Ministry for Primary Industries
Manatū Ahu Matua

Review of Submissions

Draft Import Health Standard for Pig Semen
Draft Risk Management Proposal for Pig Semen
Draft Guidance Document for Pig Semen

29 November 2017

Growing and Protecting New Zealand

Ministry for Primary Industries
Regulation & Assurance
Animal & Animal Products
PO Box 2526, Wellington 6140
animalimports@mpi.govt.nz

Ministry for Primary Industries
Te Manatū Ahu Atua
Pastoral House
25 The Terrace
P O Box 2526
Wellington
New Zealand

Telephone: +64 4 894 0100
Facsimile: +64 4 894 0733
Internet: http://www.mpi.govt.nz

Regulation & Assurance

REVIEW OF SUBMISSIONS

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29 November 2017

Approved for general release

Howard Pharo
Manager Import and Export Animals
Ministry for Primary Industries

Contents

1 Introduction

The draft import health standard for the importation into New Zealand of pig semen was notified for consultation on November 24, 2016. A second consultation for porcine reproductive and respiratory syndrome virus was notified on 21 July 2017.

The Ministry for Primary Industries (MPI) received submissions from the following:

New Zealand Pork	24 January 2017 (1st submission), 18 August 2017 (2nd submission)
Dairy New Zealand	25 January 2017
PIC New Zealand	25 January 2017
Federated Farmers	27 January 2017
Deer Industry New Zealand	30 January 2017
Canadian Food Inspection Agency	31 January 2017 (1st submission), 3 August 2017 (2nd submission)

This document summarises the issues raised in the submissions, and presents the MPI response to each.

1.1 Acronyms Used in the Document

MPI	Ministry for Primary Industries	RMP	Risk management proposal
IRA	Import risk analysis	GD	Guidance document
RRA	Rapid risk analysis	ROS	Review of submission
IHS	Import health standard	ERS	Emerging risk system
ASF	African swine fever	NZ Pork	New Zealand Pork
AD	Aujeszky's disease	PICNZ	PIC New Zealand
BVD-2	Bovine viral diarrhoea	DairyNZ	Dairy New Zealand
CSF	Classical swine fever	DINZ	Deer Industry New Zealand
FMD	Foot and mouth disease	CFIA	Canadian Food Inspection Agency
JE	Japanese encephalitis	MPI-STD-TVTL	MPI Approved Diagnostic Tests, Vaccines, Treatments and Post-arrival Testing Laboratories for Animal Import Health Standards
PRRS	Porcine reproductive and respiratory syndrome	*Code*	OIE Terrestrial Animal Health Code

SVD	Swine vesicular disease	*Manual*	OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals
TGE	Transmissible gastroenteritis	OIE	World Organisation for Animal Health
PED	Porcine epidemic diarrhoea	RGP	Requirements and Guidance Programme
PDCoV	Porcine deltacorona virus		

2 Summary of Amendments

As a result of comments made, the following is a summary of amendments to be made to the Import Health Standard (IHS) and Guidance Document (GD) for Pig Semen.

2.1 Import health standard

- **Clause 1.1 Application**: MPI will amend the application to specify that the IHS applies to semen from domestic pigs of the species *Sus scrofa* instead of 'from any domesticated species of the family Suidae'.
- **Clause 1.2 Outcome**: MPI will move this clause from Part 1 (General Requirements) of the IHS to the 'Purpose' section in the introduction of the IHS as part of the RGP template update.
- **Clause 1.5 Exporting country systems and certification**: MPI will update the wording in accordance with the RGP template.
- **Clause 1.6 Diagnostic testing, vaccination and treatment**: MPI will update the wording in accordance with the RGP template.
- **Clause 1.6 Diagnostic testing, vaccination and treatment**: MPI will amend the IHS to require a sample size sufficiently large to give at least a 95% confidence of detecting a prevalence of PRRS infection at 5% or less.
- **Clause 1.12 The documentation that must accompany goods**: MPI will update the wording in accordance with the RGP template.
- **Clause 2.8 Porcine reproductive and respiratory syndrome (PRRS) virus**: MPI will amend the clause to reflect the new *Code* chapter for PRRS.

2.2 Guidance document

- **Clause 23 Importation from countries, zones or compartments free from ASF**: MPI will amend the clause to reflect the revised *Code* recommendations for ASF.
- **Clause 24 Importation from countries or zones not free from ASF**: MPI will amend the clause to reflect the revised *Code* recommendations for ASF.
- **Clause 26 Importation from AD provisionally free countries or zones**: MPI will amend the clause to explicitly state the requirements in chapter 4.6 of the *Code*.
- **Clause 27 Importation from AD infected countries or zones**: MPI will amend the clause to explicitly state the requirements in chapter 4.6 of the *Code*.
- **Clause 30 Importation from countries, zones or compartments free from CSF**: MPI will amend the clause to explicitly state the requirements in chapter 4.6 of the *Code.*
- **Clause 31 Importation from countries or zones infected with CSF**: MPI will amend the clause to explicitly state the requirements in chapter 4.6 of the *Code*.

- **Clause 34 Importation of frozen semen from FMD free countries and zones where vaccination is practised**: MPI will amend the clause to explicitly state the requirements in chapter 4.6 of the *Code*.
- **Clause 35 Importation of frozen semen from FMD infected countries and zones**: MPI will amend the clause to explicitly state the requirements in chapter 4.6 of the *Code*.
- **Clause 39 Importation from countries, zones or compartments free from PRRS**: MPI will amend the clause to reflect the new *Code* chapter for PRRS.
- **Clause 40 Importation from countries or zones not free from PRRS**: MPI will amend the clause to reflect the new *Code* chapter for PRRS.
- **Clause 42 Transmissible gastroenteritis (TGE) virus**: MPI will amend the clause to explicitly state the requirements in chapter 4.6 of the *Code*.
- **Clause 43 *Brucella suis***: MPI will amend the clause to explicitly state the requirements in chapter 4.6 of the *Code*.

Copies of all external stakeholder submissions in their entirety are presented in Appendix 1.

3 Review of Submissions

3.1 New Zealand Pork

3.1.1 Concerns with generic approach: New Zealand's obligation to undertake its own risk analysis for pig semen

New Zealand's move toward 'generic' IHSs is logical from some perspectives as it minimises the number of IHSs that need to be managed by MPI and conceptually avoids the need to 'startup' new IHSs every time a new country and/or commodity wants to enter into trade with New Zealand. A generic process can also take advantage of the OIE recommendations that have already been developed (refer to Table 1 with respect to pig semen).

However, a generic IHS does not come without some significant deficiencies, namely:

- **Not all exotic diseases important to New Zealand are OIE listed and therefore need to have specific requirements developed anyway.**
- **New Zealand is a committed member of OIE and supports its overall objectives for international animal health. But it does not always follow that New Zealand supports a particular OIE recommendation that has been confirmed by a majority process. This may be due to New Zealand's internationally very high animal health status which is critical economically for its ability to trade. For example, the consequences of an FMD incursion on New Zealand's economy relative to the effect of the disease in other countries not dependent on dairy and meat is likely to be far higher. It may also be due to unique characteristics of the New Zealand landscape. For example, in New Zealand the population of backyard and non-commercial pigs is unknown and largely uncontrolled, is likely to feed food waste, and exists alongside the commercial pig herd.**

Therefore, regardless of the availability of risk management recommendations through OIE, New Zealand is still obliged to do its own risk assessment (rapid or otherwise) for agents relative to a given IHS. Having undertaken its own risk assessment, New Zealand like all WTO members is then entitled to identify risk management measures that would reduce the biosecurity risk to achieve an appropriate level of protection (ALOP) for the country in the least trade-restrictive manner, considering technical and economic feasibility. All WTO members are required to apply the concept of ALOP consistently across all categories.

MPI Response

The development of generic import health standards (IHS) should be distinguished from MPI's commitment to adopting international standards. Please see response 3.1.2 for a discussion of generic IHSs.

MPI's alignment with international standards includes the development of a risk analysis for the commodity which considers all risks to New Zealand. Where the risk is an OIE-listed disease, the *Code* measures will be considered and will be recommended for inclusion in the IHS where they meet New Zealand's acceptable level of protection. The risk analysis may also recommend measures for non-OIE listed diseases.

The IHS incorporates the *Code* by reference, with clarification that importers must refer to the most recent version of the *Code*. This enables the IHS to include updates to the *Code* without re-consultation when there are no changes or they are not significant (e.g. improved wording

and clarification, changes to horizontal chapters, etc) – i.e. where the measures remain unchanged. When the *Code* measures change, the new measures will be considered through the risk assessment process, and if found to be acceptable will be consulted through the IHS development process.

As noted in the risk management proposal (RMP), the draft IHS was developed from the MPI import risk analysis (IRA) *Pig Semen* (December 2012). The IRA 2012 was consulted previously with the generic pig semen IHS and the IRA was finalised with the issue of the *IHS*: *Pig Semen* (PIGSEMIC.GEN dated 18 June 2013). The IRA 2012 can be found at: http://www.mpi.govt.nz/document-vault/2834. The proposed change to BVD-2 was based on the MPI rapid risk assessment (RRA) *Bovine Viral Diarrhoea Testing Requirements for Bovine and Porcine Germplasm Imports from the European Union* (July 2014).

NZ Pork made two submissions (May 2012 and October 2012) during the consultation of the IRA 2012 and PIGSEMIC.GEN 2013. Their specific concerns in these submissions were addressed in the Review of Submissions (ROS) *Pig Semen* (May 2013) prior to issue of PIGSEMIC.GEN 2013.

It is important to emphasise that requirements in the draft IHS, excepting the bulleted points below, are unchanged from PIGSEMIC.GEN 2013.

The proposed changes in the consultation of the draft IHS relate to:

- alignment of the general requirements with the *Code* chapters 4.5 (*General Hygiene in Semen Collection and Processing Centres*)[1] and 4.6 (*Collection and Processing of Bovine, Small Ruminant and Porcine Semen*)[2]
- removal of the disease specific risk mitigation measures for BVD-2 and SVD (see response 3.2.1)
- revision of the disease specific risk mitigation measures for *Brucella suis* (see response 3.1.13).

The PRRS requirements have been amended to align with the *Code* following adoption of the new *Code* chapter *Infection with Porcine Reproductive and Respiratory Syndrome Virus*, different from what was consulted during the period from 24 November 2016 to 24 January 2017. This change was made following a risk assessment of the *Code* measures to ensure that they meet New Zealand's level of protection. See section 4 for a discussion of PRRS.

[1]OIE Terrestrial Animal Health Code: *General Hygiene in Semen Collection and Processing Centres* (http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_general_hygiene_semen.htm)
[2]OIE Terrestrial Animal Health Code: *Collection and Processing of Bovine, Small Ruminant and Porcine Semen* (http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_coll_semen.htm)

3.1.2 Developing of import health standards

Our view is that in a 'generic' approach to IHSs, diseases with similar epidemiology, routes of transmission, and pathophysiology should share similar risk mitigation strategies. Thus, identification of disparities amongst similar diseases in the current proposed recommendations have guided us in formulating our comments.

A particular concern we have over MPI's strategy to create fully generic IHSs is how to monitor (and manage as required) the occurrence of emerging and re-emerging agents. Under the previous IHS system, both MPI and the pig industry could focus their attention on agents that were emerging in those countries for which trade was permitted. Under the new philosophy, MPI and the pig industry must closely monitor the emergence and

re-emergence of agents in all countries of the world as they are all covered under the generic IHS. As an example, there is currently widespread emergence of novel influenza strains in India and other parts of South Asia. As there was no IHS for semen from India under the old non-generic approach, we would not take particular notice of this disease situation because it had little ability to impact the New Zealand industry (this is not a perfect example as influenza is not transmitted through semen). Under the generic approach it appears that every emerging agent in all countries of the world, if thought to have any possibility of infecting pigs, must be assessed by MPI and the industry.

MPI Response

The *Code* and MPI's country approval process prescribe the conditions under which disease freedom claims can be made and maintained. When MPI assesses and approves a country for export, MPI has confidence in the systems implemented and supervised by the Competent Authority of the approved country to accurately verify and certify any disease freedom claims, and immediately contact MPI if a disease of concern is suspected and/or confirmed in their country, so an assessment can be made regarding potential interruption of trade.

In addition, MPI regularly receives updates from a variety of sources including the relevant Ministry of Foreign Affairs and Trade representatives, Pro-Med and the World Animal Health Information System notifications. MPI representatives regularly attend OIE meetings and keep abreast of issues which may change the level of risk. MPI assesses the information received and if necessary a rapid risk assessment can be requested and safeguards can be put in place. This information is then communicated with relevant stakeholders.

In simple terms, under the traditional 'one-country, one commodity, one-IHS' system, risk goods could not be imported from a country unless an IHS was requested, risks assessed, and approval granted. This situation under generic standards is now somewhat reversed in that essentially all countries are preapproved under the generic standard and if their disease status changes through emergence of a disease, they are only restricted from continuing to trade with New Zealand if we or MPI are aware their disease status has changed. The exporting country is under no formal obligation to report the occurrence of an emerging agent until such time it becomes widespread or severe enough that their obligations as an OIE member cause it to happen. In the context of porcine semen, we previously had to monitor health status of six countries/regions: Australia, the United States of America (USA), Canada, the European Union, Norway, and New Caledonia. Under the new system, we must monitor nearly 200 countries. With MPIs suggestion that a generic IHS for pig meat is imminent, we will face the same issue. We request MPI's consideration of this issue and ask for guidance as to how MPI and industry can work together to manage this important issue in both the short and long term.

MPI Response

It should be noted that the current PIGSEMIC.GEN 2013 is a generic IHS.

NZ Pork has a general misconception with regard to generic IHSs; that all countries under a generic standard are 'pre-approved' to export pig semen to New Zealand. Contrary to this assertion, countries seeking to export animal products (e.g. pig semen) are not 'pre-approved', excepting exporting countries in which there is an existing IHS for trade in that commodity. Countries with existing trade would still need to negotiate a veterinary certificate under the generic IHS.

All other exporting countries would need to meet the requirements in Clause 1.5 (Exporting Country Systems and Certification) of the draft IHS, and only countries approved by MPI would be able to export pig semen to New Zealand. Clause 1.5 states:

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

    a) *The verifiable animal health status of pig populations in the exporting country, zone or compartment, with respect to biosecurity risk organisms of concern.*

    b) *The national systems and/or programmes and standards in the exporting country for regulatory oversight of the pig industry and semen collection.*

    c) *The capabilities and preferences of the exporting country's Competent Authority with respect to achieving equivalent outcomes to requirements stated in this IHS.*

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

On further reflection, MPI will amend clause 1.5 above and replace with the following as part of MPI's Requirements and Guidance Programme (RGP) template update and to better reflect the importer's continuous obligation to meet New Zealand's import requirements:

1) *Importers may import pig semen only if a CTO is satisfied, on the basis of evidence, that the Veterinary Services of the exporting country are capable of ensuring that commodity imported from that country can meet the requirements of this IHS:*

    a) *The ability of the exporting country's Competent Authority to verify the animal health status of pig semen in the exporting country, zone or compartment, with respect to the risk organisms identified in Part 2*

    b) *The adequacy of the national systems and/or programmes and standards in the exporting country for regulatory oversight of the pig industry and semen collection centres*

    c) *The capability of the exporting country's Competent Authority to support the issue of veterinary certificates as required by this IHS.*

2) *Importers may not import from a country where a CTO has determined that the Veterinary Services of the exporting country are no longer capable of ensuring that pig semen imported from that country can meet the requirements of this IHS.*

The generic IHS applies similar principles to the traditional 'one country, one commodity, one IHS' system. Assessment of the exporting country includes a desk top and/or an in-country audit based on Section 3 of the *Code* chapter *Quality of Veterinary Services*[3] and the MPI guidance document (GD) *Recognition of Export Controls and Certification Systems for Animals and Animal Products*. These documents outline the types of information considered by MPI in evaluating an exporting country's animal health status, systems for semen collection and ability to meet the requirements stated in the IHS.

MPI would only approve a country for exporting pig semen where the Competent Authority can exhibit a high standard of risk mitigation for all factors relating to pig diseases, including details surrounding pig semen collection centres. The request for country approval from a Competent

Authority is a result of an importer and exporter identifying that a market exists for the commodity. This makes it unlikely that countries other than those already recognised globally in the safe trade in pig semen will become countries approved for export.

[3]OIE Terrestrial Animal Health Code: *Quality of Veterinary Services* (http://www.oie.int/index.php?id=169&L=0&htmfile=titre_1.3.htm)

3.1.3 Table 2: Importation from ASF free countries, zones and compartments

In some respects, this standard is even less conservative than for AD as semen can be exported from free c/z/com with roughly the same requirements as AD has for only for free c/z.

No diagnostic testing requirement for ASF means complete reliant for identification on a virulent strain that produces pathognomonic signs; low virulence strains may not be detected by clinical signs in captive wild pigs (zoo, warthogs, EU wild boar, etc.) as we know at least the warthogs generally do not show clinical signs.

MPI Response
It should be noted that the requirements for ASF in the draft IHS are unchanged from PIGSEMIC.GEN 2013. Further, the IRA 2012 noted that there is no published evidence that ASF virus is found in semen of infected boars.

The *Code* chapter for *African Swine Fever*[4] makes a distinction between *Sus scrofa* and other pig species. All varieties of *Sus scrofa* are susceptible to the pathogenic effects of ASF virus while the African wild pigs are not. The *Code* provides recommendations for semen of domestic pigs. The IHS applies to semen 'from any domesticated species of the family Suidae'. Reflecting this, MPI will amend clause 1.1 (Application) to specify that only semen from domestic pigs of the species *Sus scrofa* is allowed.

[4]OIE Terrestrial Animal Health Code: *African Swine Fever* (http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_asf.htm)

3.1.4 Table 2: Importation from ASF infected countries and zones

As above, the basis for disease detection is completely around clinical signs in the absence of any diagnostic testing. To their credit, there is at least a requirement that no clinical signs have occurred for 40d post collection.

NZ should not be importing semen from countries known to be infected with ASF. The outbreak is ongoing across the EU region with only scant evidence that the regionalizaiton efforts are working.

Incursions into uninfected zones continue as well as incursions into domestic herds. It is unclear whether the ASF zoning that is occurring actually constitutes some kind of ''OIE zone or compartment' and we would like clarification around this. In any event, the zoning does not appear to be stopping spread of the disease. The epidemic is ongoing within and between countries, and between zones.

MPI Response
The *Code* recommendations for ASF have been revised since the consultation of the draft IHS. MPI will amend clauses 21 and 22 of the GD to reflect the revised *Code* recommendations.

Clause 23 (for importation from countries, zones or compartments free from ASF) will read:

Donors were kept in a country, zone or compartment free from ASF since birth or for at least three months prior to collection.

Clause 24 (for importation from countries or zones not free from ASF) will read:

Donors were kept since birth or for at least three months prior to collection in an establishment, in which surveillance in accordance with the Code demonstrates that no case of ASF has occurred in the past three years; this period can be reduced to 12 months when the surveillance demonstrates that there is no evidence of tick involvement in the epidemiology of the infection.

The IRA 2012 noted that there is no published evidence that ASF virus is found in semen of infected boars. MPI considers the *Code* recommendations for ASF to be adequate.

3.1.5 Table 2: Importation from AD provisionally free countries and zones

Generally OK. Our suspicion is this classification is generally used by countries such as the US that have eradicated AD from domestic, but not feral pigs. It also provides some flexibility in that countries can make use of diagnostic tests that can differentiate between vaccine and wild exposure. We are unsure why 'compartment' was not used in this context but instead OIE has used 'provisional'.

Our recommendation is that testing is required post collection and that semen be held in the country of origin until negative test results are returned.

MPI Response

It should be noted that in NZ Pork's submission in 2012 (see response 2.4 in ROS 2013), they supported the AD requirements as set out in the *Code* chapters 4.5[1] and 4.6[2]. The requirements in the draft IHS are unchanged from PIGSEMIC.GEN 2013.

NZ Pork has not presented any evidence to support an additional requirement of post-collection storage.

Although post-collection testing of donors is not required for importation from AD provisionally free countries or zones, testing of boars for AD virus in pre-entry isolation is required.

Clause 1.8(1) (Semen Donor Requirements) of Part 1 of the draft IHS states:

Semen donors must meet the requirements in the Code chapter (4.6) Collection and Processing of Bovine, Small Ruminant and Porcine Semen, and any additional requirements in Part 2 of this IHS.

Under the article, *Conditions Applicable to Testing of Boars*, in chapter 4.6[2] of the *Code*, boars must be have been kept in an AD free establishment since birth, have not been vaccinated against AD and subjected to a test for whole AD virus 15 days prior to movement to the pre-entry isolation facility. Boars are then held for at least 28 days in the pre-entry isolation facility, and at least 21 days after entering the facility, the boars must be tested for whole AD virus. While resident at the semen collection centre, boars must be tested every four months with a serological test for the whole AD virus.

Reflecting the above, MPI will amend clause 26 (for importation from AD provisionally free countries or zones) of the GD to explicitly state the requirements in relation to chapter 4.6 of the *Code*. The clause will read:

Donors

a) Have not been vaccinated against AD; and

b) Were kept at an AD free establishment since birth and within 15 days prior to movement to the pre-entry isolation facility were subjected to a serological test to the whole AD virus listed in MPI-STD-TVTL, with negative results; and

c) Were tested a minimum of 21 days after entering the pre-entry isolation facility with a serological test to the whole AD virus listed in MPI-STD-TVTL, with negative results; and

d) Were 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 were subjected to a serological test to the whole AD virus listed in MPI-STD-TVTL, with negative results, every four months.

MPI considers that recognised international standards exist to enable safe trade in pig semen from AD provisionally free country or zone, and the option for AD will remain in the draft IHS unchanged (other than the clarification in relation to chapter 4.6 described above).

3.1.6 Table 2: Importation from AD infected countries and zones

NZ should not be importing from countries known to be infected with AD. However, compartmentalisation does provide a means to export semen under specific conditions.

While we support the before and after testing regime, it is not clear why the post-collection testing period has been extended to include -10d from collection; we would like clarification on this matter.

MPI Response

It should be noted that in NZ Pork's submission in 2012 (see response 2.4 in ROS 2013), they supported the AD requirements as set out in the *Code* chapters 4.5[1] and 4.6[2]. The requirements in the draft IHS are unchanged from PIGSEMIC.GEN 2013.

Under the article, *Conditions Applicable to Testing of Boars*, in chapter 4.6[2] of the *Code*, boars must be have been kept in an AD free establishment since birth, have not been vaccinated against AD and on two occasions were subjected to a serological test to the whole AD virus at an interval of not less than 30 days between each test, with the second test being performed during the 15 days prior to movement to the pre-entry isolation facility. In the pre-entry isolation facility, boars must be held for at least 28 days and at least 21 days after entering the facility the boars must be tested for whole AD virus. While resident at the semen collection centre, boars must be tested every four months with a serological test for the whole AD virus

Reflecting the above, MPI will amend clause 27 (for importation from AD infected countries or zones) of the GD to explicitly state the requirements in chapter 4.6 of the *Code*. The clause will read:

Donors

a) Have not been vaccinated against AD; and

b) Were kept in an AD free establishment for at least the six months prior to entering the semen collection centre; and

c) *On two occasions, were subjected to a serological test to the whole AD virus listed in MPI-STD-TVTL, with negative results, at an interval of not less than 30 days between each test, with the second test being performed during the 15 days prior to movement to the pre-entry isolation facility; and*

d) *Were tested a minimum of 21 days after entering the pre-entry isolation facility with a serological test to the whole AD virus listed in MPI-STD-TVTL, with negative results; and*

e) *Were kept for at least the four months prior to semen collection in an semen collection centre which has the status of AD free establishment, and where all boars were subjected to a serological test to the whole AD virus listed in MPI-STD-TVTL, with negative results, every four months.*

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

3.1.7 Table 2: Importation from CSF free countries, zones and compartments

No diagnostic testing requirement for CSF means they are completely reliant on a virulent strain that produces pathognomonic signs; low virulence strains may not be detected by clinical signs.

We would encourage testing be required post collection and that semen be held in the country of origin until negative test results are returned.

MPI Response
With regard to CSF, NZ Pork's submission in the ROS 2013 states:

We support the risk management measures set out in 35 and 36. We do not support 37: this has the effect of accepting semen from a CSF positive country or zone on the basis of direct testing. We strongly recommend the appropriate requirements are those set out in the OIE Code.

Option 35 states:
Semen originates from donor boars that have lived their entire lives in countries that are free from CSF (in accordance with the guidelines of the OIE Code).

Option 36 states:
Semen originates from a semen collection centre that complies with the OIE Code guidelines for general hygiene in semen collection and processing and also complies with relevant aspects of the OIE guidelines on the collection and processing of bovine, small ruminant and porcine semen.

Option 37 states:
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.

In response, MPI removed option 37 and adopted the *Code* recommendations for pig semen from CSF free and CSF infected countries[5].

NZ Pork has not presented any evidence supporting an increased risk of importing CSF virus in pig semen from CSF free countries or zones that justifies the additional requirements for testing

and post-collection storage. Further, under the current pig semen IHSs (e.g. PIGSEMIC.NAM), semen can be imported from an approved country based on country freedom from CSF during the 12 months immediately preceding the dates of collection.

MPI considers that recognised international standards exist to enable safe trade in pig semen from either CSF free countries or zones and CSF infected countries or zones. Reflecting MPI's commitment to adopt international standards where they meet New Zealand's level of protection, the options for CSF will remain in the draft IHS.

[5]OIE Terrestrial Animal Health Code: *Infection with Classical Swine Fever* (http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_csf.htm#article_csf.7.)

3.1.8 Table 2: Importation from CSF infected countries and zones

NZ should not be importing from countries known to be infected with CSF. However, compartmentalisation does provide a means to export semen under specific conditions.

MPI Response
Please see response 3.1.7 and section 4 for a discussion of compartmentalisation.

While we support the before and after testing regime, there is no reliable means of differentiating CSF antibodies generated from exposure to wild virus or vaccine. Positive animals should not be maintained in a negative compartment or zone.

MPI Response
Under the article, *Conditions Applicable to Testing of Boars*, in chapter 4.6[2] of the *Code*, boars must be have been kept since birth or for at least the past three months in a CSF free compartment and have not been vaccinated against CSF nor are the progeny of vaccinated sows unless there are validated means of distinguishing vaccinated and infected pigs. In the pre-entry isolation facility, boars must be held for at least 28 days and at least 21 days after entering the facility the boars must be tested for CSF. All boars resident at the semen collection centre must be tested at least annually for CSF.

Reflecting the above, MPI will amend clause 31 (for importation from countries or zones considered infected with CSF) of the GD to explicitly state the requirements in chapter 4.6 of the *Code*. The clause will read:

Donors

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

b) Have not been vaccinated nor are the progeny of vaccinated sows, unless there are validated means of distinguishing between vaccinated and infected pigs; and

c) Were tested a minimum of 21 days after entering the pre-entry isolation facility with serological or virological tests for CSF (if the donor has been vaccinated it must be conclusively demonstrated that any antibody is due to vaccine or that the boar is negative for virus genome, respectively) listed in MPI-STD-TVTL, with negative results; and

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

e) 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 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 performed on a sample taken on the day of collection, and it has been conclusively demonstrated that the boar is negative for virus genome; and

f) Residing in the semen collection facilities were tested at least annually with a serological or virological test for CSF listed in MPI-STD-TVTL, with negative results.

The way the *Code* recommendations are worded for CSF recognises the challenge NZ Pork has described above, and places the onus on the Competent Authority of the exporting country to conclusively demonstrate infection from vaccination. Effectively this means that semen can only be derived from donors that have not been vaccinated against CSF until such time as a diagnostic testing strategy for vaccinated boars has been validated by the Competent Authority and approved by MPI.

The *Manual* states that the immune status in individual animals or populations post-vaccination can be determined by ELISA (enzyme-linked immunosorbent assay) antibody tests and virus neutralisation (VN) tests[6]. For an ELISA to be considered acceptable for option 2 above, for example, it would need to be validated on field samples and shown to detect all convalescent samples detected by VN tests. Once MPI is satisfied with that the any antibody is due to vaccine, the specific details regarding the diagnostic testing strategy will be included in MPI-STD-TVTL.

See response 3.2.3.

[6]OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals: *Classical Swine Fever (Hog Cholera), Infection with Classical Swine Fever* (http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/2.08.03_CSF.pdf)

Semen should be held in the country of origin until negative test results are returned.

MPI Response

Clause 1.8(4) (Semen Donor Requirements) of Part 1 of the draft IHS states:

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

The *Code* specifies that donors must be monitored for clinical signs of CSF on the day of collection and for the following 40 days. MPI considers that post-collection testing and storage as proposed by NZ Pork are met by the requirements in the draft IHS.

3.1.9 Table 2: Importation from FMD free countries, zones and compartments where vaccination is not practised

It is not clear why the fresh and frozen standards are different. Please explain.

MPI Response
There is no difference in the risk associated with fresh and frozen semen from FMD free countries or zones where vaccination is not practised, or FMD free compartments if the semen has been collected, processed and stored in accordance with the *Code*. MPI believes there is an inconsistency in the *Code* on this point and has already brought this to the attention of the OIE Terrestrial Animal Health Standards Commission.

Fresh semen is only eligible for importation from two countries (i.e. Australia and New Caledonia). Currently, imports data for pig semen indicate that the existing trade in pig semen is limited to frozen semen. Under the generic IHS, MPI will only negotiate veterinary certificates for trade in frozen semen unless an exporting country can demonstrate an exceptional disease status (e.g. PRRS freedom). Effectively, this means that importation of pig semen to New Zealand will be restricted to frozen semen.

No diagnostic testing requirement for FMD means they are completely reliant on a virulent strain that produces pathognomonic signs; low virulence strains may not be detected by clinical signs.

No diagnostic testing appears to be required. We recommend testing occur in addition to an evaluation of clinical signs.

The requirements for boars housed in a free country or zone (presumably in any kind of premises) versus those housed in an AI centre, are different. We disagree – they should be the same.

MPI Response
Clause 1.7(1) (Semen Collection Centre Requirements) of Part 1 of the draft IHS specifies that semen collection must be carried out in a semen collection centre that complies with the requirements for centres in the *Code* chapters 4.5[1] and 4.6[2].

In order to qualify for admission into the pre-entry isolation facility, boars must have been kept since birth or for at least the past three months in a FMD free country or zone where vaccination is not practised, or a FMD free compartment. Boars must then be kept for at least 28 days in the pre-entry isolation facility before entry into the semen collection centre. These requirements apply to all semen donors. Hence, there is no difference in the residency requirements of semen donors.

Additionally, the *Code* provides an outline of the requirements that must be met in order to be considered a country or zone free from FMD where vaccination is not practised. As part of these requirements, there must be no vaccination for FMD, no case of FMD during the previous 12 months, measures to prevent the entry of FMD and surveillance to detect clinical signs of FMD.

MPI has previously approved semen imports from a small number of established trading partners. Before approving any further countries as eligible to export pig semen, MPI would need to be satisfied that the exporting country operates and maintains a very high level of risk management for FMD. This has not changed from PIGSEMIC.GEN 2013. Also see response 3.1.2

We would encourage testing be required post collection and that semen be held in the country of origin until negative test results are returned.

MPI response

NZ Pork has not presented any evidence supporting an increased risk of importing FMD virus in pig semen from FMD free countries or zones to justify the additional requirements for testing and post-collection storage. Further, under the existing pig semen IHSs (e.g. PIGSEMIC.NAM, PIGSEMIC.AUS, PIGSEMIC.NCA), semen can be imported from an approved country based on country freedom from FMD during the 12 months immediately preceding the dates of collection. Similarly, there is no requirement for testing under the IHSs for bovine (BOVSEMID.GEN), ovine/caprine (OVACAGERM.GEN) and cervine (CERSEMIC.UK) semen from FMD free approved countries or zones where vaccination is not practised.

MPI considers that recognised international standards exist to enable safe trade in pig semen from FMD free countries or zones without vaccination, or FMD free compartments. Reflecting MPI's commitment to adopt international standards where they meet New Zealand's level of protection, the options for FMD will remain in the draft IHS.

3.1.10 Table 2: Importation from FMD free countries and zones where vaccination is practised

New Zealand should not be importing from vaccinated animals, regardless of their serostatus.

MPI response

The generic IHSs for pig semen (e.g. PIGSEMIC.GEN), bovine semen (BOVSEMID.GEN) and ovine/caprine semen (OVACAGERM.GEN) include options that allow the importation of semen from FMD free countries or zones where vaccination is practised in accordance with the *Code*. To date, no FMD free countries or zones where vaccination is practised have been approved to export semen to New Zealand.

MPI would only approve a country for exporting pig semen where the Competent Authority can exhibit a high standard of risk mitigation for all factors relating to pig diseases, including details surrounding pig semen collection centres. The request for country approval from a Competent Authority is a result of an importer and exporter identifying that a market exists for the commodity. This makes it unlikely that countries other than those already recognised globally in the safe trade in pig semen will become countries approved for export.

While some DIVA tests are available and perhaps suitable for use on a population basis, they are not suitable for use on individual animals and therefore as there is no reliable means of differentiating FMD antibodies generated from exposure to wild virus or vaccine, positive animals should not be maintained in a negative compartment or zone.

We would encourage testing be required post collection and that semen be held in the country of origin until negative test results are returned.

MPI Response

Under the article, *Conditions Applicable to Testing of Boars*, in chapter 4.6[2] of the *Code*, boars were kept since birth or at least the past three months in a FMD free country or zone where vaccination is practised and were subjected to a test for FMD prior to movement to the pre-entry isolation facility. Boars must then be held for at least 28 days in the pre-entry isolation facility, and at least 21 days after entering the facility, the boars must be subjected to a diagnostic test for FMD.

Reflecting the above, MPI will amend clause 34 (for importation of frozen semen from FMD free countries or zones where vaccination is practised) of the GD to explicitly state the requirements in chapter 4.6 of the *Code*. The clause will read:

Donors:

a) Were kept since birth or for at least the past three months in a FMD free country or zone where vaccination is practised and were subjected to a test for FMD listed in MPI-STD-TVTL, with negative results, prior to movement to the pre-entry isolation facility; and

b) Were tested a minimum of 21 days after entering the pre-entry isolation facility with a test for FMD listed in MPI-STD-TVTL, with negative results; and

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

d) 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.

Article 8.8.3 of the *Code* specifies the requirements that must be met in order for a country or zone to qualify as FMD free with vaccination which includes surveillance to detect clinical signs of FMD and to demonstrate no evidence of infection with FMD virus in unvaccinated animals and FMD virus transmission in vaccinated animals.

There are two types of serological tests for FMD virus which allow detection of antibodies to viral structural proteins (SP) and viral non-structural proteins (NSP). The *Manual* accepts the use of SP tests for confirming previous or ongoing infection in unvaccinated animals. This refers to option 2 above. MPI considers that SP tests are highly sensitive and specific (approaching 100 percent) and would be suitable for use on individual animals to detect antibodies to FMD. Semen from FMD positive animals would be disqualified for import to New Zealand.

NSP tests can be used to identify previous or ongoing infection with any of the seven serotypes of FMD virus, whether or not the animal has been vaccinated. The *Manual* considers the use of NSP tests to be suitable; however, further validation may be necessary. Uttenthal *et al.* (2010)[7] evaluated four commercial NSP tests and found that these tests are highly sensitive and specific (97-98 percent) in unvaccinated animals. The sensitivity in vaccinated and subsequently infected animals was much lower (i.e. false negatives possible), and the authors hypothesised that this was the result of reduced viral replication. MPI considers that NSP tests are appropriate to substantiate freedom from FMD infection, regardless of vaccination status, on a population basis. The use of NSP tests for individual animal freedom prior to movement would only be considered appropriate by MPI if the Competent Authority of the exporting country conclusively demonstrated that the test is highly sensitive and specific for the detection of FMD infection in vaccinated animals.

Thus, if tests (e.g. NSP, PCR, etc) for FMD cannot satisfactorily detect infection in vaccinated animals, then option 1 above will not be considered appropriate (i.e. only unvaccinated animals from that country can be considered for use as a semen donors for New Zealand).

MPI has previously allowed semen imports from a small number of established trading partners. MPI would need to be satisfied that the exporting country operates and maintains a very high level of risk management for FMD before approving the country as eligible to export pig semen. This has not changed from PIGSEMIC.GEN 2013.

MPI considers that recognised international standards exist to enable safe trade in pig semen from FMD free countries or zones where vaccination is practised. Reflecting MPI's commitment to adopt international standards where they meet New Zealand's level of protection, the options for FMD will remain in the draft IHS unchanged (other than the clarification in relation to chapter 4.6 of the *Code* above).

[7]Uttenthal *et al.* (2010) Strategies for Differentiating Infection in Vaccinated Animals (DIVA) for Foot-and-Mouth Disease, Classical Swine Fever and Avian Influenza. *Expert Rev. Vaccines* 9(1): 73-87

3.1.11 Table 2: Importation from FMD infected countries and zones

New Zealand should not be importing semen from infected countries and zones.

MPI Response

NZ Pork did not raise any concerns with the importation of semen from FMD infected countries in their submissions in May 2012 and October 2012. NZ Pork has not presented any evidence to justify a change to the draft IHS.

The generic IHSs for pig semen (e.g. PIGSEMIC.GEN), bovine semen (BOVSEMID.GEN) and ovine/caprine semen (OVACAGERM.GEN) include options that allow the importation of semen from FMD infected countries in accordance with the *Code*. To date, no FMD infected countries or zones have been approved to export semen to New Zealand.

MPI has previously allowed semen imports from a small number of established trading partners. MPI would need to be satisfied that the exporting country operates and maintains a very high level of risk management for FMD before approving the country as eligible to export pig semen. This has not changed from PIGSEMIC.GEN 2013.

Further, MPI considers that recognised international standards exist to enable safe trade in pig semen, including from FMD infected countries or zones. Reflecting MPI's commitment to adopt international standards where they meet New Zealand's level of protection, the options for FMD will remain in the draft IHS unchanged (other than the clarification in relation to chapter 4.6 of the *Code* - see response 3.3.1 below).

3.1.12 Table 2: Transmissible gastroenteritis

The need for different requirements for fresh and frozen is not clear; please explain.

MPI Response

There is no difference in the risk associated with fresh and frozen semen in relation to the testing regime for TGE if the semen has been collected, processed and stored in accordance with the *Code*. MPI believes there is an inconsistency in the *Code* on this point and will bring this to the attention of the OIE Terrestrial Animal Health Standards Commission.

We would encourage testing be required post collection and that semen be held in the country of origin until negative test results are returned.

New Zealand recognizes the risk of TGE transmission through semen is extremely low risk but the disease is of very high consequence and warrants control measures be implemented.

MPI Response
It should also be noted that the IRA 2012 concluded that TGE is not a risk in pig semen.

NZ Pork has not presented any evidence to support a requirement for TGE testing and post-collection storage for countries free from TGE and that meet the *Code* requirements. Under the IHSs for Australia (PIGSEMIC.AUS) and New Caledonia (PIGSEMIC.NCA), fresh or frozen pig semen can be imported without TGE testing or post-collection storage. TGE is not reported in these countries.

For countries where TGE is present, under the article, *Conditions Applicable to Testing of Boars*, in chapter 4.6[2] of the *Code*, boars must originate from an establishment in which no case of TGE was reported during the previous 12 months and during the 30 days prior movement to the pre-entry isolation facility boars were isolated and tested for TGE. In the pre-entry isolation facility, boars must be held for at least 28 days and no less than 21 days after entering the facility, the boars must be subjected to a test for TGE. Boars resident in the semen collection centre are tested for TGE at least annually.

Reflecting the above, MPI will amend clause 42 of the GD to explicitly state the requirements in chapter 4.6 of the *Code*. The clause will read:

Donors:

a) Come from an establishment where no TGE has been reported during the previous 12 months and during the 30 days prior to movement to the pre-entry isolation facility boars were isolated and subjected to a test for TGE listed in MPI-STD-TVTL, with negative results; and

b) Were tested a minimum of 21 days after entering the pre-entry isolation facility with a test for TGE listed in MPI-STD-TVTL, with negative results; and

c) Have been resident for at least 40 days in a semen collection centre, and all the pigs in the semen collection centre were free from clinical signs of TGE during the 12 months prior to collection; and

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

2) For frozen semen, donors were subjected to a test for TGE listed in MPI-STD-TVTL, with negative results, at least 14 days after collection.

d) Residing in the semen collection centre were tested at least annually.

3.1.13 Table 2: *Brucella suis*

New Zealand should not be importing semen from countries infected with brucellosis, particularly in the absence of any testing scheme.

The requirements' reliance on clinical signs is not appropriate. It is rare to see clinical signs in a boar infected with this disease. In theory, one could see general malaise and fever and occasionally orchitis but none of these are reliable or specific enough to be used as part of an export testing program.

The dx test has not been specified and this is important. 6 monthly testing is inadequate unless something about the 'AI centre' definition mandates testing of all individuals prior to entering the centre. It is only transmitted pig to pig so a test on entry would be enough, and would support the 6m testing requirement.

MPI Response

Clause 1.7(1) (Semen Collection Centre Requirements) of Part 1 of the draft IHS states:

Semen collection must be carried out in a semen collection centre that complies with the requirements for centres in the Code chapters (4.5) General Hygiene in Semen Collection and Processing Centres and Collection and (4.6) Processing of Bovine, Small Ruminant and Porcine Semen.

Clause 1.8(1) (Semen Donor Requirements) of Part 1 of the draft IHS states:

Semen donors must meet the requirements in the Code chapter (4.6) Collection and Processing of Bovine, Small Ruminant and Porcine Semen, and any additional requirements in Part 2 of this IHS.

In order to qualify for admission into the pre-entry isolation facility, boars must originate from a herd free from infection with *Brucella* in pigs[8] in accordance with the *Code*. Boars must then be kept for at least 28 days in the pre-entry isolation facility and no less than 21 days after entering the pre-entry isolation facility, the boars must be tested for *Brucella* infection. Boars that reside in the semen collection centre must be tested annually, where the country or zone where the semen collection facility is located is not free from infection with *Brucella*.

Reflecting the above, MPI will amend clause 43 of the GD to explicitly state the requirements in chapter 4.6 of the *Code*. The clause will read:

Donors:

a) Were sourced from a herd free from infection with Brucella in pigs in accordance with the Code; and

b) Have not been vaccinated against infection with Brucella; and

c) Were tested a minimum of 21 days after entering the pre-entry isolation facility with a test for Brucella listed in MPI-STD-TVTL, with negative results; and

d) Residing in the semen collection centre were subjected to a test for Brucella listed in MPI-STD-TVTL, with negative results, at least annually.

MPI considers that recognised international standards exist to enable safe trade in pig semen. Reflecting MPI's commitment to adopt international standards where they meet New Zealand's level of protection, the option for *Brucella* will remain in the draft IHS unchanged (other than the clarification in relation to chapter 4.6 of the *Code*).

[8]OIE Terrestrial Animal Health Code: *Infection with Brucella abortus, B. melitensis and B. suis* (http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_bovine_brucellosis.htm#chapitre_bovine_brucellosis)

3.1.14 Blue eye disease

We are not aware of any commercially available or validated diagnostic tests for this disease. Aside from meaning that essentially no country can therefore unequivocally generate proof of freedom (aside from a lack of clinical signs), it creates an obvious compliance issue for the IHS.

Given the lack of diagnostic tests and the fact the agent has been found in semen, testis, epididymis, prostate, seminal vesicles, and the bulbourethral glands of boars, we recommend no import of semen from Mexico be permitted until more information is available about the disease, epidemiology, and diagnostic testing.

MPI Response

The *Code* provides guidelines to demonstrate freedom from disease or infection. In relation to blue eye disease, the absence of disease or infection in a susceptible population (over a long period of time) can be substantiated by effective surveillance, disease investigation and reporting by an exporting country. Hence, MPI considers that there is no 'compliance issue for the IHS'.

With regard to diagnostic tests for blue eye disease, the IRA 2012 notes a number of serological tests have been described.

Clause 1.6(3) of Part 1 of the draft IHS states that diagnostic test(s) and vaccines used must be those that have been approved by MPI and documented in MPI-STD-TVTL. Any diagnostic test will be evaluated by experts in MPI's Investigation and Diagnostic Centre, and approved by the Chief Technical Officer prior to being documented in the MPI-STD-TVTL.

3.1.15 Bovine viral diarrhoea and other pestiviruses

NZPork is not particularly concerned about BVD-2 per se. However, several pestiviruses (that cause disease in pigs) have emerged/been discovered in the last 5-10 years (Bungowannah, border disease variants, CSF variants, atypical porcine pestivirus 'tremors') and the IHS does not deal with many of these. We would encourage MPI to investing in a more comprehensive review of porcine Pestiviruses and ensure any important risks are identified and managed.

MPI Response

Bungowannah virus (porcine myocarditis), BVD-2 and CSF virus were assessed in the IRA 2012. Risk mitigation measures for these diseases were included in PIGSEMIC.GEN 2013. With the exception of BVD-2, these measures are unchanged in the draft IHS. Disease specific risk mitigation measures for BVD-2 were removed as re-assessment in the RRA 2014 concluded BVD-2 is not a risk in pig semen. Please see response 3.2.1 for discussion of BVD-2.

Atypical porcine pestivirus (APPV) was not included in the IRA 2012. This organism was added to ERS in December 2015. APPV is not an OIE listed disease and it is unknown if APPV is present in New Zealand. However, the disease syndrome, congenital tremors, has been reported in New Zealand[10,11], and has recently been linked to APPV in addition to other aetiologies[9].

There is one report of APPV nucleic acid detected in semen by PCR of an infected and recovered boar[9]. However, there is no published evidence of viable APPV being present in semen nor that APPV can be transmitted through semen. MPI considers risk mitigation measures for APPV are not warranted at this time and will continue to monitor APPV.

[9]Schwarz *et al*. (2017) Congenital Infection with Atypical Porcine Pestivirus (APPV) is Associated with Disease and Viral Persistence. *Veterinary Research* 48(1)
[10]Fairley (1997) Infectious Diseases of Pigs in New Zealand. *Surveillance* 24(2): 5-7
[11]O'Hara PJ and Shortridge EH (1966) Congenital Anomalies of the Porcine Central Nervous System. *New Zealand Veterinary Journal* 14: 13-18

3.1.16 Japanese encephalitis

JE is associated with infertility in boars and may lead to edematous, congested testicles resulting in lowered motile sperm counts and abnormal spermatozoa.

At least one paper has been published based on experimental infection of boars that showed clear evidence of JE virus being shed in semen and subsequently infecting gilts inseminated with the semen.

We agree with the proposed risk mitigation strategy.

MPI Response
Noted.

3.1.17 Porcine myocarditis (Bungowannah virus)

Bungowannah is a known disease causing virus in Australia and continues to circulate in some parts of the country. As discussed in the Section below entitled 'General concerns not included in tracked comments above', point (2), a structured compartment established and managed using the principles laid out in OIE Code in order to permit the importation of semen from Australia.

Pre- and post-collection testing regimes as a part of managing an AI Centre located in a compartment would need to be established as well as holding semen in the country of origin until negative test results are returned.

Semen from boars that are not both antigen and antibody negative should not be permitted. Semen should not be exported from vaccinated boars.

MPI Response
The risk mitigation measures for Bungowannah virus in the draft IHS are unchanged from PIGSEMIC.GEN 2013 which takes into consideration the submissions made by NZ Pork, PICNZ and Bruce Welch (PVS Ltd) in 2012. NZ Pork has not presented any evidence to support a change in risk mitigation measures.

3.1.18 Porcine reproductive and respiratory syndrome

The stated requirements are reasonable in terms of the correct test selection and the correct timing periods. However, as described above for Bungowannah virus, 'OIE-like' compartments should be established to incorporate the AI Centres in these infected countries.

Semen should be held in the country of origin until post-collection negative test results have been returned.

MPI response
See section 4 for a discussion of PRRS.

'Vaccination' is meant to also include purposeful inoculation with farm specific virus (live) as is practiced under some PRRS control programmes in the US and elsewhere.

MPI Response
Noted.

3.1.19 Diagnostic testing, vaccination and treatment documentation

Part 1: General Requirements, Section 1.6 Diagnostic testing, vaccination and treatment, Subsection (3) of the IHS states that '*Diagnostic test(s) and vaccines used must be those that have been approved by MPI and documented in MPI-STD-TVTL.*' But the proposed IHS does not appear in this reference document.

In addition, below are the list of agents for which MPI-STD-TVTL approved tests are required but are not included in the current version of that document:
a) Blue eye disease
b) Bungowannah virus
c) PRRS virus
d) Aujeszky's disease
e) Classical swine fever
f) TGE

MPI Response
Tests have not been added to MPI-STD-TVTL because agreed tests are part of the country approval and veterinary certificate negotiation process.

3.1.20 Compartmentalisation requirement for non-OIE listed diseases

PRRS and Bungowannah virus represent two important diseases that are not covered by OIE Code chapters but are listed in the IHS. As both are high consequence diseases and occur in New Zealand's significant trading partners (Bungowannah in Australia, and PRRS in much of the rest of the world), the proposed IHS should require infected countries to adopt zoning or compartmentalisation as if they were OIE list diseases. As an example, the OIE Code Chapter 8.2 on AD sets forth requirements for establishment of a provisionally free country or zone, and for an AD free establishment. Both have requirements for:

- **Control of risk material into the compartment for an extended period of time prior to (and after) its official establishment**
- **Surveillance for the disease in and around the compartment, prior to its establishment and on an ongoing basis. A control program should be established in the event the disease is detected.**
- **Implementation of measures to prevent transmission of the disease to/from wild pigs**
- **Control by the Veterinary Authority**

- **Absence of vaccination for the disease and no presence of antibody (sic vaccine titers) in the pigs in the compartment**

Other diseases listed in the Code make provisions for establishment of disease free AI centres which generally rely on a combination of the principles listed above for disease free zones or compartments, and the application of additional testing requirements on donor animals.

Diseases such as PRRS and Bungowannah that
a) Are known to be transmitted by the venereal route or through insemination, or
b) Have been identified in semen even though transmission via semen/insemination has not been documented; or
c) Can be expected to be present in (or transmitted via) semen based on knowledge of the organism or relevant examples/literature from related agents.

should be required to adopt compartmentalisation protocols similar to those being recommended for high consequence OIE list diseases.

MPI Response
Compartmentalisation is to enable animals in a disease-affected country to be treated as disease-free for the purposes of import. See response 4 (PRRS) for a discussion on compartmentalisation for OIE diseases.

MPI will not consider compartmentalisation for non-OIE diseases. For example, animals from Australia (a country with Bungowannah virus) must meet the appropriate risk mitigation measures for this virus.

3.1.21 Testing and post-collection storage

To manage the issues related to a boar being in the pre-clinical and/or prodromal phases of an infection (yet circulating and possibly shedding the agent), a strategy combining testing of the boar (or semen) at the time of collection for presence of the agent and post-collection serology are recommended for some but not all of the OIE list diseases. We strongly support the approach for all of the diseases, but particularly for those situations that involve the AI centre being geographically located in an infected country, zone, or compartment. In addition, the semen should be held in the country of origin until all test results have been returned and found to be negative. Retention of semen in the country of origin appears only to be required for FMD, TGE and Brucellosis in the current recommendations. Because this requirement would essentially require that semen be frozen (and noting that porcine semen does not freeze particularly well), this creates a potential problem. However, input from industry stakeholders on this matter indicates that it is manageable with available technology, semen extenders, and insemination protocols.

MPI Response
The draft IHS includes risk mitigation measures from the IRA 2012 which in turn incorporates *Code* recommendations. Semen collection centre, testing and storage requirements take into account the incubation period and the possibility of subclinical infection for each risk organism of concern to New Zealand.

In addition, if MPI was asked to assess a country for approval to export pig semen to New Zealand where that country was not free from specified diseases, that country is expected to demonstrate a very high level of risk management for those risk organisms.

MPI considers that recognised international standards exist to enable safe trade in pig semen. It should also be noted that these standards are included in existing IHSs for sheep/goat (OVACAGERM.GEN), cattle (BOVSEMID.GEN) and pig semen (PIGSEMIC.GEN).

3.1.22 Population based diagnostic testing

There should always be a component of population based diagnostic testing in the source population, in addition to individual testing when required. The tests referred to for these diseases are not adequate for use in individual animals and this principle extends also to PCR, not just serology.

MPI Response
NZ Pork has made a very broad generalisation about the appropriateness of individual and population based testing which does not take into account the risk organism (e.g. epidemiology) and the properties of the specific test/assay in relation to these organisms/populations.

For OIE listed diseases, the *Manual* provides guidelines in relation to diagnostic testing and vaccination for each disease. The diagnostic test(s) and the suitability of its application to a specified disease will be evaluated by experts at MPI's Investigation and Diagnostic Centre and Animal Imports when MPI begins bilateral veterinary certificate negotiations, and is beyond the scope of this document.

3.1.23 Establishment and management of AI centre

The requirements for establishment and management of an 'AI centre' are different for each disease. In particular, it appears that there are potentially important differences in requirements such setback distances from other pigs/farms/feral populations, diagnostic testing requirements inside the centre (routine? periodic? maintenance of status? related to individuals whose semen is destined for export? etc.), and diagnostic testing requirements for animals in the surrounding population (external to the AI centre).

MPI Response
Noted. If MPI was asked to assess a country for approval to export pig semen to New Zealand where that country was not free from specified diseases, that country will be expected to demonstrate a very high level of risk management for those diseases. Details regarding semen collection centres would be part of this assessment.

3.1.24 Diagnostic tests

Except for Aujeszky's Disease, serologic tests are not currently available that can differentiate the presence of antibodies due to vaccination versus exposure to infection. PCR and genomic sequencing are not sufficiently specific enough to differentiate whether detected nucleic acids are from vaccine or infection.

MPI Response
See responses 3.1.8, 3.1.10 and 3.1.22.

3.1.25 Senecavirus A and porcine picornaviruses

Senecavirus A, a picornavirus related to FMD, has occurred widely in the North American pig industry during 2016. While the virus has been known to occur in the region previously, the reason(s) for the current outbreak (which causes clinical signs similar to FMD infection simultaneously among a large number of animals in an infected group) have not been explained. Until such information becomes available, the current situation meets the definition of an emerging or re-emerging disease as indicated by OIE: An emerging disease is defined as a new infection resulting from the evolution or change of an existing pathogen or parasite resulting in a change of host range, vector, pathogenicity or strain; or the occurrence of a previously unrecognised infection or disease. A re-emerging disease is considered an already known disease that either shifts its geographical setting or expands its host range, or significantly increases its prevalence.

Senecavirus was 'assessed and closed with no further action' in a February 2016 report from the MPI Emerging Risks System for Biosecurity (dated February 2016, reference AA 15-034 on September 23, 2015).

The scientific literature related to the outbreak is growing rapidly. An epidemiological study published in 2017 in Transboundary and Emerging Disease and a comprehensive recent factsheet is also available from the Swine Health Information Center. At least one study appears to be underway to determine the potential for transmitting the virus through semen; funding by the Minnesota Rapid Agricultural Response program. No systematic or official surveillance information on Senecavirus in the US could be located but National Pork Board through their Swine Health Monitoring Project published the results of sampling in sentinel herds in December 2016 (Figure 1); the disease is not reportable in the US. The data clearly supports a significant change in prevalence as only seven cases were reported from US pigs during the period of 2008 to 2012.

Additional porcine picornaviruses are attracting the attention of scientists over the last 1-3 years including Sapelovirus, Teschovirus, and Kobuvirus. While Teschovirus was assessed in the 2012 IRA, Sapelovirus and Kobuvirus were not. Unfortunately, as these are emerging agents the literature available to assess their risk of introduction via semen is scarce. As these viruses are related to FMD virus which we know is able to be transmitted through semen, we request MPI undertake a formal assessment of all picornaviruses known to infect pigs. In particular, we recommend that MPI require risk mitigation steps for countries known to be affected by the current re-emerging Senecavirus infection.

MPI Response

Senecavirus A was not included in the IRA 2012. Senacavirus A was assessed through ERS in October 2015. One report detected Senecavirus A nucleic acid in the semen of a single boar[12]. There are no reports of viable Senecavirus A being present in semen. There is no evidence transmission of Senecavirus A via semen; however, there is a study underway at the University of Minnesota to evaluate the shedding patterns of Senecavirus A in semen of experimentally infected boars (*personal communication Fabio Vannucci, University of Minnesota*). MPI will continue to monitor Senecavirus A. However, MPI considers risk mitigation measures for Senecavirus A are not warranted at this time.

Kobuvirus was not included in the IRA 2012. There is limited information related to the epidemiology of Kobuvirus. Although the route of transmission is presumed to be faecal-oral,

further evaluation is needed. One study has demonstrated the presence of Kobuvirus RNA in serum samples[13]. MPI has set up alerts for any reports related to Kobuvirus to facilitate monitoring. MPI considers risk mitigation measures for Kobuvirus are not warranted.

Sapelovirus was not included in the IRA 2012. Sapelovirus was assessed through ERS in August 2016. There are no reports of the presence of Sapelovirus in semen. Sapelovirus continues to be actively monitored. MPI considers risk mitigation measures for Sapelovirus are not warranted.

The IRA 2012 concluded that there is no evidence to demonstrate that Teschovirus may be spread in semen of infected boars. To date, there are no studies implicating semen in the transmission of Teschovirus. MPI has set up alerts for any reports related to Teschovirus to facilitate monitoring. MPI considers risk mitigation measures for Techovirus are not warranted.

[12]Canning *et al*. (2016) Neonatal Mortality, Vesicular Lesions and Lameness Associated with Senecavirus A in a U.S. Sow Farm. *Transboundary and Emerging Diseases* 63 (4): 373–378
[13]Reuter *et al.* (2010) Evolution of Porcine Kobuvirus Infection, Hungary. *Emerging Infectious Diseases* 16(4): 696-698

3.1.26 Porcine epidemic diarrhoea and porcine deltacoronavirus (PDCoV)

Requirements related to TGE should be extended to include PED. Much of the pig producing world experience a re-emergence of this disease in 2013 14 and the disease continues. PED is very similar to TGE in virtually all respects and should therefore be subject to risk mitigation. PED is known to become viremic at higher levels and for a longer period than TGE and therefore represents an even higher risk than TGE. Limited studies have been done to investigate PED and risk to semen but at least one controlled study has shown the virus to be present in semen of infected boar though whether it was due directly to the infection or as a result of contamination of the semen was not clear (Reicks, et al. Detection of economically important viruses in boar semen by quantitative real-time PCR technology. 2015 Annual mtg of the AASV.); in either event the risk is tangible. Similarly, the requirements for TGE should also be extended to include porcine Deltacoronavirus as its emergence in US pigs has also led to a large outbreak of a new disease.

MPI Response
It should be noted that the IRA 2012 concluded that TGE is not a risk in pig semen.

The IRA 2012 concluded that PED is not a risk in pig semen as 'there is no evidence to indicate that the virus is excreted in semen or that the semen is a vehicle for the transmission of virus'. Since that time, low levels of PED viral RNA has been reported in semen[14]. Nevertheless, there is no data available on the presence of infectious virus in semen or the possible role of semen in the transmission of PED[15]. PED has been re-assessed through the ERS on multiple occasions since June 2013, and continues to be monitored by MPI. MPI considers risk mitigation measures for pig semen are not warranted at this time.

PDCoV was not included in the IRA 2012. PDCoV was assessed through the ERS in October 2014. There is no information on the presence of PDCoV in pig semen; however, this is a rapidly evolving area. The situation continues to be monitored by MPI. MPI considers risk mitigation measures for pig semen are not warranted at this time.

[14]Sun *et al.* (2014) Multiple Factors Contribute to Persistent Porcine Epidemic Diarrhea Infection in the Field: An Investigation on Porcine Epidemic Diarrhea Repeated Outbreaks in the Same Herd. *Journal of Animal and Veterinary Advances*13: 410-415
[15]EFSA (European Food Safety Authority) (2014) Scientific Opinion on Porcine Epidemic Diarrhoea and Emerging Porcine Deltacoronavirus. *EFSA Journal* 12(10): 3877

3.2 PIC New Zealand

3.2.1 Introduction of new risks

The Draft IHS for pig semen appears to include a significant softening of NZ's position and to introduce a number of new risks. This is of significant concern to PICNZ. It is extremely difficult to reverse a loss of country health status and the consequences are forever and for many generations of New Zealanders. Financial consequences of a disease introduction can be enormous to a country. With this in mind it would be unwise to take any unnecessary risks, both tangible and intangible.

MPI response
It is unclear what PICNZ means by a 'significant softening of NZ's position and to introduce a number of new risks'.

The draft IHS has only proposed changes for bovine viral diarrhoea virus (BVD-2), swine vesicular disease (SVD), *Brucella suis* and alignment of the general requirements with the *Code* chapters for *General Hygiene in Semen Collection and Processing Centres* and *Collection and Processing of Bovine, Small Ruminant and Porcine Semen.* Since that time, a new *Code* chapter for PRRS was adopted. See section 4 for a discussion of PRRS.

SVD was delisted by the OIE because it does not meet the criteria as set out in Article 1.2.2 of the *Code* (e.g. SVD is not associated with human infection, significant morbidity or mortality in domestic animals or mortality in wildlife). Although SVD is shed in semen, artificial insemination of sows using SVD virus infected semen failed to transmit disease. As such, SVD measures are no longer justifiable.

The justification for the removal of BVD-2 from the RMP is provided below:

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.

Please see response 3.1.13 for a discussion of *Brucella suis*.

3.2.2 Consolidation of global breeding businesses

PICNZ have worked strenuously over many years to ensure that biosecurity is maintained by genetic supplier herds both outside of and within New Zealand. Any attempts to reduce standards has been strongly resisted to allow the industry to continue to import semen with confidence. This proposed IHS reduces that confidence which has the potential to be seriously damaging.

Consolidation has been a major feature of the global pig breeding business via mergers, acquisitions and attrition. Consequently, the most economically desirable pig genetic material is in the hands of an increasingly smaller number of business entities which all tend to operate to high standards of health assurance – in some cases substantially higher than some of the controls suggested in the draft IHS. This makes the need for any softening superfluous and unnecessarily risky (with a few exceptions where equivalence can be negotiated). The large global pig breeding companies are based in a small number of countries which all tend to operate to high standards globally with respect to health assurance, disease monitoring, certification, integrity etc. Hence again there is no need to open the doors to a much greater number of countries with potentially lower standards for the above and greater risk from known, emerging and as yet unidentified disease organisms.

MPI response

MPI does not consider that the draft IHS is an 'attempt to reduce standards'. The only changes from the existing PIGSEMIC.GEN 2013 align with changes to the *Code*, which is the international standard recognised by global pig breeding companies. Please refer to response 3.2.1.

MPI recognises that PIGSEMIC.GEN 2013 and the proposed draft IHS are generic IHSs; that is, allow trade with any country approved by MPI as able to meet the IHS. Please see response 3.1.2 regarding generic IHSs.

3.2.3 Multiple concerns related to risk organisms, risk mitigation measures, disease monitoring and generic standards

PICNZ is concerned about a number of areas. Most are covered in the NZPork submission which PICNZ fully supports so will not be repeated, but proposals like the following are all of major concern to PICNZ:

- **Proposal to allow importation from FMD positive countries and zones**
- **Proposal to allow importation from CSF positive countries and zones**
- **Proposal to accept semen from donor boars known to be serologically positive to Porcine Myocarditis while the knowledge base around this pestivirus (pestiviruses usually transfer very capably in semen) is incomplete**
- **A proposed reliance on clinical signs rather than testing**
- **Inadequate protection against certain emerging diseases**
- **Proposal to enable access for all countries subject to risk management, which would provide access to a large number of countries and would clearly be harder to monitor. This would undoubtedly include some countries with a less than ideal standard of certification integrity, disease surveillance and monitoring than the few countries currently exporting semen to NZ**

MPI Response

With regard to:

- importation from FMD positive countries and zones – see response 3.1.11

- importation from CSF positive countries and zones – see response 3.1.8
- reliance on clinical signs rather than testing – see responses 3.1.3, 3.1.7, 3.1.9, 3.1.12, and 3.1.13
- inadequate protection against certain emerging diseases – see responses 3.1.25 and 3.1.26
- access for all countries – see response 3.1.2.

With regard to accepting semen serologically positive to porcine myocarditis, PICNZ noted their concerns with the importation of semen from boars 'antibody positive antigen negative boars' for porcine myocarditis in their submission in April 2012.

MPI responded to PICNZ's concerns in the ROS 2013:

Section 17.2.1 of 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 8)".

This recent publication (Finlaison et al. 2012)[17] shows that long term carriage is possible It illustrates that PMC can be considered very similar in behaviour to other pestiviruses (e.g. BVD, CSF).

Finlaison et al. (2012 and 2009)[16,17] describes the use of a real time RT-PCR for monitoring virus loads and virus secretion of Bungowannah virus.

MPI therefore will add an additional RT-PCR test to option 43. This clause will then 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."

Also see response 3.1.17.

[16]Finlaison *et al.* (2009) Field and Laboratory Evidence that Bungowannah Virus, a Recently Recognised Pestivirus, is the Causative Agent of the Porcine Myocarditis Syndrome (PMC). *Vet Microbiol* 136: 259-265
[17]Finlaison *et al.* (2012) An Experimental Study of Bungowannah Virus Infection in Weaner Aged Pigs. *Vet Microbiol* 160(1-2): 245-250

3.3 Federated Farmers

3.3.1 Adequacy of import measures

Federated Farmers has concerns with the apparent over reliance on the OIE Terrestrial Animal Health Code as the standard to mitigate biosecurity risks

Nevertheless, no framework, of itself, provides a guarantee that the intended outcome will always be met as all systems, including the administration and implementation of the OIE Code and its measures as they pertain to the draft IHS, are liable to fail under certain conditions.

For this reason it is vital that MPI retains and, more importantly, uses, the other validated tools that are available to it – such as system verification and product testing – to reduce biosecurity risks to the point where they are as low as is reasonably practicable in the context of the biosecurity risks that importation of specific animal products presents to New Zealand.

In the case of the Draft IHS for Pig Semen under consideration, the Federation is not confident that the measures proposed are adequate with respect to some of the animal diseases considered.

In particular, the Federation is concerned with the measures proposed to be taken in respect of the diseases that affect the sheep and/or dairy and beef cattle sectors such as Foot and Mouth Disease (FMD) and Brucellosis.

In the case of FMD, the Federation fully agrees with the comment on page 15 of the MPI Risk Management Proposal (RMP, 2016) document that the introduction of FMD would result in "*catastrophic consequences"* for New Zealand.

However, the Federation believes that, as written in the IHS and the associated Guidance Document, the controls to be applied to the importation of pig semen from countries/zones where FMD is present are not strong enough. Any consideration of importing such potentially hazardous material must include a full in-country verification audit in conjunction with a robust level of product testing.

There should also be in one or both documents a section, preferably highlighted, where this requirement (and the diseases that it applies to) are stated.

The Federation believes that the matters raised are significant and requests that further expert advice is sought. As a consequence, the Federation believes that publication of the final IHS and Guidance Documents should be deferred until this measure has been taken.

MPI Response

With regard to:

- importation from FMD free countries or zones where vaccination is not practised – see response 3.1.9
- importation from FMD free countries or zones where vaccination is practised – see response 3.1.10.

With regard to importation from FMD infected countries or zones see response 3.1.11 and the following.

Clause 1.7(1) (Semen Collection Centre Requirements) of Part 1 of the draft IHS states:

Semen collection must be carried out in a semen collection centre that complies with the requirements for centres in the Code chapters (4.5) General Hygiene in Semen Collection and Processing Centres and (4.6) Collection and Processing of Bovine, Small Ruminant and Porcine Semen.

In order to qualify for admission into the pre-entry isolation facility, boars must show no signs of FMD and originate from an establishment where FMD has not occurred in accordance with the *Code*[18]. Boars must then be isolated for 30 and not less than 28 days after the start of the

isolation period, all animals in isolation have been subjected to virological and serological tests for FMD.

Boars must then be kept for at least 28 days in the pre-entry isolation facility before entry into the semen collection centre and not less than a minimum of 21 days after entering the pre-entry isolation facility boars were subjected to a test for FMD. Boars that reside in the semen collection centre must be tested annually.

Reflecting the above, MPI will amend clause 35 (for importation of frozen semen from FMD infected countries or zones) of the GD to explicitly state the requirements in chapter 4.6 of the *Code*. The clause will read:

Donors:

a) *Were sourced from an establishment where FMD has not occurred in accordance with the Code and were isolated for 30 days prior to movement to the pre-entry isolation facility where not less than 28 days during isolation, all animals in isolation were subjected to virological and serological tests for FMD listed in MPI-STD-TVTL, with negative results; and*

b) *Were tested a minimum of 21 days after entering the pre-entry isolation facility with a test for FMD listed in MPI-STD-TVTL, with negative results; and*

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

d) *Were kept in a semen collection 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 semen collection 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 listed in MPI-STD-TVTL, with negative results; and*

e) *Semen:*

    1) *Was subjected to a test for FMD listed in MPI-STD-TVTL, with negative results, 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; and*

f) *Residing in the semen collection facilities were tested at least annually with a test for FMD listed in MPI-STD-TVTL, with negative results.*

It should be noted that the generic IHSs for pig semen (e.g. PIGSEMIC.GEN), bovine semen (BOVSEMID.GEN) and ovine/caprine semen (OVACAGERM.GEN) include options to allow the importation of semen from FMD infected countries in accordance with the *Code*.

MPI has previously allowed semen imports from a small number of established trading partners. MPI would need to be satisfied that the exporting country operates and maintains a very high level of risk management for FMD before approving the country as eligible to export pig semen. This has not changed from PIGSEMIC.GEN 2013.

Further, MPI considers that recognised international standards exist to enable safe trade in pig semen, including from FMD infected countries or zones[18]. Reflecting MPI's commitment to adopt international standards where they meet New Zealand's level of protection, the options for FMD will remain in the draft IHS unchanged (other than the clarification in relation to chapter 4.6 of the *Code*).

Please see response 3.1.13 for a discussion of *Brucella suis*.

[18]OIE Terrestrial Animal Health Code: *Infection with Foot and Mouth Disease Virus* (http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_fmd.htm)

3.4 Dairy New Zealand

3.4.1 Generic import health standards and industry involvement

DairyNZ can appreciate that MPI wish to establish a generic IHS for porcine semen to serve as a basis for country-to-country negotiations. This IHS and the model veterinary certificate are very much based on current knowledge of pig diseases. How do emerging diseases or syndromes, which may not be covered by any OIE recommendations, come to be considered during the negotiation phase? We consider it is essential that industry has input into this process – will this routinely occur?

MPI Response
It should be noted that there are existing generic IHSs for pig semen (e.g. PIGSEMIC.GEN), bovine semen (BOVSEMID.GEN) and ovine/caprine semen (OVACAGERM.GEN). These generic IHSs are based on risk analyses that incorporate the *Code* where the *Code* requirements are recognised to meet New Zealand's risk mitigation requirements. A number of countries have been approved under these generic IHSs.

Part of the assessment for country approval is that the country has established and reputable early disease reporting systems, with obligations to report to MPI. In addition, MPI continues to monitor emerging risks that could present in semen. See response 3.1.1, 3.1.2, 3.1.24 and 3.1.25.

3.4.2 Reference to MPI-STD-TVTL

Both the Guidance Document and Import Health Standard (IHS) make reference to *MPI Approved Diagnostic Tests, Vaccines, Treatments and Post-arrival Testing Laboratories for Animal Import Health Standards* (MPI-STD-TVTL), and the IHS states 'diagnostic tests and vaccines used must be those that have been approved by MPI and documented in MPI-STD-TVTL'. However, this document does not include any IHS for pig semen so it is unclear what diagnostic tests and vaccines are approved by MPI. Without this information it is not possible to assess whether any testing or use of vaccines will be sufficient to protect New Zealand from the import of unwanted animal diseases.

MPI Response
See response 3.1.19.

3.4.3 Concerns related to international standards and FMD measures

In general, DairyNZ is supportive of using OIE standards to develop IHS. However, New Zealand still needs to undertake its own risk assessment for each disease agent. This needs to include the risk of the disease arriving in New Zealand, the likelihood of spread given our livestock husbandry practices, and the impact an outbreak of disease will have on both the target livestock and any other livestock that may be susceptible. The focus of OIE standards appears to be on reducing the risk of arrival. For some diseases, the impact of a disease outbreak in New Zealand would be so great, that it would appear justifiable to impose more stringent conditions for import than are present in OIE standards. Foot and Mouth Disease (FMD) is one such example.

MPI response
See response 3.1.1.

The requirements for FMD appear inconsistent. This is unacceptable for a disease that would have such a severe impact on all of New Zealand, not just the livestock industries.

From the proposed IHS we have extracted this summary:

- **For the importation of fresh semen from FMD free countries or zones where vaccination is not practised, or FMD free compartments, donors must have been at least 3 months in the FMD free country or zone and be kept in an AI centre. However, for frozen semen from the same countries/zones there is no requirement to keep the donors in an AI centre. Why shouldn't all boars having semen collected for export be kept in AI centres under clear veterinary supervision?**
- **For frozen semen from FMD free countries where vaccination is practised there is again no requirement to keep donors in AI centres, however the donors must be free of clinical signs of FMD on the day of collection and for the following 30 days, have been kept in the country for at least 3 months prior to collection, and be either vaccinated against FMD or tested. It is unclear how such requirements can be controlled outside of a supervised AI centre.**

MPI response
Clause 1.7(1) (Semen Collection Centre Requirements) of Part 1 of the draft IHS states:

Semen collection must be carried out in a semen collection centre that complies with the requirements for centres in the Code chapters (4.5) General Hygiene in Semen Collection and Processing Centres and (4.6) Collection and Processing of Bovine, Small Ruminant and Porcine Semen.

Clause 1.8(2) (Semen Donor Requirements) of Part 1 of the draft IHS states:

During the 28 days in which boars are held in pre-entry isolation prior to entering the semen collection centre (as prescribed in the Code), they must not be used for natural mating and must be isolated from animals not of equivalent health status.

In order to qualify for admission into the pre-entry isolation facility, boars must have been kept since birth or for at least the past three months in a FMD free country or zone, or FMD free compartment. All boars, regardless of risk organisms, must be kept for at least 28 days in the pre-entry isolation facility before entry into the semen collection centre. Thus, there is no difference in residency requirements in a semen collection centre.

See response 3.1.9 for a discussion of fresh and frozen semen from FMD free countries or zones where vaccination is not practised, or FMD free compartments. Also see response 3.1.10.

- **For frozen semen from FMD infected countries the following controls and testing requirements are described. Donors must be kept in AI centres with some requirements around entry of new animals and absence of FMD in the area, be free of FMD on the day of collection and for the following 30 days, and either be vaccinated or tested for FMD. Semen from boars that are vaccinated must be tested, boars that are not vaccinated are tested and their semen is not tested. Hence there is only one test applied to ensure the semen is free of FMD, with all other disease control measures relying on good management of the AI centre and adequate surveillance for FMD. For a disease such as FMD we do not consider such management of the risk to be acceptable for New Zealand. DairyNZ is of the view that high risk products such as semen should not be imported from FMD infected countries or zones.**

MPI response

In addition to diagnostic testing, effective biosecurity of the semen collection centre and surveillance for FMD are the cornerstone to protecting against entry of FMD virus and should not be dismissed lightly.

MPI has clarified the testing requirements for importation from FMD infected countries or zones. See response 3.3.1.

3.4.4 Reliance on clinical signs for *Brucella suis*

Within the proposal, for some diseases absence of infection is assessed only by absence of clinical signs on the day of semen collection. If clinical signs are mild, transient or inconsistent this does not seem a very robust way of ensuring freedom from disease. An example of this is Brucellosis where clinical signs in infected boars are rarely seen, and where porcine semen would be eligible for export to New Zealand if the boars are free of clinical signs on the day of collection, without the need for any prior testing. Such boars can be kept in AI centres, or in a herd free from Brucellosis that is only tested once every 6 months. There is no check here to ensure that the herd has not become infected between the last test and semen collection. New Zealand is free of Brucellosis, and Brucella suis is a zoonosis of concern, especially given the large number of backyard pigs in kept in New Zealand. DairyNZ is of the view that for any disease where disease freedom is assessed only by the absence of clinical signs on the day of collection, a review of these requirements should occur.

MPI Response

See response 3.1.13 for discussion of *Brucella suis*.

3.5 Deer Industry New Zealand

3.5.1 Concerns related to FMD measures

We have seen DairyNZ's draft submission on these three documents and share its concerns that the proposed import health standards applicable to pig semen do not adequately take into account the risk to the livestock sector of FMD-contaminated pig

semen. Even a small FMD incursion is likely to severely constrain deer farming and the export of deer products for at least a year and have longer term impacts on consumer confidence in New Zealand deer products, whether from a quality or reliability of supply perspective.

Given the likely significant impact of a FMD incursion on both the deer industry and New Zealand, DINZ agrees with DairyNZ that New Zealand is justified in imposing controls stricter than OIE guidelines, which are focussed merely on blocking transmission pathways. In particular, DINZ considers that importing pig semen from FMD-infected countries should be prohibited. Additionally, we consider that the surveillance of semen donors from other countries should be more comprehensive, for instance donor boars should be under surveillance for the duration of the FMD incubation period and be tested for infection rather than merely observed for clinical signs.

MPI Response
MPI considers that recognised international standards exist to enable the safe trade in pig semen. Reflecting MPI's commitment to adopt international standards where they meet New Zealand's level of protection, the options for FMD will remain in the draft IHS unchanged (other than the clarification in relation to chapter 4.6 of the *Code*). See responses 3.1.9, 3.1.10, 3.1.11, 3.3.1 and 3.4.3 for a discussion of FMD.

3.6 Canadian Food Inspection Agency

3.6.1 Equivalent measures for porcine respiratory and reproductive syndrome

Upon review of the related documents Canada is pleased that the import requirements follow the OIE very closely. With respect to PRRS, the OIE recommendations testing however there is no chapter in the OIE Terrestrial Animal Health Code that details further recommendations for this disease. The code states (on-farm, isolation and resident herd):

PRRS -The test complying with the standards in the Terrestrial Manual.
Hence, other than recommending the type of tests that are approved, a country is left to develop import requirements as they feel required to prevent the introduction of this disease.

As a result, I would like to request that MPI consider the PRRS section of the Canadian Food Inspection Agency's Artificial Insemination Program as offering equivalent risk mitigation as that proposed in New Zealand's IHS.

The proposed statements for the certificate as per the Canadian AIP are as follows:

8. Porcine reproductive and respiratory syndrome (PRRS) virus:

8.1 Prior to entering the pre-entry isolation facility the following conditions have been complied with, Qualification of the herd: (i) source herd is not under quarantine and not vaccinated against PRRS Qualification of boars on farm of origin: (i) donor boars are identified according to the national standards for swine, have undergone a clinical examination by an accredited veterinarian and found to be healthy and free of evidence of infectious or contagious swine diseases transmissible by semen.

(ii) Within the 30 days prior to arrival to the pre-entry isolation facility of an approved semen collection centre donor boars underwent a multivalent serum ELISA for PRRS antibodies that uses both European and American strain antigens with negative results.

8.2 Qualification of boars at pre-entry isolation: Boars have been kept for at least 30 days in a pre-entry isolation facility of the semen collection centre and underwent serological testing for PRRS after a minimum of 21 days in this facility with negative results. A multivalent serum ELISA for PRRS antibodies was used that includes both European and American strain antigens. The isolation is operated as an all-in all-out facility.

8.3 Qualification of boars in the resident herd: Resident donor boars in the artificial insemination centre have been tested at least annually for PRRS with negative results. A multivalent serum ELISA for PRRS antibodies was used that includes both European and American strain antigens.

MPI Response
See section 4 for a discussion of PRRS.

3.6.2 Equivalent measures for leptospirosis antibiotic treatment

The other equivalency I would like to discuss is for the antibiotic regime added to the diluent to manage Leptospira spp. New Zealand offers the following: a) 50 µg tylosin, 250 µg gentamicin, 150 µg lincomycin, 300 µg spectinomycin; or b) 500 IU penicillin, 500 µg streptomycin, 150 µg lincomycin, 300 µg spectinomycin; or c) 25 µg dibekacin, 75 µg amikacin. I would like to suggest that any combination producing an equivalent effect shall be acceptable.

MPI Response
The request can be considered in the veterinary certificate specifically negotiated for the importation of pig semen from Canada to New Zealand.

4 Porcine Reproductive and Respiratory Syndrome Virus

4.1 New Zealand Pork (second submission)

4.1.1 Definition and consideration for establishment and maintenance of semen collection and processing centres

OIE Terrestrial Code chapters 4.5 and 4.6 describe the general conditions for semen collection and processing centres. Semen collection and processing centres may comprise an artificial insemination centre (which amongst others includes animal accommodation areas, a semen collection room, and importantly a pre-entry isolation facility), a semen collection facility, and a semen laboratory. The Code glossary describes an artificial insemination centre as a 'facility approved by the Veterinary Authority and which meets the conditions set out in the Terrestrial Code for the collection, processing, and/or storage of semen.'

In chapters 4.5 and 4.6, OIE does not establish any requirements around where semen collection and processing centres can be located. In other words, it appears that they can be located in any free compartment, zone, or country but also in any infected country, apparently including any containment, infected, and protection zones within an infected country. While the text we have been asked to comment on only refers to PRRS,

the provisions for semen collection and processing centres in chapter 4.5 and 4.6 apply across diseases. NZPork has raised its concerns previously with MPI that the language in chapters 4.5 and 4.6 (particularly when viewed in light of the PRRS chapter 15, Articles 5.3.8. and 5.3.9) permits the establishment and maintenance of these centres potentially 'next door' to commercial farms, non-commercial farms, concentration points, and feral populations any of which may be infected with PRRS virus.

MPI Response

MPI believes this is an incorrect use of these terms (i.e. containment, protection zone). Containment is used in the context of free countries or zones, specifically to maintain the free status of the country or zone, limiting the trade implications on the remainder of the country or zone in the event of a disease incursion.

Protection zone means a zone established to protect the health status of animals in a free country or free zone, from those in a country or zone of a different animal health status, using measures based on the epidemiology of the disease under consideration to prevent spread of the causative pathogenic agent into a free country or free zone. These measures may include, but are not limited to, vaccination, movement control and an intensified degree of surveillance.

These zones are only allowed when this is agreed as part of the country approval process.

In the unfortunate case of PRRS relative to other more notable multispecies diseases of livestock, most of the countries from which NZ would be eligible to import semen from are endemically infected with this critically important exotic disease. PRRS incursions into boar studs that are constructed and managed as highly biosecure facilities are routine and have been responsible for a number of outbreaks of the disease (especially in North America), most of which are not published in the peer-reviewed literature but some of which are reported through proceedings of scientific meetings. Examples of these are listed below and represent outbreaks in the US, Ireland, and Germany; the reference lists within these papers provide an even longer list of boar studs becoming infected with PRRS virus:

- **Borobia J. PRRSV outbreak in a pig unit by infected semen (O.093). Proceedings of the 2014 IPVS, p 182.**
- **Turner M et al. Keeping the damage to a minimum. Proceedings of the 2009 AASV, pp 15-18.**
- **Dhom G et al. Cross-sectional study one year after an acute PRRS outbreak (536_PO-PW1-121). Proceedings of the 2016 IPVS, p 973.**
- **Huinker CD. How boar studs are adapting to the recent PRRS breaks. Proceedings of the 2002 Allen D. Leman Swine Conference, pp 65-67.**
- **Connor JF. Hanson Lecture: Biosecurity and studs. Proceedings of the 2005 Allen D. Leman Swine Conference, pp 20-34. [attached as Appendix 1]**

While the above papers do not represent an exhaustive search of the literature, a number of themes are consistent throughout:

- **Boars infected with PRRS do not predictably show clinical signs that are significant enough, or unique enough, to be reliably noticed by farm staff who then are prompted to seek veterinary input or diagnostic testing.**

MPI Response

The *Code* notes that clinical signs are useful for early detection; however, it also recognises that clinical signs may not be present or are seen only in young animals with PRRS infections which involve low virulence strains. The *Code* states that clinical surveillance should be supplemented with serological and virological surveillance (see Article 15.3.15 *Surveillance Strategies*). This would be especially relevant to countries, zone or compartments claiming freedom from PRRS. For countries or zones not free from PRRS, there is not a reliance on clinical signs alone; rather, boars are subjected to a suite of risk mitigation measures which include testing in both the pre-entry isolation facility and semen collection centre.

[∞]It should be noted that pig semen has been exported from Canada to New Zealand for many years without any disease incursion, and the measures for PRRS in the IHS that is currently used for trade (PIGSEMIC.NAM) are lower than measures in the draft IHS.

Further, the draft IHS includes a more robust system of country approval that will recognise and require a higher level of protection from regions such as the very high disease prevalence and high pig density areas in the USA (e.g. the Midwest) where many of the disease outbreaks cited by NZ Pork occurred.

[∞]PIGSEMIC.NAM has been amended, effective 11 November 2017, to reflect the *Code* measures for PRRS.

- **It is common for at least some downstream breeding farms to become infected when a boar stud becomes infected. It is rare that stud testing prevents transmission to sow farms, though it does limit the number of sows and farms that become infected.**

MPI Response
MPI recognises that ensuring a semen collection centre is free from PRRS infection is challenging. See response 4.1.2 and 4.1.3 for a discussion of risk mitigation measures for PRRS.

- **Monthly testing of studs is an ineffective means of monitoring for PRRS infection. In the last week, NZPork has surveyed three US veterinarians with significant clinical involvement with large US commercial studs – admittedly not a statistically valid sample but the best that could be achieved in the commenting timeframe that was available. All confirmed that commercial studs they work with rely on a combination of testing every boar at the time of collection (PCR in semen and/or serum) in addition to biweekly testing of >30 boars (serum PCR and ELISA) to maximise the likelihood of detection and minimise the onward transmission of virus to downstream customers.**

MPI Response
See response 4.1.3 for further discussion of herd monitoring and individual animal testing.

- **The pathway by which boar studs become infected is almost always undetermined. It is important to remember that boar studs are the most biosecure sites in any production system yet they still remain susceptible to incursions of PRRS virus.**
- **Appropriate pre-entry isolation procedures are important. At least two negative tests are generally required before release of the boars, the second being near the time the boar is released.**

MPI Response
See response 4.1.2.

We ask MPI to review the paper by Connor referenced above and included as Appendix 1. It describes a major survey of North American boar studs done after a particularly bad seasonal outbreak of PRRS in 2001 and 2002 in the US. Though the paper is now over 10 years old, it still quite accurately describes routine management and behaviours of studs in North America (which are anticipated to be a key supplier of semen under the proposed IHS).

MPI has provided NZPork with two additional papers describing relevant work done in Switzerland (Nathues et al 2014, 2016) and a third paper by Rovira et al 2007 that describes results of simulation modelling done to evaluate the effectiveness of various PRRS surveillance strategies in boar studs. While the Rovira work is of a very high standard and therefore appears to have considerably influenced the OIE semen recommendations for PRRS, the results do not align well with the substantial field experience in North America highlighted in the papers we have referenced above. In particular, the concepts that a) one-time per month sampling of an inadequately defined 'statistically representative number of donors' [from the OIE Code], and b) daily testing of donor boars is 'considered impractical and aiming for an overly high level of protection' [RMP, page 20] simply do not square with reality. We strongly recommend that New Zealand establish at least the same level of protection that is being routinely implemented on North American boar studs today, for the purpose of protecting their own internal customers.

MPI Response

The examples presented by NZ Pork illustrate that semen collection centres can become infected with PRRS which has long been acknowledged by MPI. Connor (2005) and Huinker (2002) considered risk factors for PRRS virus introduction into the semen collection centre and discussed the biosecurity procedures in place to prevent introduction of PRRS infection into the semen collection centre. These two papers highlight that there is considerable variability in the practices undertaken at commercial boar studs (e.g. isolation population monitoring, stud population monitoring, percent of boar population tested, diagnostic testing strategy, stud certification, etc). For example, Connor (2005) reported that PRRS monitoring in stud populations varied widely (e.g. 13% bi-weekly, 60% monthly, 15% quarterly and 5% without any testing) as did the percentage of boars sampled per testing period (range of 4% to 100%, median of 10%).

Of relevance to the discussion is the paper of Connor (2005) which states that 'control of health of boars entering an artificial insemination centre can be managed by 1) understanding the health status of the source herd, 2) restricting the number of sources and 3) disciplined period of isolation/acclimation of boars prior to admission into the stud'.

MPI considers that the measures in the draft IHS appropriately mitigate the risk of PRRS in semen.

In order to qualify for entry to the semen collection centre, boars must have been kept in a country, zone or compartment free from PRRS since birth or at least the past three months prior to entry into the pre-entry isolation facility. Boars must then be kept for at least 28 days in the pre-entry isolation facility. For importation from countries or zones not free from PRRS, boars must be tested twice while in pre-entry isolation. In the semen collection centre, the boars are subjected either to a herd monitoring scheme or to individual animal testing to ensure that the semen collection centre or the donors remain free from PRRS, respectively.

It should be noted that point b) in NZ Pork's submission above is in reference to the IRA 2012 risk mitigation options for PRRS which involved daily herd testing (confidence level 95%, prevalence 5%) in addition to individual animal testing. Daily herd testing is impractical due to stressful nature of restraining boars from an animal welfare and human safety standpoint and aims for an overly high level of protection. This conclusion was reached following targeted consultation with the domestic industry in 2011.

Please see response 4.1.3 for further discussion of herd monitoring.

The available evidence suggests that the incidence and severity of PRRS in North America is not decreasing which indicates New Zealand needs to take a very conservative approach in establishing an IHS for semen. It is well-documented that boar stud infections are an important part of the disease epidemiology that is not yet well understood. Until there is further understanding of the means by which boar studs are becoming infected with PRRS, one has to consider all routes of infection including insects, windborne, inanimate vectors, etc. as possible explanations for the incursion. Close proximity to areas known to be infected with PRRS virus surely must place the boar stud at increased risk of becoming infected through these pathways.

MPI Response
Agreed and noted.

NZPork believes the OIE chapters 4.5 and 4.6 upon which NZ partially uses as the basis for its proposed generic IHS do not provide adequate protections against boar studs becoming infected with PRRS and other infectious agents included in the IHS.

We request that MPI include additional requirements in the IHS that ensure only semen collection and processing centres (and their associated pre-entry isolation facilities) be located in free compartments, zones, or countries.

MPI Response
The possibility for semen collection centres to be 'next door' to populations of pigs potentially infected with PRRS is mitigated by the application of biosecurity measures which includes chapters 4.5 and 4.6 of the *Code,* the disease specific requirements in the *Code* (for OIE listed diseases) and Part 2 of the IHS. The disease specific chapters of the *Code* and Part 2 of the IHS provide the risk mitigation measures appropriate to a country's disease status. A country in which a particular disease is endemic is subjected to a greater degree of risk mitigation (e.g. testing, post-collection storage, etc) than a country, zone or compartment where the disease is absent. For example, there is no requirement for individual animal testing in countries, zones or compartments considered free from PRRS (see Article 15.3.3 of the *Code* in relation to country, zone or compartment free from PRRS).

Whereas, donor boars from countries or zone where PRRS is endemic must have been kept since birth or at least the three months prior to entry into the pre-entry isolation facility in an establishment in which no infection with PRRS was detected and the pigs have not been vaccinated against PRRS. In order to qualify for entry into the semen collection centre, the pigs were kept in pre-entry isolation for at least 28 days and were subjected to serological tests on samples collected on two occasions, the first occasion on the day of entry into isolation and the second occasion no less than 21 days after entry. In the semen collection centre, either herd monitoring or individual testing of donors is done.

MPI considers that these requirements effectively mitigate the risks associated with the importation of pig semen from PRRS endemic countries or zones. Similar requirements form the basis of trade in germplasm, and without these there would be no imports of semen (including existing imports for sheep, goat, pig and cattle semen) into New Zealand.

See response 4.1.3 for a discussion of herd monitoring or individual testing in the semen collection centre.

4.1.2 Testing in pre-entry isolation facilities

When read directly from the Code, Article 15.3.9, Section 1(c) dictates that donor males 'were kept in the pre-entry isolation facility for at least 28 days and were subjected to a serological test with negative results on samples collected no less than 21 days after entry.' This differs from the text provided by MPI in the RMP in Table 1 on Page 21 whereby it is indicated that pigs will be 'subjected to serological tests for PRRS with negative results on two occasions, the first occasion on the day of entry into the pre-entry isolation facility and the second occasion no less than 21 days after entry.'

Clarification of this difference is requested.

MPI Response
Article 15.3.9(1)(b) and (c) of the *Code* chapter *Infection with Porcine Reproductive and Respiratory Syndrome Virus*[23] states:

b) Showed no clinical signs of PRRS on the day of entry into the pre-entry isolation facility and were subjected to a serological test with negative results on samples collected on the same day;

c) Were kept in the pre-entry isolation facility for at least 28 days and were subjected to a serological test with negative results on samples collected no less than 21 days after entry.

The text from Table 1 in the RMP consolidates these two clauses from the *Code*.

Of more significance in the RMP (and the Code) is the lack of protection afforded by the timing of the '21 days or later after entry' blood testing event. While 21 days in isolation should provide adequate time for seroconversion to occur, even if the boar had only just become infected at the time of entry, it does not deal with the issue of detecting any exposure that might happen after Day 28. The way the requirement is worded could allow for a Day 0 negative test, followed by a Day 21 negative test, then exposure to occur sometime after Day 21, but with no further testing required. There are a number of reasons that a boar may stay in isolation longer than 28 days and the second testing needs to be done at a point in time that is at least 21 days after entry, and as close as possible to the time at which the boar exits isolation. This requirement is critical, particularly as there are currently no siting requirements for the location of the pre-entry isolation or the boar stud itself meaning either or both the facilities could be located in an area that is endemically infected with PRRS virus.

OIE does appear to partially understand this issue in Article 15.3.6, Section 4 (testing live pigs for breeding or rearing) but it is not clear why they did not follow the same correct logic in the semen Article.

We request that MPI revise the requirements around procedures in the pre-entry isolation area to require at least two tests, the first upon arrival into the establishment (serum ELISA) and the final at a time at least 21 days later and no more than 5 days prior to exiting the establishment (using both serum ELISA and serum PCR). Donor boars should be re-tested (serum ELISA) in the artificial insemination centre, 21 days after arrival.

MPI Response

MPI will amend clause 40(a)(iii) (for importation from countries or zones not free from PRRS) of the GD to incorporate the testing interval in Article 15.3.6 to account for an extended pre-entry isolation. The clause in relation to testing in pre-entry isolation will read:

Were tested on two occasions with a serological test listed in MPI-STD-TVTL, the first occasion on the day of entry into the pre-entry isolation facility and the second occasion no less than 21 days after entry and within 15 days prior to movement to the semen collection centre.

In the semen collection centre, boars are either subject to a herd monitoring scheme or individual animal testing in accordance with the *Code* to ensure that the semen collection centre remains free from PRRS infection. MPI does not consider testing in the semen collection centre other than prescribed in the *Code* to be necessary.

4.1.3 Testing in the artificial insemination centre

Article 15.3.9, Section 1(d)(i) requires testing 'at least every month, serum samples from a statistically representative number of all donor males' and that the sampling scheme should be designed to ensure that all donor males are tested every 12 months and at least once during their stay.

It is our belief that the Rovira paper that supports this requirement has been misinterpreted and that other relevant literature, particularly from North America, has not been properly accounted for. Rovira's data suggest that for a given total number of samples during a month, little additional herd sensitivity was achieved by spreading those samples over the course of the month rather than as a single event, one time per month. The issue of sample size is however very relevant as his data also showed that more samples were better than fewer samples (within the limits of the study). Simply stating that a 'statistically representative number' be sampled at least every month is not specific enough to afford the protection required and we are not satisfied with the statement in the RMP (footnote to Table 1 on page 22) that 'sample size, confidence level, expected prevalence and test sensitivity will be determined during certificate negotiation' will necessarily or reliably manage the risk, nor is it transparent, nor does it appear to be consistent with current practice in North America.

MPI Response

A statistically representative (i.e. randomly selected) number of boars that need to be sampled has not been specified in the draft IHS as this depends on the required confidence, design prevalence, test sensitivity and population/herd size. Although the sample size will not be specified in the IHS, MPI will amend the IHS to require a sample size sufficiently large to give at least a 95% confidence of detecting a prevalence of PRRS infection at 5% or less. For example, where the diagnostic test's sensitivity is 90% (based on PIGSEMIC.NAM) and the average herd size is 300 animals, 89 samples will provide a 99% confidence of detecting infection at 5% prevalence in the semen collection centre. This represents sampling of 31% of the boars in the semen collection centre. Table 1 shows the sample size required for a test sensitivity of 90% and a given confidence level, design prevalence and population size.

The appropriate sample sizes based on the confidence level, design prevalence, population size, proportion of animals tested, diagnostic tests and sampling frequency will be considered by MPI during certificate negotiation.

See response 4.1.3 below for a discussion of herd monitoring and individual animal testing.

Table 1. Sample size required for a confidence level of 95% (99%)† for a given population size, design prevalence and test specificity of 90%. Calculations based on Epitools *Sample Size for Demonstration of Freedom (Detection of Disease) in a Finite Population*.

	Prevalence						
Population size	*0.01*	*0.02*	*0.03*	*0.04*	*0.05*	*0.1*ˣ	*0.2*ˣ
*50**			44 (50)	44 (50)	36 (44)	26 (34)	15 (21)
*100**		87 (100)	71 (88)	59 (76)	51 (67)	29 (42)	16 (23)
200	173 (200)	118 (152)	88 (120)	70 (98)	58 (83)	31 (46)	17 (25)
300	211 (262)	132 (179)	95 (134)	74 (107)	61 (89)	32 (48)	17 (25)
500	251 (335)	144 (206)	101 (147)	78 (115)	63 (94)	33 (49)	17 (26)

†The sample size for a confidence level of 99% is given in parentheses.
Blank cells indicate that it is not possible to attain the desired level of probability even if the entire population is tested.
ˣDesign prevalence of greater than or equal to 10% will not be considered by MPI. Rovira et al.'s model shows that median prevalence of infection is less than 10% two weeks post-PRRS introduction. A design prevalence of 5% or less maximises the likelihood of detecting an infection early.

Further, given the significance of PRRS from both an economic and health and welfare standpoint, we believe that our previous recommendation that semen for export be held for a number of days post-collection, until such time the donor has been retested and found to be negative is valid. While this may be restrictive for most countries (given most are already infected with the disease), we believe it is an appropriate condition to add to the NZ IHS given our unique PRRS free status. There is no evidence to the contrary provided in the RMP.

MPI Response
MPI will only negotiate veterinary certificates for trade in frozen semen with the exception of countries that have an existing IHS for fresh semen (e.g. Australia) or those that demonstrate freedom from PRRS. For frozen semen this means that there is a 30 day post collection holding period. This relates to the disease specific measures (e.g. frozen semen from FMD free countries or zones where vaccination is not practised, or FMD free compartments) where there is a requirement for monitoring the donors for the 30 days following semen collection.

See response 4.1.3 below for a discussion of individual animal testing.

We request that MPI revise the requirements around testing in the artificial insemination centre to require biweekly testing (serum PCR or ELISA) of a random selection of all animals housed in the centre at a level expected to have a 95% likelihood of detecting a 5% prevalence of infection; the sampling scheme should also be designed to ensure that all donor males are tested at least once every 12 months and at least once during their stay. In addition, each boar from which semen will be destined for export shall be tested (serum PCR) and found to be free of the virus at the time of collection. Further, semen

shall be held in the country of origin until the boar has been retested (serum ELISA) for PRRS 14 to 21 days after collection and found to be negative.

MPI Response

The *Code* recommends either herd monitoring or individual donor testing.

[∞]The herd monitoring scheme described in the *Code* provides a higher level of protection than PIGSEMIC.NAM which is the existing IHS for trade in pig semen from Canada and the USA. PIGSEMIC.NAM requires that the semen collection centre is free from PRRS for at least the 12 months immediately prior to semen collection for export. The semen collection centre's continuing freedom from PRRS infection is supported by herd monitoring at a frequency of no greater than every six months.

[∞]PIGSEMIC.NAM has been amended, effective 11 November 2017, to reflect the *Code* measures for PRRS.

The *Code* recommends that serum samples from a statistically representative number of all boars are subjected to an appropriate test for PRRS at a frequency of no more than one month. The monitoring scheme should be designed such that all boars are tested annually and at least once during their stay in the semen collection centre. The way in which the *Code* is worded recognises that different monitoring schemes may be appropriate as long as the interval between sampling is not greater than one month, i.e. sampling could occur daily, weekly or biweekly as long as the total number of animals sampled per month achieves the required statistical confidence that the semen collection centre remains free from PRRS.

MPI recognises that more aggressive herd monitoring schemes (e.g. three times per week, weekly, biweekly) may be undertaken at some commercial boar studs in North America[20], and believes this reflects the situation in North America and other parts of the world where fresh pig semen is the main commodity being traded, i.e. where semen is collected early in the week and used to inseminate sows/gilts within the same week. Early/rapid detection of PRRS infection in the semen collection centre minimises the impact on the centre itself and downstream farms/recipients of the semen.

Fresh pig semen however, is not currently imported to New Zealand. MPI will only negotiate veterinary certificates for trade in frozen semen with the exception of countries that have an existing IHS for fresh semen (e.g. Australia) or those that demonstrate freedom from PRRS. Thus, MPI considers herd monitoring, at least monthly, would be adequate to demonstrate the semen collection centre's continuing freedom from PRRS.

With regard to individual animal testing, the RMP states:

MPI considers the Code recommendations for donor testing achieve an equivalent level of protection to PIGSEMIC.GEN because virological (e.g. PCR) and serological (e.g. ELISA) tests for PRRS taken on the day of semen collection would allow infected donors to be identified. Reicks et al. (2006) reported a median time to detection for PRRS virus (i.e. time post inoculation by which 50% of the boars tested positive) in serum of 36 hours (90% confidence interval, 36-48 hours) using nested PCR. All boars tested positive using nested PCR on serum by 48 hours post inoculation. PRRS virus has been detected with PCR on serum as early as 24 hours post infection and with PCR on semen as early as three days post infection (Christopher-Hennings et al. 1995). In Reicks et al.'s (2006) study above, PRRS virus in semen was not detectable until 96 hours post inoculation. It can be argued that there is a window when a boar can be PRRS infected and not be detectable on PCR; however, PRRS virus is unlikely to be shedding in semen immediately following infection. Looking at the pathogenesis of PRRS,

Christopher-Hennings et al. (1998) proposed that after initial viraemia PRRS virus enters various tissues (e.g. reproductive macrophages) before being shed in semen. Thus, detection of PRRS virus in serum precedes that of semen.

It is possible that the boar is not showing clinical signs of PRRS infection and PRRS virus may not be detected using serum PCR (e.g. if the boar is no longer viraemic). In this situation, the use of a serological test would allow detection of antibodies to PRRS.

Turner and Robbins (2009)[24] proposed that the ideal testing strategy is to blood sample donors at the time of semen collection and individually test the sample by PCR. MPI considers that individual donor testing, using serum samples taken on the day of semen collection and subjected to both serological and virological tests for PRRS, effectively mitigates the risks associated with PRRS.

The *Code* measures for PRRS and in turn the draft IHS represent the international consensus on the appropriate risk mitigation for PRRS. ∞These measures are significantly greater than those in the existing IHS PIGSEMIC.NAM which has allowed pig semen imports from Canada to New Zealand for many years without any disease incursion.

∞PIGSEMIC.NAM has been amended, effective 11 November 2017, to reflect the *Code* measures for PRRS.

See response 4.2.1.

[19]Connor (2005) Hanson Lecture: Biosecurity and Studs. *Proceedings of the 2005 Allen D. Leman Swine Conference*: 20-34
[20]Nathues et al. (2014) An outbreak of Porcine Reproductive and Respiratory Syndrome Virus in Switzerland Following Import of Boar Semen. *Transboundary and Emerging Diseases* 63: 251-261
[21]PIC North America (2015) Boar Manual (accessed 06/09/2017: http://na.picgenus.com/sites/genuspic_com/Uploads/Boar%20Manual.pdf)
[22]Pepin *et al.* (2015) Comparison of specimens for detection of porcine reproductive and respiratory syndrome virus infection in boar studs. *Transboundary and Emerging Diseases* 62: 295-304
[23]OIE Terrestrial Animal Health Code: *Infection with Porcine Reproductive and Respiratory Syndrome Virus* (http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_prrs.htm)
[24]Turner and Robbins (2009) Keeping the damage to a minimum. *Proceedings of the AASV 2009*: 15-18 (accessed 5 September 2017, https://www.teagasc.ie/media/website/animals/pigs/2009.AASV.Turner.Boars---keeping-damange-to-min.pdf)

4.2 New Zealand Pork (response to provisional issue of PIGSEMIC.NAM)

4.2.1 'Normal industry practice' in North America

Consistent with normal industry practices in Canada and the USA, NZPork supports a requirement for laboratory testing of boars +/- semen for PRRS virus or exposure, post-collection. While the commodity of interest to New Zealand is frozen pig semen (in contrast to fresh pig semen, the commodity most commonly traded within North America), normal industry practice in North America is frequent on-going testing of donor boars +/- semen at the time of collection or shortly thereafter. This practice is a critical measure to minimise the likelihood and extent of PRRS introduction to downstream breeding herds via semen. NZPork has provided MPI with published and lay information supporting this position.

MPI Response
See response 4.1.3 for a discussion of herd monitoring.

Yet the prior requirement for post-collection laboratory testing has been removed in the provisional IHS.

MPI Response
The post-collection testing in PIGSEMIC.NAM was in reference to PCR testing of semen. Pepin *et al*. (2015) showed that likelihood of detecting PRRS infection using PCR for semen (either whole semen or cell fraction semen) was low compared to other specimens such as serum, blood swab or oral fluids. The percent positive by seven days post-inoculation was 30.8% and 43.5% for whole semen and cell fraction semen, respectively, compared to 99.9% for the other specimens. The information provided by industry supports this conclusion (*personal communication, Bruce Welch 13 October 2017*), namely, that PCR testing of semen is not undertaken as part of the semen collection centre's routine surveillance due to reduced sensitivity compared to other sample types (e.g. blood, serum). Note the reference to the semen collection centre above applies the exporting centre supplying pig semen to New Zealand, and is hereafter referred to as 'normal industry practice'.

MPI believes that post-collection testing (e.g. serum ELISA) is not routinely undertaken as a part of 'normal industry practice' as the most commonly traded commodity in North America is fresh semen. Nevertheless, MPI considers that the manner in which the *Code* is worded allows for herd monitoring protocol which includes both virological and serological tests for detecting PRRS infection. Tailoring the herd monitoring protocol to include both virological and serological tests would be consistent with 'normal industry practice' (e.g. 80 of the 89 samples allocated to PCR and 8-9 of the 89 subjected to ELISA – see discussion of herd monitoring below) and within the scope of the draft IHS.

Despite being the most biosecure and intensively monitored compartment of a pig industry, North American studs consistently, though infrequently, become infected with PRRS, generally through unknown mechanisms. Give the speed and scale at which semen is distributed from typically large studs in North America, these incursions can produce large and very expensive outbreaks of the disease in downstream breeding herds.

MPI Response
As noted by NZ Pork, the commodity most commonly traded in North America is fresh semen. MPI considers that fresh semen is an inherently riskier commodity as semen is collected and used to inseminate sows/gilts within the same week. Sow/gilts could potentially be inseminated with infected semen before a PRRS introduction into a semen collection centre is detected. Fresh semen from PRRS infected countries, however, will not be eligible for importation to New Zealand.

NZPork believes it is inappropriate to design standards for international trade in pig semen that are less restrictive than those currently considered 'normal practice' by the industries in North America. This is particularly relevant when New Zealand remains one of very few PRRS-free countries in the world.

MPI Response
Based on the information supplied by NZ Pork and domestic industry, 'normal industry practice in North America' is not more restrictive than the proposed risk mitigation measures for PRRS in the *Code* and draft IHS and can be best illustrated with a side-by-side comparison for the semen collection process (i.e. prior to pre-entry isolation/herd of origin, pre-entry isolation and semen collection centre – see Tables 2-4). It should be noted that the information representing 'normal industry practice' comes from a single source (i.e. an individual semen collection centre in North America) and there is likely to be variability in practices at commercial boar studs.[19] Nevertheless, MPI considers the source to be relevant as it is one of the current exporters of pig semen to New Zealand.

Table 2. Comparison of risk mitigation measures in the draft IHS and 'normal industry practice' in the herd of origin (prior to movement to the pre-entry isolation facility).

Draft IHS	Information supplied by NZ Pork/domestic industry
• Donors have not been vaccinated against PRRS; and • Donors were kept, since birth or for at least three months prior to entry into the pre-entry isolation facility in an establishment in which no pigs have been vaccinated against PRRS, no infection with PRRS virus was detected within that period and pigs were subjected to a test for PRRS, with negative results, within 30 days prior to entry into the pre-entry isolation facility.	• Meeting held on 5 October 2017, NZ Pork and domestic industry indicated that donors are sourced from the Gene Transfer Centre's own herds.

MPI considers that the measures prior to pre-entry isolation with regard to the herd of origin in the draft IHS to be appropriate.

Table 3. Comparison of risk mitigation measures in the draft IHS and 'normal industry practice' in the pre-entry isolation facility.

Draft IHS	Information supplied by NZ Pork/domestic industry
• Donors were tested on two occasions with a serological test, the first occasion on the day of entry into the pre-entry isolation facility and the second occasion no less than 21 days after entry and within 15 days prior to movement to the semen collection centre. • It should be noted that all donors in pre-entry isolation must be tested and there is no pooling of samples.	• Donors were tested on two occasions, the first occasion (at day 2 to 7) and the second occasion no less than 27 days after entry and within 3 days prior to movement to semen collection centre. • On the first occasion, serum samples from 30 animals or the entire pre-entry isolation population (whichever is less) are tested via a serological test (individually) and PCR (pooled), or oral fluids. • On the second occasion, serum samples on all donors are tested via serological test (all animals) and PCR (pooled).

MPI considers that the measures for pre-entry isolation in the draft IHS to be appropriate. Please see response 4.1.2 for further discussion on testing in pre-entry isolation facility.

Table 4. Comparison of risk mitigation measures in the draft IHS and 'normal industry practice' in semen collection centre.

Draft IHS	Information supplied by NZ Pork/domestic industry

Donors were kept in a semen collection centre where: • At least every month, serum samples from a statistically representative number of all donor males were subjected to a test for infection with PRRS listed in MPI-STD-TVTL, with negative results (the sampling scheme is listed in MPI-STD-TVTL and should be designed to ensure that all donor males are tested every 12 months and at least once during their stay); or • Serum samples, taken on the day of collection for each donor, were tested with serological and virological tests for infection with PRRS listed in MPI-STD-TVTL, with negative results.	Herd testing on a weekly basis at: • 70% confidence level, 2% prevalence and diagnostic test sensitivity 92%; or • 90% confidence level, 2% prevalence, and diagnostic test sensitivity 92%.

The differences in the level of confidence (70% and 90%) reflect a risk based assessment undertaken by the semen collection centre, and considers the likelihood of introduction into the semen collection centre and transmission from centre to recipient herd, and the potential impact on the recipient herd. A confidence level of 70% represents lower likelihood and impact.

Using the herd monitoring protocol for higher likelihood and impact and a herd size of 185 animals, 89 samples are needed to give 90% confidence of detecting PRRS infection at 2% prevalence in the semen collection centre. Of these 89 samples, 80 are allocated for PCR testing and 8-9 for serological testing (e.g. ELISA) on a weekly basis (spread over the number of semen collection days, e.g. over 2 or 3 days). This represents a large number of samples; however, the samples are not tested individually (i.e. are pooled into groups of 5 samples per pool) which means that only 16 PCR tests are done and not 80 tests as on initial evaluation. As a result, there may be a reduction in sensitivity of the monitoring protocol. Further, sampling does not appear to be representative (random); rather, prioritised based on the recipient of the semen (e.g. nucleus herds cf. commercial herds).

In contrast, the draft IHS specifies a confidence level of at least 95% and a design prevalence of no more than 5%. For a herd size of 185 animals, 53 serum samples will be collected for individual testing. Where an exporting country is recognised to have a very high disease prevalence and pig density (as assessed through the country approval process), the confidence level, design prevalence and sample size (e.g. 99% confidence, 2% prevalence and sample size 138 animals) will be appropriately adjusted during certificate negotiation to meet New Zealand's level or protection. See Table 1 for additional sample size calculations based on confidence level and prevalence.

Reflecting the above, MPI considers that the 'normal industry practice' in North America does not confer a higher level of protection than the measures in the draft IHS. Based on the information supplied by NZ Pork and industry, the 'normal industry practice' (i.e. herd monitoring /surveillance) described is unlikely to meet the measures in the draft IHS (e.g. pooling of samples for PCR testing, use of blood swabs rather than serum, non-representative sampling, etc). See response 4.1.3 for further discussion of herd monitoring.

With regard to the option for individual animal testing, MPI considers that virological (e.g. PCR) and serological (e.g. ELISA) tests for PRRS using serum samples taken on the day of semen collection would allow infected donors to be identified. See response 4.1.3 for further discussion of individual animal testing.

MPI recognises that the individual animal testing protocol proposed by NZ Pork and industry is equivalent to the draft IHS. Specifically, in relation to the timing of the serological tests (i.e. 14-21 days following semen collection).

Clause 40 (for importation from countries or zones not free from PRRS) of the GD will read:

Donors:

a) Have not been vaccinated against PRRS; and

b) Were kept, since birth or for at least three months prior to entry into the pre-entry isolation facility in an establishment in which no pigs have been vaccinated against PRRS, no infection with PRRS virus was detected within that period and pigs were subjected to a test for PRRS listed in MPI-STD-TVTL, with negative results, within 30 days prior to entry into the pre-entry isolation facility; and

c) Were tested on two occasions with a serological test listed in MPI-STD-TVTL, the first occasion on the day of entry into the pre-entry isolation facility and the second occasion no less than 21 days after entry and within 15 days prior to movement to the semen collection centre; and

d) Were kept in a semen collection centre where:

1) At least every month, serum samples from a statistically representative number of all donor males were subjected to a test for infection with PRRS listed in MPI-STD-TVTL, with negative results (the sampling scheme is listed in MPI-STD-TVTL and should be designed to ensure that all donor males are tested every 12 months and at least once during their stay); or

2) Serum samples for each donor, taken on the day of semen collection, were subjected to serological and virological tests for infection with PRRS listed in MPI-STD-TVTL, with negative results; or

3) Serum samples from each donor were taken on two occasions, the first occasion on the day of collection and subjected to a virological test for PRRS, and the second occasion 14-21 days after collection and subjected to a serological test for PRRS; both tests listed in MPI-STD-TVTL, with negative results.

4.2.2 Post-collection testing

Notably the post-collection holding period has been retained in the provisional IHS, but without any requirement for laboratory testing of the donor boars. Though these donor boars are to be watched for the appearance of clinical signs of disease during this period, no testing is required. Adult boars, in otherwise good-health, may not develop significant signs of disease (especially PRRS) such as 'reproductive failure' or 'respiratory disease' symptoms post-infection with the virus; regardless, neither group of clinical signs is pathognomonic for PRRS and could easily be overlooked, or perhaps

ignored as simply an occurrence of a less significant disease not warranting any diagnostic investigation.

MPI Response
See response 4.2.1 above for further discussion on post-collection testing.

4.3 Canadian Food Inspection Agency (second submission)

4.3.1 PRRS submission

Canada supports the addition of requirement in the OIE for PRRS in live animals and porcine semen and the inclusion of the OIE porcine semen measures in NZ porcine import requirements. However Canada expects NZ to apply the OIE requirements without additional measures.

MPI Response
Noted.

5 Appendix 1: Copies of Submissions

5.1 New Zealand Pork

[Link to full submission]

New Zealand PORK

Submission:
Draft IHS for importing pig semen and accompanying suite of documents

January 2017

Contact:

Frances Clement
Policy Manager
(frances.clement@pork.co.nz; +64 21 422 301)
c/- 2a / 9 Sir Gil Simpson Drive, Burnside
PO Box 20176, Bishopdale
CHRISTCHURCH

Page 1 of 25

[Link to full submission]

NZPork comments on Risk Management Proposal (Pig Semen) 2017

August 17, 2017

Submitted to:
Animal Imports Team
Ministry for Primary Industries
Pastoral House 25 The Terrace
Wellington, New Zealand
Email: animalimports@mpi.govt.nz

NZPork Contact:
Frances Clement
Policy and Issues Manager
NZPork
2a/9 Sir Gil Simpson Drive
Christchurch, New Zealand
Email: frances.clement@pork.co.nz
Phone: +64 21 422 301

[Link to full submission]

New Zealan
PORK

New Zealand Pork
PO Box 20-176
Christchurch 8543
New Zealand

p 0800 697 675
p 03 3571407
e info@pork.co.nz

WWW.NZPORK.CO.NZ

October 10, 2017

Animal Imports
Animal & Animal Products Directorate
Regulation and Assurance
Ministry for Primary Industries, New Zealand
PO Box 2526
25 The Terrace
Wellington
NEW ZEALAND

Via email: animalimports@mpi.govt.nz

Dears Sirs

PROVISIONAL IMPORT HEALTH STANDARD FOR PIG SEMEN FROM CANADA OR THE UNITED STATES OF AMERICA dated: October 2017 (released October 27, 2017)

NZPork has consulted with pork industry stakeholders to form an opinion on the suitability of provisions in the import health standard (IHS) described above to effectively manage the risk of introducing exotic pathogens into New Zealand through the importation of pig semen. During their consultation with the industry, NZPork also communicated on several occasions by telephone, email, and in person to MPI staff to become more familiar with the proposed changes to the IHS and exchange views and information on the matter. As a matter of course, these discussions covered both the proposed changes to this IHS, and also to planned changes to the 'generic' IHS for Pig Semen (pigsemen.gen) that is also currently under review by MPI.

NZPork will not be requesting an Independent Review of the provisionally released IHS (pigsemic.nam) as it includes some improvements around mitigation of the risk of PRRS virus being introduced through importation of semen. However, NZPork does have concerns about several aspects of the provisional IHS that also carry-over to the generic IHS for Pig Semen. NZPork reserves its position in respect of its right to request an Independent Review of the generic IHS for Pig Semen in respect of these concerns.

NZPork's concerns regarding the provisional IHS are set out below. When the new provisional generic IHS for pig semen is released, NZPork will review the generic standard and a determination will be made as to the merits of requesting an Independent Review of the generic standard at that time.

Our concerns related to the provisional Import Health Standard for Pig Semen from Canada or the United States of America include:

5.2 PIC New Zealand

[Link to full submission]

PIC New Zealand

PIC New Zealand Ltd
5 Ross Street
P O Box 43019
Darfield 7541
New Zealand
Tel: +64-3-317 9035
www.picnz.co.nz

Animal Imports

Ministry for Primary Industries

PO Box 2526 Wellington 6140

Email to animalimports@mpi.govt.nz

Tuesday 24th January 2017

PICNZ Submission – Draft Import Health Standard for Importation of Pig Semen into New Zealand

PIC New Zealand (PICNZ) is a franchise holder and representative for PIC genetics in New Zealand. PIC International represents one of the world's largest pig breeding companies, represented in over 30 countries and playing a major role in the structure and success of the global pork industry.

PICNZ is the second largest pork production business in New Zealand and operates over multiple farming sites providing employment opportunities and contributing significantly to the local economy. PICNZ is also one of two major breeding companies represented in New Zealand that imports and disseminates pig genetics. Frozen semen has been imported at intervals of between 6 and 12 months to minimise genetic lag and ensure that the most advanced genetic material is delivered to the NZ industry to maintain its competitiveness.

PICNZ considers that ongoing access to the world's best genetic material at frequent intervals to minimise genetic lag are vital to the survival of the NZ pork industry and of PICNZ. While historically importing frozen semen has incurred some substantial costs and compliance challenges to meet the stringent NZ import standards, PICNZ are fully supportive of such a position and would be extremely concerned about any attempts to soften the position and increase risk of introducing a new disease. The value of a country's health status is far too important to put at risk. It is PICNZ's view that PICNZ's and New Zealand's high health status plus access to the world's best genetic material are prime competitive advantages.

The Draft IHS for pig semen appears to include a significant softening of NZ's position and to introduce a number of new risks. This is of significant concern to PICNZ. It is extremely difficult to reverse a loss of country health status and the consequences are forever and for many generations of New Zealanders. Financial consequences of a disease introduction can be enormous to a country. With this in mind it would be unwise to take any unnecessary risks, both tangible and intangible.

5.3 Federated Farmers

[Link to full submission]

SUBMISSION

TEL PHONE 0800 327 646 | WEBSITE WWW.FEDFARM.ORG.NZ

FEDERATED FARMERS OF NEW ZEALAND

To:	Ministry for Primary Industries
Submission on:	**Draft Import Health Standard: Pig Semen**
From:	Federated Farmers of New Zealand
Date:	27 January 2017

Contact:

DAVID BURT
SENIOR ADVISOR PRIMARY SECTOR

Federated Farmers of New Zealand
PO Box 715, Wellington 6140
P 04 494 9182

E dburt@fedfarm.org.nz

5.4 Dairy New Zealand

[Link to full submission]

DairyNZ

Corner Ruakura
& Morrinsville Roads
Private Bag 3221
Hamilton 3240
New Zealand

Ph +64 7 858 3750
Fax +64 7 858 3751
www.dairynz.co.nz

24 January 2017

Animal Imports
Ministry for Primary Industries
PO Box 2526
Wellington 6140

By email to: animalimports@mpi.govt.nz

DairyNZ submission on:

- **Draft Risk Management Proposal: Pig Semen**
- **Draft Import Health Standard: Pig Semen**
- **Draft Guidance Document: Pig Semen**

Introduction

1. DairyNZ is the industry good organisation representing New Zealand's dairy farmers. Funded by a levy on milksolids and through government investment, our purpose is to secure and enhance the profitability, sustainability and competitiveness of New Zealand dairy farming. We deliver value to farmers through leadership, influencing, investing, partnering with other organisations and through our own strategic capability. Our work includes research and development to create on-farm practical tools, leading on-farm adoption of best practice farming, promoting careers in dairying and advocating for farmers with central and regional government.

2. DairyNZ has looked at these consultation documents from the perspective of the overall management of animal health for the livestock industries in New Zealand. There are a number of diseases not present in New Zealand that affect pigs, as well as cattle, sheep, deer and goats, therefore the impact of importing these diseases via porcine semen would extend well beyond the pig industry.

3. The dairy industry in New Zealand is a major exporter of milk products. Arrival of an exotic disease would not only impact on the health and productivity of the national dairy herd, but in all likelihood, would have serious ramifications for the industry's ability to export milk products. Annual export revenue for New Zealand from dairy products has ranged from $12.2 to $17 billion dollars over the last five years (June ended years), and this has accounted for 26-34% of New Zealand's merchandise trade annually (29% average on last five seasons). Loss of dairy export revenue would have a very significant impact on the country's economy.

5.5 Deer Industry New Zealand

[Link to full submission]

Deer Industry
New Zealand

25 January 2017

Animal Imports
Ministry for Primary Industries
PO Box 2526
Wellington 6140

By email: animalimports@mpi.govt.nz

Review of draft porcine material import health measures: *draft Risk Management Proposal (Pig semen); draft Import Health Standard (Pig semen); draft Guidance Document (Pig semen)*

Deer Industry New Zealand (DINZ) is a levy funded industry-good body established by the Deer Industry New Zealand Regulations 2004 under the Primary Products Marketing Act 1953. It represents producers of farmed deer, and processors, marketers and of products from farmed deer, which are principally venison and velvet.

The New Zealand deer industry has about 900,000 farmed deer, and in 2015 exported products to a total value of about $255 million. These exports are primarily made up by venison, velvet, co-products, leather and hides.

As the team knows from its recent assistance to DINZ in relation to import controls for Chronic Wasting Disease-risk material, DINZ takes seriously risks from imported material to deer and pasture/fodder health. Given that many such risks arise from the importation of material not directly associated with deer, DINZ seeks that controls on such material appropriately take into account the effect of the material and the proposed control on the deer industry.

We have seen DairyNZ's draft submission on these three documents and share its concerns that the proposed import health standards applicable to pig semen do not adequately take into account the risk to the livestock sector of FMD-contaminated pig semen. Even a small FMD incursion is likely to severely constrain deer farming and the export of deer products for at least a year and have longer-term impacts on consumer confidence in New Zealand deer products, whether from a quality or reliability of supply perspective.

Given the likely significant impact of a FMD incursion on both the deer industry and New Zealand, DINZ agrees with DairyNZ that New Zealand is justified in imposing controls stricter than OIE guidelines, which are focussed merely on blocking transmission pathways. In particular, DINZ considers that importing pig semen from FMD-infected countries should be prohibited. Additionally, we consider that the surveillance of semen donors from other countries should be more comprehensive, for instance donor boars should be under surveillance for the duration of the FMD incubation period and be tested for infection rather than merely observed for clinical signs.

We also note that some requirements (such as for testing of products for contamination or veterinary

PO Box 10702 | The Terrace
Wellington 6143 | New Zealand
Phone +64 4 472 4503
Fax +64 4 472 5543

www.deernz.org www.nzvenison.com www.velvet.org.nz

5.6 Canadian Food Inspection Agency

[Link to full submission]

From: Charlene Harradine
To: Animal Imports
Cc: Leigh Sinclair
Subject: Canada"s Comments on New Zealand"s guidance document regarding import health standards (IHS) for imported pig semen.
Date: Tuesday, 31 January 2017 5:06:40 a.m.

New Zealand Animal Imports:

Thank you for the opportunity to review New Zealand's guidance document regarding import health standards (IHS) for imported pig semen.

Upon review of the related documents Canada is pleased that the import requirements follow the OIE very closely. With respect to PRRS, the OIE recommendations testing however there is no chapter in the OIE Terrestrial Animal Health Code that details further recommendations for this disease. The code states (on-farm, isolation and resident herd):
PRRS -The test complying with the standards in the Terrestrial Manual. Hence, other than recommending the type of tests that are approved, a country is left to develop import requirements as they feel required to prevent the introduction of this disease.

As a result, I would like to request that MPI consider the PRRS section of the Canadian Food Inspection Agency's Artificial Insemination Program as offering equivalent risk mitigation as that proposed in New Zealand's IHS.

The proposed statements for the certificate as per the Canadian AIP are as follows:

8.Porcine reproductive and respiratory syndrome (PRRS) virus:

8.1Prior to entering the pre-entry isolation facility the following conditions have been complied with,
Qualification of the herd: (i) source herd is not under quarantine and not vaccinated against PRRS
Qualification of boars on farm of origin: (i) donor boars are identified according to the national standards for swine, have undergone a clinical examination by an accredited veterinarian and found to be healthy and free of evidence of infectious or contagious swine diseases transmissible by semen.
(ii) Within the 30 days prior to arrival to the pre-entry isolation facility of an approved semen collection centre donor boars underwent a multivalent serum ELISA for PRRS antibodies that uses both European and American strain antigens with negative results.

8.2 Qualification of boars at pre-entry isolation: Boars have been kept for at least 30 days in a pre-entry isolation facility of the semen collection centre and underwent serological testing for PRRS after a minimum of 21 days in this facility with negative results. A multivalent serum ELISA for PRRS antibodies was used that includes both European and American strain antigens. The isolation is operated as an all-in all-out facility.

8.3 Qualification of boars in the resident herd: Resident donor boars in the artificial insemination centre have been tested at least annually for PRRS with negative results. A multivalent serum ELISA for PRRS antibodies was used that includes both European and American strain antigens.