealand will be prioritised according to MPI resources available at the time of application.

(2) A model veterinary certificate is provided in this guidance document and can be used by the Competent Authority as a reference for country-specific veterinary certificate negotiation.

(3) All country-specific veterinary certificates agreed between an exporting country's Competent Authority and MPI are included in the table below:

| Country | Link to certificate | S27 CTO direction # | Date agreed | Date applicable for use |
|---|---|---|---|---|
| | | | | |

(4) Country-specific veterinary certificates with equivalent measures will be recorded with a number relevant to a Chief Technical Officer (CTO) direction 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.

(5) When a newly negotiated country-specific veterinary certificate replaces one which is currently in use, the application of new import conditions will apply according to the dates listed in the table. At that time previous veterinary certificates for that country can no longer be used.

## 5.6 Diagnostic tests and vaccines for international trade

(1) MPI lists all approved diagnostic tests and vaccines in the MPI document: *Approved Diagnostic Tests, Vaccines, Treatments and Post-Arrival Testing Laboratories for Animal Import Health Standards* (MPI-STD-TVTL).

(2) Where OIE recommended diagnostic tests and vaccines are listed, details can be found in the OIE *Manual of Diagnostic Tests and Vaccines* (the *Manual*) found on the OIE website: http://www.oie.int/en/international-standard-setting/terrestrial-manual/access-online/.

(3) The OIE *Terrestrial Animal Health Code* chapter listing the prescribed and alternative diagnostic tests for OIE listed diseases is found on the OIE website: http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_1.1.3.htm.

# 6 Specified Requirements for Identified Risk Organisms

(1) The risk management requirements for identified risk organisms are outlined in Part 2 of the IHS.

# 7 Model Veterinary Certificate

(1) Below is a model veterinary certificate for trade in pig semen. This model meets the requirements of the IHS.

(2) This model veterinary certificate format is based on the *Code* chapter for model veterinary certificates for international trade in pig semen.

**Part 1: Details of dispatched consignment**

| | |
|---|---|
| 1.1. Consignor (Exporter):<br>Name:<br>Address: | 1.2. Certificate reference number:<br>1.3. Competent Authority: |
| 1.4. Consignee (Importer):<br>Name:<br>Address: | |
| 1.5. Country of origin:<br>ISO Code* | 1.6. Zone or compartment of origin:** |
| 1.7. Country of destination:<br>ISO Code* | 1.8. Zone or compartment of destination:** |
| 1.9. Place of origin:<br>Name of semen collection centre:<br>Approval number:<br>Address: | |
| 1.10. Place of shipment: | 1.11. Date of departure: |
| 1.12. Means of transport:<br>☐ Aeroplane ☐ Ship<br>Identification: | 1.13. Expected border post:<br>1.14. CITES permit No(s):** |
| 1.15. Description of commodity: | 1.16. Commodity Code (ISO Code*):<br>1.17. Total number of straws: |
| 1.18. Temperature of commodities for transport: | 1.19. Total number of containers: |
| 1.20. Identification of container/seal number: | 1.21. Type of packaging: |

1.22. Identification of commodity:

| Species (Scientific Name) | Donor identification | Date of entry into semen collection centre | Date(s) of collection | Straw identification | Number of straws |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |

* Optional ** If referenced in Part 2

**Part 2: Veterinary Information**

| **Country:** | **Certificate reference number:** |
|---|---|

I, ……..., the undersigned Official Veterinarian, certify that the semen described above satisfy(ies) the following requirements:

**GENERAL REQUIREMENTS**

**Semen eligibility**

(1) The semen is from domestic pigs (family *Suidae*).

(2) The semen is fresh or frozen (*delete as appropriate*) and is not genetically modified.

**Diagnostic testing, vaccination and treatment**

(3) All required laboratory testing was conducted at a laboratory approved to conduct export testing by the Competent Authority of a country recognised to export pig semen to New Zealand.

(4) Tests and vaccines used are listed in MPI-STD-TVTL.

(5) Copies of laboratory reports or an endorsed, tabulated summary, including test date, type and results for each donor, are attached to this veterinary certificate.

(6) All products and vaccinations administered to meet specific disease requirements were administered according to the manufacturer's instruction.

**Semen collection centre requirements**

(7) Semen collection has been carried out in a semen collection centre that meets the conditions in the *Code* chapters *General Hygiene in Semen Collection and Processing Centres* and *Collection and Processing of Bovine, Small Ruminant and Porcine Semen*.

(8) The semen collection centre is:

- (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.

(9) The name and approval number of the semen collection centre are recorded on this veterinary certificate.

(10) When donors were transferred from one approved semen collection centre to another approved centre of equal health status without isolation or testing, the following conditions were applied (*delete if donors were not transferred*):

- (a) Donors were examined by the approved semen collection centre veterinarian, and showed no clinical evidence of infectious disease transmissible in semen on the day of entry into the centre
- (b) Transfer was direct
- (c) Donors were protected from insect attack during transit
- (d) Donors were not in direct or indirect contact with animals of lower health status
- (e) The means of transport used was disinfected before use.

**Semen donor requirements**

(11) The donors meet the conditions in the *Code* chapter *Collection and Processing of Bovine, Small Ruminant and Porcine Semen*.

(12) During the 28 days in which boars were held in pre-entry isolation prior to entering the semen collection centre, donors were not used for natural mating and were isolated from animals not of equivalent health status.

(13) The approved semen collection centre veterinarian ensured that, on the day(s) of collection of semen, the health status of each donor was monitored and abnormalities recorded, and the donor did not show any clinical evidence of infectious diseases transmissible in semen.

**Semen collection, processing, storage and transport**

(14) Semen was collected, processed and stored in accordance with the *Code* chapter *Collection and Processing of Bovine, Small Ruminant and Porcine Semen*.

(15) Antibiotics, as listed in MPI-STD-TVTL, were added to semen diluent to manage *Leptospira* spp.

Name and concentration of antibiotics:

_____

(16) None of the cryogenic or cooling agents used have been previously used in association with any other product of animal origin.

(17) Semen is 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 marking is in accordance with the *Code* and conforms to international standards of the International Committee for Animal Recording (ICAR; www.icar.org). A code is used for this information and its decipher accompanies the consignment (*delete if a code and decipher were not used*).

(18) Semen was only stored with germplasm that was collected and processed in accordance with the *Code*. Semen was held until export in a storage place approved by the Competent Authority of the exporting country.

(19) Semen was transferred from one transport container to another for further processing (*delete if semen was not transferred*).

Transfer date, centre, reason and name of veterinarian involved in transfer:

_____

(20) The semen in this consignment originates from a different country than the country of export: <insert name of country of origin> (*delete as appropriate and initial*). The third country and the country of origin are both recognised to export pig semen to New Zealand and the 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 in the IHS, at a facility approved by the Competent Authority; and either

(i) The veterinary certificate certified by the country of origin's Competent Authority and meets New Zealand's import requirements; or

(ii) A letter from the country of origin's Competent Authority indicating that the semen meets New Zealand's current import requirements.

**SPECIFIC REQUIREMENTS FOR IDENTIFIED RISK ORGANISMS**

**African swine fever (ASF) virus**

(21) For importation from ASF free countries, zones or compartments

(a) Donors were kept in an ASF free country, zone or compartment since birth or for at least 40 days prior to collection; or

(22) For importation from countries or zones considered infected with ASF

(a) Donors:

(i) Were kept in an ASF free compartment since birth or for at least the 40 days prior to collection; and

(ii) Showed no clinical sign of ASF on the day of collection of the semen and for the following 40 days.

**Aujeszky's disease (AD) virus**

(23) For importation from AD free countries or zones

(a) Donors were kept in an establishment or artificial insemination centre located in an AD free country or zone at the time of semen collection; or

(24) For importation from AD provisionally free countries or zones

(a) Donors have been kept for at least the four months prior to semen collection in an artificial insemination centre which has the status of AD free establishment, and where all boars are subjected to a serological test to the whole AD virus listed in MPI-STD-TVTL, with negative results, every four months; or

(25) For importation from AD infected countries or zones

(a) Donors:

(i) Were kept in an AD free establishment for at least the six months prior to entering the artificial insemination centre; and

(ii) Have been kept for at least the four months prior to semen collection in the artificial insemination centre which has the status of AD free establishment, and where all boars are subjected to a serological test to the whole AD virus listed in MPI-STD-TVTL, with negative results, every four months; and

(iii) Were subjected to a serological test to the whole AD virus listed in MPI-STD-TVTL, with negative results, between 10 days prior to and 21 days after semen collection.

**Blue eye disease virus**

(26) Donors have lived their entire lives in a country free from blue eye disease; or

(27) Donors have been subjected to a serological test listed in MPI-STD-TVTL, with negative results.

**Classical swine fever (CSF) virus**

(28) For importation from countries, zones or compartments free from CSF

(a) Donors were kept in a country, zone or compartment free from CSF since birth or for at least the three months prior to collection; or

(29) For importation from countries or zones considered infected with CSF

(a) Donors:

(i) Were kept in a compartment free from CSF since birth or for at least the three months prior to collection; and

(ii) Showed no clinical sign of CSF on the day of collection of the semen and for the following 40 days; and

(iii) Met one of the following conditions:

1. Have not been vaccinated against CSF and were subjected to a serological test listed in MPI-STD-TVTL performed at least 21 days after collection, with negative results; or

2. Have been vaccinated against CSF and were subjected to a serological test listed in MPI-STD-TVTL performed at least 21 days after collection, and it has been conclusively demonstrated that any antibody is due to the vaccine; or

3. Have been vaccinated against CSF and were subjected to a virological test listed in MPI-STD-TVTL performed on a sample taken on the day of collection, and it has been conclusively demonstrated that the boar is negative for virus genome.

**Foot and mouth disease (FMD) virus**

(30) For importation of fresh semen from FMD free countries or zones where vaccination is not practised, or FMD free compartments

(a) Donors:

(i) Were kept for at least the three months prior to collection in a FMD free country or zone where vaccination is not practised or FMD free compartment; and

(ii) Were kept in an artificial insemination centre where none of the animals had a history of infection with FMD virus; or

(31) For importation of frozen semen from FMD free countries or zones where vaccination is not practised, or FMD free compartments

(a) Donors:

(i) Showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days; and

(ii) Were kept for at least the three months prior to collection in a FMD free country or zone where vaccination is not practised or FMD free compartment; or

(32) For importation of frozen semen from FMD free countries where vaccination is practised

(a) Donors:

(i) Showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days; and

(ii) Were kept for at least the three months prior to collection in a FMD free country or zone where vaccination is practised; and either

1. Have been vaccinated at least twice, with the last vaccination not less than one month and not more than six months prior to collection, unless protective immunity has been demonstrated for more than six months; or

2. Were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMD virus listed in MPI-STD-TVTL, with negative results; and

(iii) The semen was stored in the country of origin for a period of at least one month following collection, and during this period no animal on the establishment where the donor animals were kept showed any sign of FMD; or

(33) For importation of frozen semen from FMD infected countries or zones

(a) Donors:

(i) Showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days; and

(ii) Were kept in an artificial insemination centre where no animal had been added in the 30 days before collection, and that FMD has not occurred within a 10 kilometre radius of the artificial insemination centre for the 30 days before and after collection; and either

1. Have been vaccinated at least twice, with the last vaccination not less than one month and not more than six months prior to collection, unless protective immunity has been demonstrated for more than six months; or

2. Were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMD virus listed in MPI-STD-TVTL, with negative results; and

(iii) Semen:

1. Was subjected, with negative results, to a test for evidence of FMD virus listed in MPI-STD-TVTL if the donor animal has been vaccinated within the 12 months prior to collection; and

2. Was stored in the country of origin for a period of at least one month following collection, and that during this period no animal on the establishment where the donor animals were kept showed any sign of FMD.

**Japanese encephalitis (JE) virus**

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

**Porcine myocarditis (Bungowannah) virus**

(35) Donors have lived their entire lives in a country, zone or compartment that is free from porcine myocarditis virus; or

(36) 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 being exported to New Zealand was subjected to a RT-PCR test listed in MPI-STD-TVTL, with negative results.

**Porcine reproductive and respiratory syndrome (PRRS) virus**

(37) Donors have lived their entire lives in a country free from PRRS; or

(38) 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.

**Transmissible gastroenteritis (TGE) virus**

(39) Donors have been resident since birth in a country in which TGE is officially notifiable and no clinical case has been recorded in the previous three years; or

(40) Donors have been resident for at least 40 days in an artificial insemination centre, and all the pigs in the artificial insemination centre were free from clinical signs of TGE during the 12 months prior to collection; and

(a) For fresh semen, donors were subjected to a diagnostic test for TGE listed in MPI-STD-TVTL, with negative results, during the 30 days prior to collection; or

| | | |
|---|---|---|
| | (b) For frozen semen, donors were subjected to a diagnostic test for TGE listed in MPI-STD-TVTL, with negative results, at least 14 days after collection.<br><br>***Brucella suis***<br><br>(41) Donors were not vaccinated against infection with *Brucella*. | |
| | Official Veterinarian<br><br>Name:<br><br>Address:<br><br>Email: | Signature:<br><br>Date:<br><br>[Official Veterinarian signature, Official stamp and date] |

# Appendix 1 – Document History

| Date First Issued | Title | Shortcode |
|---|---|---|
| TBA | Guidance Document: Pig Semen | GD PIGSEMEN.GEN |
| **Date of Issued Amendments** | **Title** | **Shortcode** |
| | | |
| | | |