Ministry for Primary Industries
Manatū Ahu Matua

Risk Management Proposal

Pig Semen

2016

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Regulation and Assurance Branch

RISK MANAGEMENT PROPOSAL

Importation of Pig Semen

2016

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Contents

Purpose

The purpose of this document is to:

- present the risks associated with pig semen
- outline options considered for managing those risks
- show how the options have been assessed
- provide recommendations for import requirements to be included in the import health standard (IHS).

Background

Pig semen is considered a risk commodity, with the potential to harbour exotic viral and bacterial diseases that could establish in New Zealand.

In March 2012, the Ministry for Primary Industries (MPI) released a draft IHS for the importation of pig semen into New Zealand from all countries for consultation. This was developed from the 2011 draft import risk analysis (IRA) for pig semen from Australia, the United States of America (USA), Canada, the European Union and Norway. The 2011 draft IRA identified six organisms of potential concern in porcine semen (blue eye disease virus, foot and mouth disease virus, Nipah virus, Teschovirus serotype 1, Venezuelan encephalitis virus, and vesicular exanthema virus) but did not assess the risk due to these since Australia, the USA, Canada, the European Union and Norway claim freedom from these diseases. At the time, the thought was that countries other than the ones specified in the 2011 draft IRA requesting approval under the generic IHS would either need to be free from these diseases or be subject to a formal risk assessment.

This approach however, was not in line with MPI's strategy to create a fully generic approach (i.e. all hazards, all countries). The subsequent IRA *Pig Semen* (IRA 2012) included the additional risk organisms not addressed in the 2011 draft IRA.

Based on the IRA 2012, a generic IHS for *Pig Semen* (PIGSEMIC.GEN) was issued in 2013.

To date, no veterinary certificates have been issued under PIGSEMIC.GEN and current trade in pig semen is only possible under existing IHSs:

- *IHS for Porcine Semen into New Zealand from Australia* (PIGSEMIC.AUS dated 23 July 1998)
- *IHS for Pig Semen from Canada or the United States of America* (PIGSEMIC.NAM dated 26 January 2011)
- *IHS for Pig Semen from New Caledonia* (PIGSEMIC.NCA dated 5 March 1999)
- *IHS for Pig Semen from Norway* (PIGSEMIC.NOR dated 12 January 1998)

An amendment to PIGSEMIC.GEN is considered necessary due to changes to the World Organisation for Animal Health (OIE) *Terrestrial Animal Health Code* (the *Code*) for swine vesicular disease and *Brucella* spp., and specific concerns with regard to risk management measures for bovine viral diarrhoea virus. These changes are discussed under the section for *Recommendations for Identified Risk Organisms* below.

Furthermore, the general requirements in PIGSEMIC.GEN have been revised to align with the *Code* chapters on *General Hygiene in Semen Collection* and

Processing Centres and Collection and *Processing of Bovine, Small Ruminant and Porcine Semen*.

Objective

The objective is to effectively manage biosecurity risks associated with the importation of pig semen, consistent with New Zealand's domestic legislation and international obligations.

Options assessment

Under Article 3.3 of the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement), risk management measures which provide a level of protection greater than provided by international standards may be imposed only when they can be scientifically justified on the basis of a risk assessment.

For a detailed assessment of hazards and their risks, refer to the IRA and rapid risk assessment (RRA) below, which contains the relevant risk assessments and management options for each risk organism.

- IRA: *Pig Semen*, December 2012 (IRA 2012)
- RRA: *Bovine Viral Diarrhoea Virus Testing Requirements for Bovine and Porcine Germplasm Imports from the European Union*, July 2014 (RRA 2014)

The IRA 2012 assessed the risk associated with pig semen imported from all countries. This IRA 2012 identified 12 organisms that may warrant risk management measures.

- Aujeszky's disease (AD) virus
- Blue eye disease virus
- Bovine viral diarrhoea (BVD) virus [*Reassessed as a negligible risk 2016*]
- Classical swine fever (CSF) virus
- Foot and mouth disease (FMD) virus
- Japanese encephalitis (JE) virus
- Porcine myocarditis/Bungowannah virus
- Porcine reproductive and respiratory syndrome (PRRS) virus
- Swine vesicular disease (SVD) virus [*No longer an OIE listed disease and measures revised 2016*]
- *Brucella suis* [*Measures revised 2016*]
- *Leptospira* spp.
- *Salmonella* spp.

African swine fever (ASF) virus and transmissible gastroenteritis (TGE) virus were not assessed to be risks in semen in the IRA 2012. However, the *Code* has specific measures for the safe trade of semen for these two diseases. Measures for ASF and TGE were included in PIGSEMIC.GEN to align New Zealand's standards with the *Code*. This risk management proposal (RMP) has not proposed any changes from PIGSEMIC.GEN for ASF and TGE.

Risk management measures for *Salmonella* spp. were not included in PIGSEMIC.GEN in line with New Zealand's IHS for *Bovine Semen* dated 27 June 2011.

General requirements

The general requirements in PIGSEMIC.GEN have been revised to align with the *Code* chapters on *General Hygiene in Semen Collection* and *Processing Centres*

and Collection and *Processing of Bovine, Small Ruminant and Porcine Semen*. Additional requirements have been included where these are not explicitly stated or covered in the *Code* chapters.

Requirements for storage of semen in a third country and transfer of donors between approved semen collection centres have been included. These changes have been added to facilitate trade and semen collection practices, and are consistent with the IHS for *Semen and Embryos from Sheep (Ovis aries) and Goats (Capra hircus)* dated 22 June 2015.

Recommendations for identified risk organisms

African swine fever (ASF) virus

Options presented in the IRA *Pig Semen* 2012

ASF virus was not identified as a hazard in pig semen.

Code recommendations (2016)

Recommendations for importation from ASF free countries, zones or compartments

For semen of domestic pigs

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

1. *the donor animals:*
   a. *were kept in an ASF free country, zone or compartment since birth or for at least 40 days prior to collection;*
   b. *showed no clinical sign of ASF on the day of collection of the semen;*
2. *the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.*

Recommendations for importation from countries or zones considered infected with ASF

For semen of domestic pigs

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

1. *the donor animals:*
   a. *were kept in an ASF free compartment since birth or for at least 40 days prior to collection;*
   b. *showed no clinical sign of ASF on the day of collection of the semen and for the following 40 days;*
2. *the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.*

Discussion (2016)

No changes are proposed to the import requirements from PIGSEMIC.GEN for ASF.

Recommendation (2016)

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.

ASF discussion from RMP 2012

- *Option 1*
  Semen originating from donor boars that have lived their entire lives in countries or zones free from ASF (in accordance with the OIE Code) could be imported without further sanitary measures.
- *Option 2*
  Semen originating from collection centres certified as compliant with OIE Code Chapters 4.5 and 4.6 could be considered suitable for importation.

The import risk analysis for pig semen identified that African swine fever (ASF) was a preliminary hazard. After further risk assessment it was concluded not to be a hazard requiring any risk mitigation measures.

In contrast the OIE Code has recommended measures for the importation of semen for ASF.

Chapters 4.5 and 4.6 of the OIE Code are the current internationally recognised standards for managing the risk of ASF in pig semen.

Chapter 4.6 of the OIE Code contains requirements for ASF for boars resident in semen collection centres.

Given the existence of international standards for ASF-free (Article 15.1.8 of the OIE Code) and ASF-infected countries (Article 15.1.9 of the OIE code) the most appropriate measures for risk management here would be to accept these Code articles for importation of pig semen.

MPI will seek to influence the OIE to reassess the risk basis of ASF but in the interests of expedience, at this point in time measures that are in line with the OIE Code for ASF will remain in the IHS.

Both options described above are considered to effectively manage the risk of ASF in imported pig semen.

Aujeszky's disease (AD) virus

Options presented in the IRA *Pig Semen* 2012

1. Aliquots of each batch of semen to be imported could be tested by PCR for the presence of virus. Importation of semen giving positive results could be prohibited.
2. Semen originating from collection centres certified as compliant with OIE *Code* Chapters 4.5 and 4.6 could be considered suitable for importation.
3. Semen for export to New Zealand could come from donor boars that were kept in an establishment or artificial insemination centre located in an AD-free country or zone at the time of semen collection.

Code recommendations (2016)

Recommendations for importation from AD free countries or zones
For semen of pigs

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

1. *the donor animals:*
   a. *showed no clinical sign of AD on the day of collection of the semen;*

   b. *were kept in an establishment or artificial insemination centre located in an AD free country or zone at the time of semen collection;*
2. *the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.*

Recommendations for importation from AD provisionally free countries or zones
For semen of pigs

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

1. *the donor animals:*
   a. *have been kept for at least 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, with negative results, every four months;*
   b. *showed no clinical sign of AD on the day of collection;*
2. *the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.*

Recommendations for importation from AD infected countries or zones
For semen of pigs

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

1. *the donor animals:*
   a. *were kept in an AD free establishment for at least six months prior to entering the artificial insemination centre;*
   b. *have been kept for at least 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, with negative results, every four months;*
   c. *were subjected to a serological test to the whole AD virus, with negative results, within 10 days prior to or 21 days after semen collection;*
   d. *showed no clinical sign of AD on the day of collection;*

   the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.

Discussion (2016)

Chapter 4.6 of the *Code* contains AD requirements for boars standing at semen collection centres in relation to AD status of a country or zone. The *Code* chapter for AD defines AD free country or zone, AD provisionally free country or zone and AD free establishment. Countries or zones which do not meet the conditions to be considered free from AD are considered infected. MPI considers the measures outlined in the *Code* for AD (options 2 and 3 above) to effectively manage the risk of AD virus in imported semen.

No changes are proposed to the import requirements from PIGSEMIC.GEN for AD.

Recommendation (2016)

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.

AD discussion from RMP 2012

- *Option 1*
  Semen for export to New Zealand could come from donor boars that were kept in an establishment or semen collection centre located in an AD-free country or zone (in accordance with the requirements of the OIE Code) at the time of semen collection.
- *Option 2*
  Semen originating from collection centres certified as compliant with OIE Code Chapters 4.5 and 4.6 could be considered suitable for importation.
- *Option 3*
  Aliquots of each batch of semen to be imported could be tested by a MPI approved PCR test for the presence of virus. Importation of semen giving positive results could be prohibited.

PCR tests provide a rapid and highly sensitive method for detecting AD virus in pig semen, however the option for PCR testing alone was subsequently removed from the IHS due to a stakeholder submission. The explanation and the MPI response for not having this option as a measure in the IHS is in point 2.4 in the Review of Submissions.

Chapter 4.6 of the OIE Code contains requirements for AD for boars resident in semen collection centres. Chapters 4.5 and 4.6 of the OIE Code are the current internationally recognised standard for managing the risk of AD in pig semen. Given the existence of international standards for AD-free (8.2.13) and AD-infected countries (8.2.15) the most appropriate measures for risk management here would be to accept these Code articles for importation of pig semen.

Options 2 and 3 are considered to effectively manage the risk of Aujeszky's disease (AD) virus in imported semen.

Blue eye disease virus

Options presented in the IRA *Pig Semen* 2012

1. Semen for export to New Zealand could come from donor boars that were kept in an establishment or artificial insemination centre located in a porcine rubulavirus (PoRV)-free country or zone at the time of semen collection.
2. Donor boars could be subject to serological testing with negative results.

Code recommendations (2016)

There are no *Code* recommendations for blue eye disease.

Discussion (2016)

No changes are proposed to the import requirements from PIGSEMIC.GEN for blue eye disease.

Recommendation (2016)

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.

Blue eye disease discussion from RMP 2012

The final version of the risk analysis (December 2012) was amended so that it includes chapters assessing the risks associated with blue eye disease virus, foot and mouth disease virus, Nipah virus, Teschovirus serotype 1, Venezuelan

encephalitis virus, and vesicular exanthema virus. Blue eye disease was concluded to pose a risk in porcine semen.

Blue eye disease, also known as La-Piedad Michoacan paramyxovirus disease or porcine rubulavirus (PoRV), has only been described in Mexico so sanitary measures are not required for imports of porcine semen originating from pigs in any country other than Mexico.

Both option 1 and option 2 are considered to effectively manage the risk.

Bovine viral diarrhoea (BVD) virus

Options presented in the IRA *Pig Semen* 2012

1. Semen originating from collection centres certified as compliant with OIE *Code* Chapters 4.5 and 4.6 could be considered suitable for importation.
2. Every batch of semen to be imported could be tested by a group-specific reverse transcriptase PCR test that detects all relevant pestiviruses. A positive test on any batch of semen could result in disqualification of that semen.
3. Donor boars could have lived their entire lives in countries that are free from both CSFV and BVDV-2.

Code recommendations (2016)

There are no *Code* recommendations for BVD in pig semen.

Discussion (2016)

The IRA 2012 concluded that risk management measures for BVDV-2 were justified for the importation of pig semen. This was based on the assumption that infected pigs excrete BVD virus in their semen which is known to occur with classical swine fever (also a *pestivirus*), and BVD virus is excreted in bull semen. However, direct evidence for BVD virus in pig semen is provided by a single study in which BVD virus was isolated from a viraemic and BVD immunotolerant boar. The infected semen samples however, did not contain spermatozoa.

Congenitally infected pigs appear to excrete large amounts of virus and it would be expected that if BVD virus was associated with pig semen it would be more readily reported in the literature. Experience from the international trade in pig semen has shown that BVD virus does not appear to be a risk in this commodity. On consideration of these observations and the absence of *Code* recommendations for BVD, the RRA 2014 concluded that BVD is not a risk in pig semen.

In countries where BVD is present, cattle are considered to be the main source of infection for pigs as they may co-habit the same farms. The amended IHS will specify that semen donors must be compliant with the *Code* chapter *General Hygiene in Semen Collection and Processing Centres*, which requires segregation from other species of livestock.

Recommendation (2016)

No specific measures are proposed other than those in Part 1 General Requirements of the IHS.

BVD discussion in RMP 2012

- *Option 1*

Donor boars could have lived their entire lives in countries that are free from BVD-2.

- *Option 2*

Donor boars could be required to be tested for antibody to BVD-2 virus by a MPI approved test at least 21 days after collection of the semen batch for export, with negative results.

Classical swine fever (CSF) virus and bovine viral diarrhoea (BVD) virus have been listed as two separate diseases in this RMP as opposed to the integrated approach in the IRA.

Some stakeholders raised concerns during targeted consultation in 2011 that there should be no testing for BVD-2 virus as it is not a listed disease of pigs in the OIE Code.

However, New Zealand is free of BVD-2 (Horner 2000; Vilcek et al 1998; OIE 2008b). Investigations of suspected BVD-2 in cattle have not detected any BVD-2 in ruminants in New Zealand. The only isolates of BVD-2 recorded in New Zealand were from two commercial serum samples of overseas origin in 1997.

As the IRA states, field infection to boars can occur and result in persistent testicular infections with BVD-2, and transmission via semen to New Zealand pigs could occur. Whilst the consequences are likely to be low to the New Zealand pig population, the consequences of any infection to the New Zealand cattle industry could be high.

Measures to prevent transmission of BVD-2 virus are already in place for importation of bovine semen. Risk management measures for BVD-2 virus in pig semen are therefore justified.

Both options described above are considered to effectively manage the risk of BVD-2 virus in imported semen.

Classical swine fever (CSF) virus

Options presented in the IRA *Pig Semen* 2012

1. Semen originating from collection centres certified as compliant with OIE *Code* Chapters 4.5 and 4.6 could be considered suitable for importation.
2. Every batch of semen to be imported could be tested by a group-specific reverse transcriptase PCR test that detects all relevant pestiviruses. A positive test on any batch of semen could result in disqualification of that semen.
3. Donor boars could have lived their entire lives in countries that are free from both CSFV and BVDV-2.

Code recommendations (2016)

Recommendations for importation from countries, zones or compartments free from CSF

For semen of domestic and captive wild pigs

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

1. *the donor animals:*
   a. *were kept in a country, zone or compartment free from CSF since birth or for at least three months prior to collection;*
   b. *showed no clinical sign of CSF on the day of collection of the semen;*
2. *the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.*

Recommendations for importation from countries or zones considered infected with CSFV

For semen of domestic and captive wild pigs

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

1. *the donor animals:*
   a. *were kept in a compartment free from CSF since birth or for at least three months prior to collection;*
   b. *showed no clinical sign of CSF on the day of collection of the semen and for the following 40 days;*
   c. *met one of the following conditions:*
      i. *have not been vaccinated against CSF and were subjected to a serological test performed at least 21 days after collection, with negative results; or*
      ii. *have been vaccinated against CSF and were subjected to a serological test performed at least 21 days after collection and it has been conclusively demonstrated that any antibody is due to the vaccine; or*
      iii. *have been vaccinated against CSF and were subjected to a virological test performed on a sample taken on the day of collection and it has been conclusively demonstrated that the boar is negative for virus genome;*
2. *the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.*

Discussion (2016)

No changes are proposed to the import requirements from PIGSEMIC.GEN for CSF.

Recommendation (2016)

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.

CSF discussion from RMP 2012

- *Option 1*

Donor boars could have lived their entire lives in countries that are free from CSF (in accordance with the requirements of the OIE Code).

- *Option 2*

Semen originating from collection centres certified as compliant with OIE Code Chapters 4.5 and 4.6 could be considered suitable for importation.

- *Option 3*

Every batch of semen to be imported could be tested by a MPI approved reverse transcriptase (RT) PCR test. A positive test on any batch of semen could result in disqualification of that semen.

Chapter 4.6 of the OIE Code contains requirements for CSF for boars resident in semen collection centres. Chapters 4.5 and 4.6 of the OIE Code are the current internationally recognised standard for managing the risk of CSF in pig semen.

Options 1 and 2 are considered to effectively manage the risk of classical swine fever (CSF) in imported pig semen.

Given the existence of international standards for CSF-free (8.2.13) and CSF-infected countries (8.2.15) the most appropriate measures for risk management here would be to accept these Code articles for importation of pig semen.

The option for PCR testing alone was removed from the IHS due to a stakeholder submission. The MPI response to this submission is point 2.5 in the Review of Submissions.

Foot and mouth disease (FMD) virus

Options presented in the IRA *Pig Semen* 2012

1. The international standards described in articles 8.5.15 to 8.5.18. of the OIE *Code* could be adopted to effectively manage the risk associated with FMDV in porcine semen.
2. In addition to the measures described in Option 1, MPI may also require approval of each semen collection and processing and storage facility/ies in the exporting country intended to be used during the preparation of an export consignment to New Zealand. This approval may be dependent on the facility, its location and operating standards and that the verification systems of the Veterinary Authority achieve a very high level of risk management for FMD. The process for MPI approval may include site inspection. MPI may also reserve the right to supervise collection, require the use of New Zealand approved semen collection personnel, or require any other measures deemed necessary to ensure compliance with facility and operating standards upon which the approval is based.
3. Imports of porcine semen could be limited to countries recognised to be free of FMDV without vaccination.

Code recommendations (2016)

Recommendations for importation from FMD free countries or zones where vaccination is not practised or FMD free compartments
For fresh semen of domestic ruminants and pigs

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

1. *the donor males:*
   a. *showed no clinical sign of FMD on the day of collection of the semen;*
   b. *were kept for at least three months prior to collection in a FMD free country or zone where vaccination is not practised or FMD free compartments;*
   c. *were kept in an artificial insemination centre where none of the animals had a history of infection with FMDV;*
2. *the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.*

Recommendations for importation from FMD free countries or zones where vaccination is not practised or FMD free compartments
For frozen semen of domestic ruminants and pigs

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

1. *the donor males:*
   a. *showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;*

b. *were kept for at least three months prior to collection in a FMD free country or zone where vaccination is not practised or FMD free compartments;*

2. *the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.*

Recommendations for importation from FMD free countries or zones where vaccination is practised

For frozen semen of domestic ruminants and pigs

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

1. *the donor males:*
   a. *showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;*
   b. *were kept for at least three months prior to collection in a FMD free country or zone where vaccination is practised;*
   c. *either*
      i. *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*
      ii. *were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMDV, with negative results;*
2. *the semen:*
   a. *was collected, processed and stored in accordance with Chapters 4.5. and 4.6.;*
   b. *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.*

Recommendations for importation from FMD infected countries or zones

For frozen semen of domestic ruminants and pigs

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

1. *the donor males:*
   a. *showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;*
   b. *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;*
   c. *either*
      i. *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*
      ii. *were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMDV, with negative results;*
2. *the semen:*
   a. *was collected, processed and stored in accordance with Chapters 4.5. and 4.6.;*
   b. *was subjected, with negative results, to a test for evidence of FMDV if the donor male has been vaccinated within the 12 months prior to collection;*

c. *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 males were kept showed any sign of FMD.*

Discussion (2016)

The IRA 2012 considered the *Code* recommendations for FMD could effectively manage the risk associated with FMD (option 1). For countries or zones presenting a risk of FMD (i.e. FMD free countries or zones with vaccination and FMD infected countries or zones), PIGSEMIC.GEN required that the semen collection centre be approved by MPI specifically. On reflection, MPI considers the specific wording in PIGSEMIC.GEN with regard to semen collection, processing and storage facility (option 2(b) from *FMD discussion from RMP 2012* below) will be addressed during the country recognition process.

Option 2(b) from *FMD discussion from RMP 2012* will be removed from the IHS. This change is consistent with the FMD requirements in the IHS for *Semen and Embryos from Sheep (Ovis aries) and Goats (Capra hircus)*.

Recommendation (2016)

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.

FMD discussion from RMP 2012

- *Option 1*

Donors were resident for at least the 3 months before semen collection in a country or zone that is free from FMD without vaccination (in accordance with the OIE Code).

- *Option 2*

a. *The herds of origin, semen collection centre, donor animals and semen for export must comply with OIE Code recommendations for export of pig semen from countries or zones presenting a risk of FMD.*
   AND
b. *Each semen collection, processing and storage facility in the exporting country intended to be used during the preparation of an export consignment to New Zealand must be approved by MPI. The approval will be dependent on the facility, its location and operating standards, and that the verification systems of the veterinary authority achieve a very high level of risk management for FMD. The process for MPI approval may include site inspection. MPI reserves the right to supervise collection, require the use of New Zealand approved semen collection personnel, or require any other measures deemed necessary to ensure compliance with facility and operating standards upon which the approval is based.*

Chapter 4.6 of the OIE Code contains requirements for FMD for boars resident in semen collection centres. Chapters 4.5 and 4.6 of the OIE Code are the current internationally recognised standard for managing the risk of FMD in pig semen.

Because of the extreme seriousness of the disease and the catastrophic consequences that would result from its introduction, it was concluded that importation of pig semen should be limited to countries or zones that are free of FMD virus in accordance with the OIE Code, or countries or zones in which compliance with measures in accordance with the recommendations of the OIE Code for import of semen from FMD infected countries or zones has been reviewed and accepted by MPI.

Both options described above are considered to effectively manage the risk of FMD in imported pig semen.

Japanese encephalitis (JE) virus

Options presented in the IRA *Pig Semen* 2012

1. Semen donors could be tested for presence of antibody at the time of collection and again 30 days after collection of semen. Importation of semen from donors that were positive at the time of collection could be permitted on the basis that seropositive animals are not viraemic. Semen from boars that were negative at the time of collection and negative 30 days later could be permitted while semen from donors that were negative at collection and positive 30 days later could be prohibited on the basis that they may have been viraemic at the time of semen collection.
2. Importation could be restricted to semen collected from donors resident in regions that are free from JEV.

Code recommendations (2016)

There are no *Code* recommendations for JE in semen from any species.

Discussion (2016)

No changes are proposed to the import requirements from PIGSEMIC.GEN for JE.

Recommendation (2016)

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

JE discussion from RMP 2012

- *Option 1*

Semen donors could be tested for presence of antibody by a MPI approved test at the time of collection and again 30 days after collection of semen. Importation of semen from donors that were positive at the time of collection could be permitted on the basis that seropositive animals are not viraemic. Semen from boars that were negative at the time of collection and negative 30 days later could be permitted while semen from donors that were negative at collection and positive 30 days later could be prohibited on the basis that they may have been viraemic at the time of semen collection.

- *Option 2*

Importation could be restricted to semen collected from donors resident in regions that are free from JE virus.

Option 2 is considered to be the most appropriate measure to manage the risk of JE virus in imported semen. The OIE Code does not include recommendations for managing the risk of JE virus in semen of any species. JE occurs very rarely in some parts of Northern Australia and those regions of Australia considered to be at risk from JE virus infection are likely to be remote from commercial pigs.

Due to a stakeholder submission, the term "region" has been replaced with "zones". The MPI response to this submission is contained in 3.7 of the Review of Submissions.

Option 2 is considered to effectively manage the risk of JE in imported porcine semen.

Porcine myocarditis (Bungowannah) virus

Options presented in the IRA *Pig Semen* 2012

1. Porcine semen could be imported from countries other than Australia without sanitary measures.
2. Semen originating from Australian studs which can be certified as not including individuals from properties where porcine myocarditis has been identified could imported without any further sanitary measures.
3. Donor boars originating from properties where porcine myocarditis has been recognised should be isolated and tested to demonstrate they are seropositive and negative for Bungowannah virus RNA before entering the collection centre.

Code recommendations (2016)

There are no *Code* recommendations for porcine myocarditis.

Discussion (2016)

No changes are proposed to the import requirements from PIGSEMIC.GEN for porcine myocarditis.

Recommendation (2016)

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.

Porcine myocarditis discussion from RMP 2012

- *Option 1*

Pig semen could be imported from countries that are free from porcine myocarditis virus without sanitary measures.

- *Option 2*

Semen originating from Australian semen collection centres which can be certified as not including individuals from properties where porcine myocarditis has been identified could be imported without any further sanitary measures.

- *Option 3*

Donor boars originating from properties where porcine myocarditis has been recognised should be isolated and tested to demonstrate they are seropositive for porcine myocarditis virus, but negative for porcine myocarditis virus RNA before entering the semen collection centre.

Porcine myocarditis is confined to a single enterprise composed of a number of small properties in New South Wales, Australia. There have been no other reports of the disease outside this enterprise. This enterprise includes an artificial insemination facility which uses boars from the positive site after testing with a protocol to ensure

they are antibody positive and antigen negative for porcine myocarditis virus. Since this enterprise was placed under quarantine in 2003, approximately 275,000 semen doses have been used to inseminate 50,000 sows annually in both the positive site and in negative farms with no further spread of this disease. Considering there has been no further spread of the virus, it is reasonable to conclude that these current measures are effectively managing the risk of spread in pig semen.

A peroxidise-linked assay to detect antibodies to porcine myocarditis virus and an RT-PCR test to detect porcine myocarditis virus RNA have been described.

Public consultation resulted into further consideration of the proposed measures.

The draft IRA states: "Although the disease occurs extremely rarely and there is no evidence suggesting that long-term carriers of virus occur, given that the Bungowannah virus has been identified as a Pestivirus, it is assumed that there is a non-negligible likelihood of transmission in semen (see Chapter 10)". A recent publication (Finlaison et al. 2012. Experimental Bungowannah virus infections in weaner pigs and pregnant sows – virology and serology studies. Proceedings 22nd International Pig Veterinary Society Congress 2012) shows long term carriage is more likely than assumed in the draft IRA. Furthermore, it illustrates that PMV can be considered very similar in behaviour to other pestiviruses (eg. BVD, CSF). Taking this new scientific information into account, a more cautious approach is justified.

MPI recognises that there has been limited surveillance to demonstrate freedom from Bungowannah virus in properties not linked to the infected enterprise. Furthermore, the failure to eradicate this disease and the reported disease breakdown on a site where eradication had been previously achieved indicate ongoing biosecurity lapses. MPI also notes that animals from the infected enterprise in New South Wales are sent to Victoria for growing out and slaughter with no restrictions being placed on these Victorian properties.

Reflecting these concerns, Option 2 is considered not to effectively manage the risk of introducing porcine myocarditis virus in imported pig semen, and adding an additional testing option to option 3 is recommended.

> *Option 3 will now read:*
>
> *Donor boars originating from properties where porcine myocarditis has been recognised should be isolated and tested with an MPI approved test to demonstrate they are seropositive for porcine myocarditis virus, but negative for porcine myocarditis virus RNA before entering the semen collection centre*
>
> *AND*
>
> *Every batch of semen to be imported was tested by a MPI approved RT-PCR test, with negative results.*

Please refer to 2.6, 3.8, 6.2 and 7.1 in the Review of Submissions for further discussion.

Either options 1 or 3 are considered to effectively manage the risk of introducing porcine myocarditis virus in imported pig semen.

Porcine reproductive and respiratory syndrome (PRRS) virus

Options presented in the IRA *Pig Semen* 2012

1. Pig semen could be imported from countries that are recognised as free from PRRS without sanitary measures.
2. Boars should be sourced from donor herds that do not vaccinate against PRRSv, and be shown to be negative for PRRSv before entering the stud as described in Chapters 4.5 and 4.6 of the *Code*; and
   a. Individual donor boars should be tested by serum PCR each day of collection with negative results; and
   b. During each day of the collection period, all boars on the stud should be tested for PRRSv by serum PCR, with the number of boars sampled sufficient to give a 95% confidence of detecting a 5% prevalence rate; and
   c. 30 to 50 days after the final sample collection, boars on the stud should be tested by a multi-valent serum ELISA for PRRSv that uses both European and American strain antigens, with the number of boars sampled sufficient to give a 95% confidence of detecting a 5% prevalence rate.
3. Boars should be sourced from donor herds that do not vaccinate against PRRSv, and be shown to be negative for PRRSv before entering the stud as described in Chapters 4.5 and 4.6 of the *Code*; and
   a. Individual donor boars should be tested by serum PCR each day of collection with negative results; and
   b. During each day of the collection period, all boars on the stud should be tested for PRRSv by serum PCR, with the number of boars sampled sufficient to give a 95% confidence of detecting a 5% prevalence rate; and
   c. 30 to 50 days after the final sample collection, boars on the stud should be tested by a multi-valent serum ELISA for PRRSv that uses both European and American strain antigens, with the number of boars sampled sufficient to give a 95% confidence of detecting a 5% prevalence rate; and
   d. Semen should be accompanied by certification that during the three months since the last collection date there has been no clinical or serological evidence of PRRS in the donor herds or the stud itself.
4. The semen collection centre could be required to have a documented absence from PRRS. All pigs entering the semen collection centre must originate from herds which have never recorded a clinical case of PRRS; and
   a. The semen collection centre could be required to have never used a modified live PRRS virus vaccine nor introduced pigs from herds that have used a modified live PRRS virus vaccine; and
   b. All pigs in the semen collection centre could be required to have completed a 5 week period of isolation. While undergoing this 5 week isolation period the pigs must be exposed throughout the isolation period to direct contact with at least an equal number of sentinel grower pigs and the total number of pigs in the semen collection centre undergoing isolation could be required to be at least ten at all times; and
   c. The sentinel grower pigs used could be required to be between 12 and 24 weeks of age and derived from 3 or more herds which have been shown by an approved multi-valent ELISA to be free of PRRS within two months prior to the commencement of the isolation period; and
   d. During the isolation period, all pigs undergoing isolation could be tested for PRRS using an approved multi-valent ELISA test, on two occasions at the start and finish of the isolation period, with a negative result in each case; and

e. Semen collected from donor boars during the 5 week period of isolation (either during approval of the semen collection centre or prior to entry of a donor boar onto an approved semen collection centre) could become eligible for export to New Zealand upon successful completion of isolation (i.e. no positive test for PRRS in any donor boar or sentinel simultaneously undergoing isolation).

5. Reflecting that breakdowns in boar studs still occur despite intensive monitoring, the importation of pig semen from countries with PRRSv could be prohibited.

Note the option for testing in PIGSEMIC.GEN was not described in the IRA 2012 and consequently has not been listed above. For a discussion of how the testing option in PIGSEMIC.GEN was developed, refer to the section below for *PRRS discussion from RMP 2012*.

Code recommendations (2016)

Chapter 4.6 of the *Code* contains requirements for PRRS for boars resident in semen collection centres. Currently, there is no *Code* chapter for PRRS.

Discussion (2016)

No changes are proposed to the import requirements from PIGSEMIC.GEN for PRRS.

Recommendation (2016)

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 sample collection, donors were tested by a multivalent serum ELISA for PRRS antibodies that uses both European and American strain antigens listed in MPI-STD-TVTL, with negative results.

PRRS discussion from RMP 2012

- *Option 1*

Pig semen could be imported from countries that are recognised as free from PRRS without sanitary measures.

- *Option 2*

The semen collection centre has remained free of PRRS for the collection period and 21 days after the end of the collection period by the following ways:

a. Boars were sourced from donor herds that do not vaccinate against PRRS, and were tested by a multivalent serum ELISA for PRRS antibodies that uses both European and American strain antigens with negative results before entering the semen collection centre.
AND

b. At the start of the collection period and no less than 30 days subsequently, donor boars were tested for PRRS virus by serum PCR, with negative results AND

c. 21 to 50 days after the final sample collection, donor boars were tested by a multivalent serum ELISA for PRRS antibodies that uses both European and American strain antigens, with negative results.

- *Option 3*

a. *Boars should be sourced from donor herds that do not vaccinate against PRRS, and be shown to be negative for PRRS before entering the semen collection centre as described in Chapter 4.6 of the OIE Code*
   AND
b. *Individual donor boars should be tested by serum PCR each day of collection with negative results.*
   AND
c. *During each day of the collection period, boars in the semen collection centre should be tested for PRRS virus by serum PCR, with the number of boars sampled sufficient to give a 95% confidence of detecting a 5% prevalence rate*
   AND
d. *30 to 50 days after the final sample collection, boars in the semen collection centre should be tested by a multivalent serum ELISA for PRRS antibodies that uses both European and American strain antigens, with the number of boars sampled sufficient to give a 95% confidence of detecting a 5% prevalence rate.*

- *Option 4*

a. *Boars should be sourced from donor herds that do not vaccinate against PRRS, and be shown to be negative for PRRS before entering the stud as described in Chapter 4.6 of the OIE Code*
   AND
b. *Individual donor boars should be tested for PRRS virus by serum PCR each day of collection with negative results.*
   AND
c. *During each day of the collection period, boars in the semen collection centre should be tested for PRRS virus by serum PCR, with the number of boars sampled sufficient to give a 95% confidence of detecting a 5% prevalence rate*
   AND
d. *30 to 50 days after the final sample collection, boars in the semen collection centre should be tested by a multivalent serum ELISA for PRRS antibodies that uses both European and American strain antigens, with the number of boars sampled sufficient to give a 95% confidence of detecting a 5% prevalence rate.*
   AND
e. *Semen should be accompanied by certification that during the three months since the last collection date there has been no clinical or serological evidence of PRRS in the donor herds or the semen collection centre itself*

- *Option 5*

a. *The semen collection centre could be required to have a documented absence from PRRS. All pigs entering the semen collection centre must originate from herds which have never recorded a clinical case of PRRS.*
   AND
b. *The semen collection centre could be required to have never used a modified live PRRS virus vaccine nor introduced pigs from herds that have used a modified live PRRS virus vaccine*
   AND
c. *All pigs in the semen collection centre could be required to have completed a 5 week period of isolation. While undergoing this 5 week isolation period the pigs must be exposed throughout the isolation period to direct contact with at least an equal number of sentinel grower pigs and the total number of pigs in the semen collection centre undergoing isolation could be required to be at least ten at all times*
   AND
d. *The sentinel grower pigs used could be required to be between 12 and 24 weeks of age and derived from 3 or more herds which have been shown by*

an approved multivalent ELISA to be free of PRRS within two months prior to the commencement of the isolation period
AND

e. *During the isolation period, all pigs undergoing isolation could be tested for PRRS using an approved multivalent ELISA test, on two occasions at the start and finish of the isolation period, with a negative result in each case.*
AND
f. *Semen collected from donor boars during the 5 week period of isolation (either during approval of the semen collection centre or prior to entry of a donor boar onto an approved semen collection centre) could become eligible for export to New Zealand upon successful completion of isolation (i.e. no positive test for PRRS in any donor boar or sentinel simultaneously undergoing isolation).*

- *Option 6*

Reflecting that breakdowns in semen collection centres still occur despite intensive monitoring, the importation of pig semen from countries with PRRS could be prohibited.

Chapter 4.6 of the OIE Code contains requirements for PRRS for boars resident in semen collection centres. Chapters 4.5 and 4.6 of the Code provide some assurance that infected boars are not introduced into a semen collection centre, although ensuring a centre remains free from infection is recognised to be challenging. Additional requirements over and above the measures of the OIE Code are therefore suggested to meet New Zealand's appropriate level of protection for PRRS in pig semen.

Option 2 was added to this chapter after MPI received feedback during targeted consultation (2011). This option balances different views in regards to compliance to the OIE Code, frequency and interval of testing of the donor boars while in the semen collection centre and consideration of possible seroconversion post collection.

Generally, it was perceived that daily testing of the entire semen collection centre population during collection was impractical and was aiming for an unnecessarily high level of protection (Options 3 and 4).

Stakeholders have stated in their submissions on the draft import risk analysis from 2009 that very few semen collection centres or the isolation units supplying a semen collection centre are designed to handle sentinel pigs, so would be unable and unwilling to accommodate Option 5 in any way without compromising their own biosecurity or animal welfare. Also, semen collection centres are mostly sourced from a single breeding herd or at least a few herds with a similar health status. Customers of a semen collection centre (including importers within the New Zealand industry) would not be willing to add to the risk of disease introduction by agreeing to further sources of pigs coming into proximity with donor boars, especially from completely separate sources. Improvements in the understanding of PRRS monitoring in semen collection centres, the recognition of serum testing as being more sensitive than semen testing to detect PRRS, and the wide availability of molecular diagnostic techniques now mean that the risk of introducing PRRS virus in imported semen can now be effectively managed without the use of sentinel pigs in semen collection centres (Option 5).

Stakeholders have also indicated in their 2009 submissions that they believe it would be desirable to require semen to be held for a period of three months after collection and only released if accompanied by certification that during the three months since the last collection date there has been no clinical or serological evidence of PRRS in the donor herd. Option 2 requires semen to be held for at least 21 days (due to

possible seroconversion occurring 14 to 21 days post infection) before the donor serology is undertaken to demonstrate freedom from PRRS. Further requirements to demonstrate freedom from exposure beyond this and in the donor herd are considered unnecessarily trade restrictive.

Option 1 would limit pig semen imports to countries that are free of PRRS.

Background

Of all the OIE-listed porcine diseases that are considered to be a risk in semen, PRRS is unique in that no OIE Code chapter has been written to outline standards for sanitary measures to manage the risk of international transmission of this disease. New Zealand has traditionally taken a very cautious position regarding the requirements for managing the risk of PRRS virus.

Historically PCR testing of semen has been used in donor boars to monitor for PRRS. However, serum PCR (using either a TaqMan PCR test or a nested PCR test) is more sensitive than semen PCR for PRRS virus detection during the first six days following infection and boars can be detected as PRRS-positive by serum PCR before semen PCR. Serum is currently considered to be the preferred sample to use as PRRS virus is present in much higher levels in serum than in semen and is detectable at least 1-2 days sooner. PCR testing of pooled serum samples has been shown to be as effective as testing individual samples for detection of PRRS virus in donor boars. Due to viral mutation, some strains of PRRS virus may be undetected by PCR testing, so post collection testing of boars by serum ELISA is also recommended.

Either options 1 or 2 are considered to effectively manage the risk of introducing PRRS virus in imported pig semen.

Please refer to 1.6, 2.7, 3.9 of the Review of Submissions for further discussion.

Swine vesicular disease (SVD) virus

Options presented in IRA *Pig Semen* 2012

1. Semen originating from donor boars that have lived their entire lives in countries free from SVD could be imported without further sanitary measures.
2. Semen originating from donor boars from countries considered infected with SVD could be required to comply with the recommendations contained in 15.4.10 of the OIE *Code*, including compliance with Chapters 4.5 and 4.6 of the *Code*.
3. Every batch of semen to be imported could be tested by PCR as described by van Rijn *et al*. (2004). A positive test on any batch of semen could result in disqualification of that semen.

Code recommendations (2016)

There are no *Code* recommendations for SVD.

Discussion (2016)

Although SVD virus is shed in semen, artificial insemination of sows using SVD virus-infected semen failed to transmit disease. Further, SVD is not associated with significant morbidity and mortality in domestic and wild pigs. Consequently, SVD has been delisted by the OIE and the *Code* no longer includes recommendations for SVD in pig semen.

Because SVD may be clinically indistinguishable from FMD, the IRA 2012 considered clinical SVD infection would likely trigger a massive FMD response. For

this reason, MPI considered that measures for SVD may be justified despite the disease being delisted. On further reflection, a laboratory confirmation of viral aetiology would be required before a full FMD response would be initiated, and such laboratory confirmation could be attained within one day. SVD measures are no longer justifiable.

Recommendation (2016)

No specific measures are proposed other than those in Part 1 General Requirements of the IHS.

SVD discussion from RMP 2012

- *Option 1*

Semen originating from donor boars that have lived their entire lives in countries free from SVD (in accordance with the requirements of the OIE Code) could be imported without further sanitary measures.

- *Option 2*

Semen originating from donor boars from countries considered infected with SVD could be required to comply with the recommendations contained in 15.4.10 of the OIE Code, including compliance with Chapters 4.5 and 4.6 of the Code.

- *Option 3*

Every batch of semen to be imported could be tested by a MPI approved PCR. A positive test on any batch of semen could result in disqualification of that semen.

Historically, virus isolation has been considered an insensitive test for pig semen due to the toxicity of semen to tissue culture. However, the development of molecular techniques provides a rapid and highly sensitive test for the detection of SVD virus in pig semen. The option for PCR testing alone was removed from the IHS due to a stakeholder submission. The MPI response to this submission is point 2.8 in the Review of Submissions.

Chapter 4.6 of the OIE Code contain requirements for SVD for boars resident in semen collection centres. Chapters 4.5 and 4.6 of the OIE Code are the current internationally recognised standard for managing the risk of SVD virus in pig semen. Given the existence of international standards for SVD free countries (15.4.9) and SVD-infected countries (15.4.10) the most appropriate measures for risk management here would be to accept these Code articles for importation of pig semen.

Options 1 and 2 only are considered to effectively manage the risk of Swine vesicular disease (SVD) in imported pig semen.

Transmissible gastroenteritis virus

Options presented in the IRA *Pig Semen* 2012

TGE was not identified as a hazard in pig semen.

Code recommendations (2016)

Recommendations for the importation of semen of pigs

Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate attesting that:

1. *the donor animals showed no clinical sign of TGE on the day of collection of the semen;*
2. *either;*
   a. *the donor animals have been resident for at least 40 days on an artificial insemination centre, and all the pigs on this artificial*

insemination centre were free from clinical signs of TGE during the 12 months prior to collection;

i. for fresh semen, the donor animals were subjected to a diagnostic test for TGE with negative results during the 30 days prior to collection;

ii. for frozen semen, the donor animals were subjected to a diagnostic test for TGE with negative results at least 14 days after collection;

b. the donor animals 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;

3. *the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.*

Discussion (2016)

No changes are proposed to the import requirements from PIGSEMIC.GEN for TGE.

Recommendation (2016)

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

TGE discussion from RMP 2012

- *Option 1*

Semen originates from donor boars that 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;
AND
the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

- *Option 2*

The donor boars showed no clinical sign of TGE on the day of collection of the semen;
AND
the donor boars have been resident for at least 40 days on a semen collection centre, and all the pigs on this semen collection centre were free from clinical signs of TGE during the 12 months prior to collection;
AND
for fresh semen, the donor boars were subjected to a diagnostic test for TGE with negative results during the 30 days prior to collection;
for frozen semen, the donor boars were subjected to a diagnostic test for TGE with negative results at least 14 days after collection;
AND
The semen was collected, processed and stored in conformity with the provisions of Chapters 4.5 and 4.6.

The import risk analysis for pig semen identified that transmissible gastroenteritis (TGE) was a preliminary hazard. After further risk assessment it was concluded not to be a hazard requiring any risk mitigation measures. In contrast the OIE Code has recommended measures for the importation of semen for TGE.

Chapters 4.5 and 4.6 of the OIE Code are the current internationally recognised standards for managing the risk of TGE in pig semen. Chapter 4.6 of the OIE Code contains requirements for TGE for boars resident in semen collection centres.

Given the existence of international standards for recommendations for the importation of porcine semen with regard to TGE (Article 15.5.4 of the OIE Code) the most appropriate measures for risk management here would be to accept these Code articles for importation of pig semen.

MPI will seek to influence the OIE to reassess the risk basis of TGE but in the interests of expedience, at this point in time measures that are in line with the OIE Code for TGE will remain in the IHS

Please also see point 3.11 in the Review of Submissions.

Either option 1 or 2 are considered to effectively manage the risk of TGE in imported pig semen.

Brucella suis

Options in the IRA *Pig Semen* 2012

1. The requirements of Article 15.3.5. (including compliance with Chapters 4.5 and 4.6) would ensure that imported semen was free from *B. suis*.
2. Semen from donor boars that have lived their entire lives in countries that are free from *B. suis* could be imported without restrictions.

Code recommendations (2016)

Recommendations for the importation of semen

Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate attesting that:

1. *the donor animals showed no clinical sign of infection with Brucella on the day of collection of the semen;*
2. *the donor animals were not vaccinated against infection with Brucella and either:*
   a. were kept in an artificial insemination centre complying with Chapter 4.5. and the semen was collected and processed in accordance with Chapter 4.6.;
   b. were kept in a herd or flock free from infection with Brucella and tested every six months for infection with Brucella with negative results, and the semen was collected, processed and stored in accordance with Articles 4.5.3. to 4.5.5. and Articles 4.6.5. to 4.6.7.

Discussion (2016)

The *Code* chapter for *Brucella* has been revised. The option for country freedom in PIGSEMIC.GEN is inconsistent with the *Code* because the *Code* only describes herd freedom from infection with *Brucella* in pigs and not country freedom.

One of the criteria to qualify for herd freedom is that no pigs in the herd have been vaccinated for *Brucella* for at least the past three years. Thus, semen originating from donors that meet the general requirements of the IHS (i.e. no clinical signs of disease transmissible in semen and compliance with chapters 4.5 and 4.6 of the Code) and the new *Code* recommendations for importation of semen (i.e. have not been vaccinated against infection with *Brucella*) would be eligible for importation, making the option of herd freedom unnecessary.

Recommendation (2016)

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

Brucella discussion from RMP 2012

- *Option 1*

Pig semen could be imported from countries that are free from B. suis without sanitary measures.

- *Option 2*

The requirements of Article 15.3.5 (including compliance with Chapters 4.5 and 4.6) would ensure that imported semen was free from B. suis.

Chapter 4.6 of the OIE Code contains requirements for B. suis for boars resident in semen collection centres. Chapters 4.5 and 4.6 of the OIE Code are the current internationally recognised standard for managing the risk of B. suis in pig semen.

Either option 1 or option 2 are considered to effectively manage the risk of introducing B. suis in imported pig semen.

Leptospira spp.

Options presented in the IRA Pig Semen 2012

1. The disease could be considered to be of negligible risk to human or animal health, and trade without restrictions could be permitted.
2. Donor boars could be tested serologically with a variety of antigens that occur in the exporting country and not in New Zealand, with negative results.
3. Donor boars could be treated with effective antibiotics within one week of semen collection. Streptomycin is the antibiotic of choice although it may not be available in all countries.
4. Semen diluents containing antibiotics that are effective against *Leptospira* spp. could be used in the preparation of the semen.

Code recommendations (2016)

There are no specific *Code* recommendations for infection from *Leptospira* spp.

Discussion (2016)

No changes are proposed to the import requirements for *Leptospira* spp.

Recommendation (2016)

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

Leptospira discussion from RMP 2012

- *Option 1*

The disease could be considered to be of negligible risk to human or animal health, and trade without restrictions could be permitted.

- *Option 2*

Donor boars could be tested serologically with a variety of antigens that occur in the exporting country and not in New Zealand, with negative results.

- *Option 3*

Donor boars could be treated with effective antibiotics within one week of semen collection. Streptomycin is the antibiotic of choice although it may not be available in all countries.

- *Option 4*

Semen diluents containing antibiotics that are effective against Leptospira spp. could be used in the preparation of the semen.

Because of the occurrence of long-term carriers of infection, quarantine is not a suitable option.

Diagnosis in donor boars by means of serology is complex to perform and the results are difficult to interpret because of the many serovars and the difficulty in interpreting cross reactions and low-titre reactions.

Testing of semen samples by culture or PCR is problematic because isolation of organisms is difficult and selection of primers for PCR that will recognise all serovars has not yet been achieved.

Leptospira are sensitive to a variety of antibiotics, and treatment of animals or inclusion of antibiotics in prepared semen has traditionally been used to prevent dissemination of Leptospira spp. by international trade.

The limited availability of streptomycin in a number of countries limits the usefulness of option 3.

The recent IHS for bovine semen considered the use of antibiotics in semen diluents to be sufficient to manage the risk of Leptospires in semen. Consistent with this position, option 4 would be the most appropriate measure for pig semen.

Option 4 is considered to effectively manage the risk of introducing exotic Leptospira spp. in imported pig semen.

Salmonella spp.

Options presented in the IRA *Pig Semen* 2012

1. Semen from healthy pigs not showing clinical signs of salmonellosis and housed on an artificial insemination centre could be imported without restriction.
2. Faecal samples from donor boars could be cultured using suitable pre-enrichment and enrichment media (Davies 2008), on at least 3 occasions, twice in the 3 weeks prior to semen collection and once within 1 week of the completion date of collection of semen. All isolated *Salmonella* spp. could be identified to serotype and for *S*. Typhimurium and *S*. Enteritidis to phage type. The results could be reported to the director of Biosecurity New Zealand. Semen from boars carrying exotic *Salmonella* spp. could be prohibited from importation. The decision whether to import semen from boars infected with endemic species could be made by the importer.
3. An aliquot of semen from each batch could be cultured using suitable pre-enrichment and enrichment media (Davies 2008). When culturing processed semen it could be assumed that if *Salmonella* spp. are not isolated they are not present or have been inactivated by the antibiotics used in preparation of the semen. Culturing from processed semen samples could therefore be recommended. Any isolated *Salmonella* spp. could be fully identified to serotype, and to phage type for *S*. Typhimurium and *S*. Enteritidis, and the results reported to the director of Biosecurity New Zealand. Semen infected with exotic *Salmonella* spp. could be prohibited from importation. The decision whether to import semen infected with an endemic *Salmonella* spp. could be made by the importer.

Code recommendations (2016)

There are no specific *Code* recommendations for infection from *Salmonella* spp.

Discussion (2016)

Salmonella spp. were assessed in the IRA as a potential risk in pig semen. However, requirements for managing the risk of transmission of *Salmonella* spp. were removed in line with New Zealand's IHS for *Bovine Semen*.

Recommendation (2016)

No specific measures are proposed other than those in Part 1 General Requirements of the IHS.