



## Review of Submissions:

Draft Import Health Standard for Pig Semen

Draft Import Risk Analysis for Pig Semen

Draft Risk Management Proposal for Pig Semen

Draft Guidance Document for Pig Semen

**31 May 2013**

**Ministry for Primary Industries**

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**Standards Branch**

**REVIEW OF SUBMISSIONS ON:**

Draft Import Health Standard for Pig Semen

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Draft Guidance Document for Pig Semen

31 May 2013

Approved for general release

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Ministry for Primary Industries

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## Introduction

The draft import risk analysis, draft risk management proposal, draft import health standard and draft guidance document for importing pig semen were notified for public consultation on 9 March 2012 and the WTO notification period started on 15 March 2012. Submissions closed for public consultation April 25 and May 14 for WTO notification.

This import health standard will provide for the importation of pig semen from approved countries. Current approved countries including Australia, the United States of America, Canada, the European Union, and Norway will be required to re-negotiate their veterinary/export certificate with MPI subsequent to issue of this import health standard.

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

|                                 |  |   |
|---------------------------------|--|---|
| European Union (EU)             | EU Notification Authority and Enquiry Point of the WTO Agreement on SPS measures | 5 May 2012  |
| New Zealand Pork Industry Board | Frances Clement, Policy and Issues Manager                                       | 14 May 2012   |
| New Zealand Pork Industry Board | Frances Clement, Policy and Issues Manager                                       | 05 October 2012 (late submission)                       |
| Australian Government           | DAFF   | 14 May 2012   |
| Canada                          | CFIA   | 14 May 2012   |
| PIC New Zealand                 | Peter MacDonald/Bruce Welch  | 14 May 2012   |
| PVS Limited                     | Bruce Welch  | 15 June 2012 (additional information on PIC submission) |

This document summarises the issues raised in the submissions and presents the MPI response to each. Copies of all external stakeholder submissions in their entirety are presented in Appendix 1.

## Acronyms Used in the Document

|                 |   |                 |  |
|-----------------|---|-----------------|--|
| AD              | Aujeszky's disease  | NSW             | New South Wales  |
| AI              | Artificial insemination   | NZ              | New Zealand  |
| BD              | Border disease  | OIE             | The World Organisation for Animal Health   |
| BVD             | Bovine viral diarrhoea  | OIE Code        | The World Organisation for Animal Health Terrestrial Animal Health Code. Any reference in this standard to the OIE Code is to the most current as found on the OIE website |
| BVDV-2          | Bovine viral diarrhoea virus -2   | PCR             | Polymerase chain reaction  |
| CFIA            | Canadian Food Inspection Agency   | PIC New Zealand | Pig Improvement Company New Zealand  |
| CSF             | Classical swine fever   | PMC             | Porcine myocarditis (Bungowannah virus)  |
| DAFF            | Department of Agriculture, Fisheries and Forestry (Australia)   | PRRS            | Porcine reproductive and respiratory syndrome  |
| ELISA           | Enzyme-linked immunosorbent assay   | PTV-1           | Porcine teschovirus 1  |
| EU              | European Union  | RMP             | Risk Management Proposal   |
| EU-NZ Agreement | Agreement between the European Community and New Zealand on sanitary measures applicable to trade in live animals and animals products (Council Decision 97/132/EC) | RNA             | Ribonucleic acid   |
| IDC             | The Investigation and Diagnostic Centre (IDC) Animal Health Laboratory  | RT-PCR          | Reverse transcription polymerase chain reaction  |
| IHS             | Import Health Standard  | SVD             | Swine vesicular disease  |
| IRA             | Import Risk Analysis  | SPS Agreement   | WTO Agreement on Sanitary and Phytosanitary Measures   |
| MPI             | Ministry for Primary Industries   | WTO             | World Trade Organization   |
| NATA            | National Association of Testing Authorities (Australia)   |                 |  |

## Summary of Amendments

The following is a summary of amendments made to the *Import Health Standard for Pig Semen*, the risk management proposal and the associated guidance document as a result of submissions received by MPI during the consultation period:

All documents below were adjusted to reflect the new name and logo. Ministry of Agriculture and Forestry ("MAF") has been replaced by Ministry of Primary Industries ("MPI").

### Import health standard amendments

- A definition for "collection period" will be included in Part D. Definitions of the IHS.
- A definition for "batch" will be included in Part D. Definitions of the IHS.
- What was clause 27 (A general requirement for freedom from Blue eye disease, Nipah virus, Teschovirus serotype 1, Venezuelan encephalitis and Vesicular exanthema) has been removed.
- What was clause 32 (Aujeszky's disease) which stated "An aliquot of each batch of semen to be imported was tested by a MPI approved PCR test for the presence of AD virus, with negative results" has been removed.
- A clause to manage the risk of blue eye disease has been added:  
"Semen originates from donor boars that have lived their entire lives in a country recognised by MPI as being free from blue eye disease.  
OR  
Semen originates from donor boars that have been subject to serological testing using MPI approved tests with negative results".
- What was clause 37 (classical swine fever) which stated "Every batch of semen to be imported was tested by an MPI approved reverse transcriptase (RT) PCR test, with negative results" has been removed.
- What was clause 40 has been amended from stating "Donor boars are resident in regions that are free from JE virus" to read "Donor boars are resident in zones that are free from JE virus".
- What was clause 41 (porcine myocarditis virus) which stated " Semen originates from donor boars that have been resident in a country that is free from porcine myocarditis virus" has been replaced with the wording "Semen originates from donor boars that have lived their entire lives in a country, zone or compartment that is free from porcine myocarditis virus".
- What was clause 42 (porcine myocarditis virus) which stated "Semen originates from donor boars that have been resident in Australian semen collection centres not including animals from properties where porcine myocarditis has been diagnosed" has been removed.
- What was clause 43 (porcine myocarditis virus) which stated "Donor boars originated from properties where porcine myocarditis has been diagnosed and were isolated and tested with an MPI approved test to demonstrate they were seropositive for porcine myocarditis virus and negative for porcine myocarditis virus RNA before entering the semen collection centre" has had an additional testing requirement added which stated "AND An aliquot of each batch of semen to be imported was tested by a RT-PCR test, with negative results".
- What was clause 44 which stated "The exporting country has been recognised as free from PRRS" has been replaced with the wording: "Semen originates from donor boars that have lived their entire lives in a country recognised as being free from PRRS".
- What was clause 45.a has been amended to read "Boars were sourced from donor herds that do not vaccinate against PRRS, and were tested by a multivalent serum

ELISA for PRRS antibodies that uses both European and American strain antigens with negative results before entering the semen collection centre”.

- What was clause 47 (swine vesicular disease) which stated “Semen originates from donor boars from a country considered infected with SVD and is compliant with the recommendations contained in Article 15.4.10 of the OIE Code, including compliance with Chapters 4.5 and 4.6 of the OIE Code” has been reworded to state “Semen originates from a semen collection centre that complies with OIE guidelines for General hygiene in semen collection and processing centres (Chapter 4.5) and also complies with OIE guidelines on the Collection and processing of porcine semen (Chapter 4.6).
- What was clause 48 (swine vesicular disease) which stated “Every batch of semen to be imported was tested by a MPI approved PCR test for SVD virus, with negative results” has been removed.

### **Risk Management Proposal amendments**

- The chapter on Aujeszky’s disease justifies only including options 1 and 2 to effectively manage the risk of AD in imported semen. Explanation is recorded under options assessment and considerations.
- A chapter on blue eye disease has been added to the RMP.
- The chapter on classical swine fever justifies only including options 1 and 2 to effectively manage the risk of CSF in imported semen. Explanation is recorded under options assessment and considerations.
- An option under Japanese encephalitis has been amended from stating “Donor boars are resident in regions that are free from JE virus” to read “Donor boars are resident in zones that are free from JE virus”.
- The chapter on porcine myocarditis virus justifies only including option 1 and option 3 with option 3 having an additional testing requirement added. Explanation is recorded under options assessment and considerations.
- Option 2 part a. in the chapter on porcine reproductive and respiratory syndrome has been amended to read “Boars were sourced from donor herds that do not vaccinate against PRRS, and were tested by a multivalent serum ELISA for PRRS antibodies that uses both European and American strain antigens with negative results before entering the semen collection centre”. Explanation is recorded under options assessment and considerations.
- The chapter on swine vesicular disease justifies only including option 1 and 2 to effectively manage the risk of SVD in imported semen.

### **Guidance Document amendments**

- The clause which was a general requirement for freedom from blue eye disease, Nipah virus, Teschovirus serotype 1, Venezuelan encephalitis and vesicular exanthema) has been removed.
- What was clause 19 (Aujeszky’s disease) which stated “An aliquot of each batch of semen to be imported was tested by a MPI approved PCR test for the presence of AD virus, with negative results” has been removed.
- A clause to manage the risk of blue eye disease has been added:  
“Semen originates from donor boars that have lived their entire lives in a country recognised by MPI as being free from blue eye disease.  
OR  
Semen originates from donor boars that have been subject to serological testing using MPI approved tests with negative results”.

- The clause for classical swine fever which stated “Every batch of semen to be imported was tested by an MPI approved reverse transcriptase (RT) PCR test, with negative results” has been removed.
- The clause for Japanese encephalitis has been amended from stating “Donor boars are resident in regions that are free from JE virus” to read “Donor boars are resident in zones that are free from JE virus.”
- The clause for porcine myocarditis virus which stated “ Semen originates from donor boars that have been resident in a country that is free from porcine myocarditis virus” has been replaced with the wording “Semen originates from donor boars that have lived their entire lives in a country, zone or compartment that is free from porcine myocarditis virus”.
- The clause for porcine myocarditis virus which stated “Semen originates from donor boars that have been resident in Australian semen collection centres not including animals from properties where porcine myocarditis has been diagnosed” has been removed.
- The clause for porcine myocarditis virus which states “Donor boars originated from properties where porcine myocarditis has been diagnosed and were isolated and tested with an MPI approved test to demonstrate they were seropositive for porcine myocarditis virus and negative for porcine myocarditis virus RNA before entering the semen collection centre” has had an additional testing requirement added which states “AND An aliquot of each batch of semen to be imported was tested by a RT-PCR test, with negative results”.
- The clause for porcine reproductive and respiratory syndrome which states “The exporting country has been recognised as free from PRRS” has been replaced with the wording: “Semen originates from donor boars that have lived their entire lives in a country recognised by MPI as being free from PRRS”.
- What was clause 45.a for PRRS has been amended to read “Boars were sourced from donor herds that do not vaccinate against PRRS, and were tested by a multivalent serum ELISA for PRRS antibodies that uses both European and American strain antigens with negative results before entering the semen collection centre”.
- What was the clause for swine vesicular disease which stated “Semen originates from donor boars from a country considered infected with SVD and is compliant with the recommendations contained in Article 15.4.10 of the OIE Code, including compliance with Chapters 4.5 and 4.6 of the Code” has been reworded to state “Semen originates from a semen collection centre that complies with OIE guidelines for General hygiene in semen collection and processing centres (Chapter 4.5) and also complies with OIE guidelines on the collection and processing of porcine semen (Chapter 4.6).
- What was a clause for swine vesicular disease which stated “Every batch of semen to be imported was tested by a MPI approved PCR test for SVD virus, with negative results” has been removed.

All equivalences and disease freedom claims will be assessed during country to country bilateral negotiations of the approved veterinary/export certificate.

## Other Amendments

The following changes have been made to the documents. These changes are the result of MPI's own further consideration of the documents:

### Guidance Document amendments

- In Part C. a link is provided for the Terrestrial Animal Health Code and the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals



- In the model health certificate the following has been added:
  - A box for 2. b. "Import permit number"
  - A box for 8. "Place of destination"
  - Amendment box 11 to fill in last 3 lines only when transport container is new
  - Box 15 first column now reads "Donor animal"
- Where multiple risk management options are given for individual diseases in the "specific requirements" section, "delete as applicable" is added to ensure only one option is selected.

# Review of Submissions

## 1. European Union (EU)

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- 1.1 EU request to NZ: to delete requirements concerning post collection testing for BVD-2 and PRRS in Part C or provide options waiving these requirements in case of fresh semen or to change the scope of the import health standard.**

**Rationale: Porcine semen is mostly traded as fresh semen. Therefore requirements concerning post-collection testing, restrict exports of porcine semen to New Zealand to frozen semen only.**

***MPI response:***

Where country freedom from BVDV-2 and PRRS cannot be claimed, post collection testing protocols for these diseases apply, which limits eligibility for imports of fresh semen.

- 1.2 EU request to NZ: to delete the requirement for documentation accompanying the consignment as it creates huge administrative burden.**

**Rationale: Based on the principles of the EU-NZ Agreement.**

***MPI response:***

MPI will accept this request on the condition that, consistent with MPI's documentation requirements for bovine germplasm from the EU, where documentation non-compliances are detected in the border clearance of germplasm shipments, MPI reserves the right to request copies of the actual laboratory reports.

- 1.3 EU request to NZ: to change “in the exporting country for at least 90 days” for “within the European Union for at least 90 days”.**

**Rationale: The recognition of the EU as whole in the EU-NZ Agreement.**

***MPI response:***

This request can be considered in the veterinary certificate specifically negotiated for the import of pig semen from the European Union into New Zealand.

- 1.4 EU request to NZ: to delete blue eye disease, Teschovirus serotype I and vesicular exanthema.**

**Rationale: The OIE Code does not provide any requirements as regards those diseases; does not consider those diseases to be a risk; not in the OIE listed diseases.**

***MPI response:***

MPI accepts that these three diseases are of no concern in the EU and will not incorporate these requirements in the veterinary certificate for importation of pig semen from the EU to New Zealand.

MPI further response: Since the above MPI response was made Teschovirus serotype 1 and vesicular exanthema and blue eye disease are three of six diseases that have been incorporated into the final import risk analysis. Vesicular exanthema and Teschovirus were concluded not to be a risk in porcine semen, however blue eye disease was concluded to be a risk in porcine semen, and measures for managing this risk are laid out in the RMP and IHS. Blue eye disease has only been described in Mexico

## 1.5 EU request to NZ:

**to delete from Point 35 the requirements concerning country freedom of BVD-2**

**to delete Point 37 concerning testing for BVD-2**

**Rationale: The OIE Code does not consider this disease to be a risk as regards to pigs; not an OIE listed disease as regards to pigs; OIE Code does not require testing of pigs for BVD-2; NZ should provide information on the presumption that NZ is free of the BVD-2 virus in pigs.**

### ***MPI response:***

Chapter 1.2 of the OIE Code includes bovine viral diarrhoea in the OIE list under cattle diseases.

Although there is no reference to swine in the OIE Manual Chapter for bovine viral diarrhoea, the chapter on CSF states:

"The viruses that cause classical swine fever (CSF), bovine viral diarrhoea (BVD) and border disease (BD) are members of the family Flaviviridae, genus *Pestivirus*, and are closely related, both antigenically and structurally. Clinical signs and lesions seen at post-mortem in pigs affected with CSF are highly variable due to both viral and host factors. Furthermore, congenital infections with ruminant pestiviruses in pigs can give rise to a clinical disease that is indistinguishable from CSF"

New Zealand is free of BVDV-2 (Horner 2000; Vilcek et al 1998; OIE 2008). This is based on the absence of clinical syndromes as reflected in normal veterinary monitoring and surveillance mechanisms in the New Zealand livestock industries as well as suspected exotic disease investigations. Freedom from BVDV-2 has been confirmed by microbiological surveys. Investigations of suspected BVD-2 in cattle have not detected BVD-2 in New Zealand. The only isolates of BVDV-2 recorded in New Zealand were from two commercial serum samples of overseas origin in 1997.

New Zealand is recognised as free from BVDV-2 by the EU (Council Direction 97/132/EC).

As the IRA states, field infection to boars can occur and result in persistent testicular infections with BVDV-2, and transmission via semen to New Zealand pigs could occur. There is sufficient evidence to indicate that BVDV infection of swine is not uncommon and congenital infection of pigs with BVDV leads to excretion in semen.

Whilst the consequences of introducing BVDV-2 are likely to be low to the New Zealand pig population, the consequences of any infection to the New Zealand cattle industry could be high.

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

When veterinary certificates are discussed during bilateral negotiations, MPI will consider a case put forward by the EU to show that tests for classical swine fever used in accordance with EU legislation would cross-react and therefore demonstrate donor freedom from BVDV-2.

## **1.6 EU request to NZ:**

**Criteria for country freedom for PRRS should be provided to delete Point 45(c) to add the following option:**

**“OR**

**“Semen originates from a semen collection centre that complies with OIE Code Chapters 4.5 and 4.6”**

**Rationale: No Chapter on PRRS in the OIE Code; Article 4.6.4 of the OIE Code provides that boars shall be tested negative for PRRS using a test compliant with the standards of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual) during the quarantine period of at least 28 days and, at least 21 days after entering the quarantine station, followed by an annual test on resident boars in the semen collection centre.**

### ***MPI response:***

Currently, Finland and Sweden are the only EU countries recognised by MPI as free from PRRS. A case has to be put forward by the member state of the EU to claim freedom status.

Under Article 3.1 of the WTO Agreement on Sanitary and Phytosanitary Measures (the SPS Agreement) the measures adopted in import health standards are to be based on international standards, guidelines and recommendations, where these exist. It also states (under Article 3.3) that measures providing a higher level of protection than international standards can be applied, if there is scientific justification, or if there is a level of protection that the member country considers is more appropriate following a risk assessment.

Chapters 4.5 and 4.6 of the Code contain requirements for PRRSv for boars standing at semen collection centres. Under these requirements, boars from a country or zone that is not free of PRRS must be clinically healthy, physiologically normal, and subject to testing complying with the standards in the Terrestrial Manual. Boars are tested within 30 days before entering quarantine (pre-entry isolation), boars must remain in this quarantine station for at least 28 days and, at least 21 days after entering the quarantine station must be tested negative for PRRSv using a test compliant with the standards of the Terrestrial Manual. Any boars resident in the semen collection facility must also be tested at least annually using a test compliant with the standards in the Terrestrial Manual.

While these requirements from the Code provide assurance that infected boars are not introduced into a stud, ensuring a stud remains free of infection is recognised to be extremely challenging (Huinker 2002; Connor 2003; Polson and Reicks 2009). Therefore annual testing alone (as described above) cannot be relied upon to demonstrate that semen from a centre compliant with 4.6 of the Code is free from PRRSv.

## 2. New Zealand Pork Industry Board

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- 2.1. Countries are listed in the (Draft) Guidance Document based on claim of freedom from a number of hazards. The competent authority is required to attest freedom from these hazards within a Veterinary Certificate accompanying pig semen to be imported into New Zealand. We support this requirement.**

MPI response:  
Noted.

- 2.2. How does MPI verify that the list with claims of freedom is current? What requirements are in place to require potential source countries to notify New Zealand of change in their health status?**

***MPI response:***

MPI relies on the systems implemented and supervised by the Competent Authorities of the approved countries to accurately verify and certify any disease freedom claims. Part of these systems consists of Chief Veterinary Officers of the Competent Authorities of our trading partners contacting MPI in case 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 Embassy contact points, Ministry of Finance 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 this information is communicated with relevant stakeholders. A recent example of this would be communications between MPI and domestic stakeholders following outbreak of Schmallenburg virus in Europe.

- 2.3. Laboratory testing, Donor eligibility, Semen collection centre requirements, Donor and semen collection centre health status, Semen collection, processing, storage and transport:**

**Is the effect of these general requirements to ensure that boar collection centres meet all the requirements of the OIE Code for collection centres? We recommend that this is the requirement and it should be stated as such.**

***MPI response:***

Clause 21 of the draft import health standard states:

“Semen must be collected, handled, prepared, processed and stored under the supervision of the approved semen collection centre veterinarian and in accordance with the World Organisation for Animal Health Terrestrial Animal Health Code (OIE Code)”.

This requirement (or compliance with a national system of semen collection which MPI deems equivalent) will be incorporated in the negotiated veterinary certificate with the approved country.

Where relevant these OIE Code requirements are also given as an option to certify disease freedom when country freedom cannot be claimed.

**2.4. Aujeszky's Disease: We support the risk management measures set out in 30 and 31.**

**We do not support 32. We strongly recommend the appropriate requirements are those set out in OIE chapters 4.5 and 4.6; which are shown as 30 and 31.**

***MPI response:***

Option 32 states, "An aliquot of each batch of semen to be imported was tested by a MPI approved PCR test for the presence of AD virus, with negative results"

Option 32 has been removed. Recognised international standards exist to enable safe trade in porcine semen from either AD-free<sup>1</sup> or AD-infected<sup>2</sup> countries. Reflecting MPIs organisational strategy of adopting international standards where they exist<sup>3</sup>, options 30 and 31 (which reflect these international standards) will remain in the IHS.

**2.5. Classical Swine Fever: 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.**

***MPI response:***

Option 37 states, "Every batch of semen to be imported was tested by an MPI approved reverse transcriptase (RT) PCR test, with negative results".

Option 37 has been removed. Recognised international standards exist to enable safe trade in porcine semen from either CSF-free<sup>4</sup> or CSF-infected<sup>5</sup> countries. Reflecting MPIs organisational strategy of adopting international standards where they exist<sup>6</sup> options 35 and 36 (which reflect these international standards) will remain in the IHS.

**2.6. Porcine myocarditis: We support the risk management measure set out in 41. We do not support 42 in isolation: this has the effect of accepting semen from animals whose health status is unknown. Absence of clinical disease is not an acceptable risk management strategy. We strongly recommend 42 requires the addition of negative testing prior to entry into the boar stud as per the OIE schedule for CSF.**

**We do not support 43.**

***MPI response:***

Option 42 states, "Semen originates from donor boars that have been resident in Australian semen collection centres not including animals from properties where porcine myocarditis has been diagnosed".

Option 43 states, "Donor boars originated from properties where porcine myocarditis has been diagnosed and were isolated and tested to demonstrate they were seropositive for porcine myocarditis virus and negative for porcine myocarditis virus RNA before entering the semen collection centre. Tests used have been approved by MPI".

<sup>1</sup> See article 8.2.13 of the OIE Code

<sup>2</sup> See article 8.2.15 of the OIE Code

<sup>3</sup> See "Our strategy 2030" (weblink to 2030 strategy)

<sup>4</sup> See article 15.2.8 of the OIE Code

<sup>5</sup> See article 15.2.9 of the OIE Code

<sup>6</sup> See "Our strategy 2030" (weblink to 2030 strategy)

There are concerns about relying on the absence of clinical signs as an indicator of freedom based on the evidence available and more proof of freedom in the unaffected properties in Australia is needed especially given the difficulties Australia has had eradicating this disease 10 years after it was recognised

In 2011, MPI was informed that PMC (porcine myocarditis) was nationally notifiable, the disease remains confined to a single enterprise with properties in New South Wales and Victoria (although the Victorian properties remain free of disease), and the affected enterprise is subject to quarantine and movement restrictions. There are no reports of this disease outside this enterprise and the affected enterprise was undergoing strategic depopulation and repopulation under government supervision with the aim of eradication by late 2011.

In 2012 it was confirmed that disease was still confined to this single enterprise, in a small number of properties in NSW. However, PMC had been seen in a site where it had been previously eradicated - this was blamed on aerosol transmission from a site 1.5km away. The Victorian properties belonging to this enterprise remain free of disease and were no longer under restrictions. Pigs from the infected New South Wales property were being introduced into the Victorian property (under permit) and there have been limited sero-surveys of the Victorian properties.

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

Reflecting these concerns, Option 42 has been removed from the HIS.

MPI 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”.*

Please see also response 3.8, 6.2 and 7.1 for further discussion of this amended option.

**2.7. Porcine reproductive and respiratory syndrome: We support the risk management measure set out in 44.**

**In regard to the risk management measure set out in 45:**

- a. This needs to better clarify that it is the semen collection centre that is described in chapter 4.6 of the OIE Code. What is the test referred to, to demonstrate PRRS freedom prior to entry to the semen collection centre? There is no reference to tests in the OIE Code.**
- b. What does „collection “ period mean?**

**c. Requires a minimum of 30 days to provide appropriate assurance of PRRS freedom, given the acknowledged challenge to keep sites free from PRRS.**

***MPI response:***

- a. Option 45.a states, "Boars.... were shown to be negative for PRRS before entering the semen collection centre in accordance with Chapter 4.6 of the OIE Code"

To demonstrate PRRS freedom for the donor before entry into the semen collection centre, two phases have to be completed:

Chapter 4.6 of the Code, Article 4.6.4 section 1 outlines the testing protocol for boars prior to entering the pre-entry isolation facility.

Chapter 4.6 of the Code, Article 4.6.4.section 2 outlines the testing protocol for boars prior to entering the semen collection facility.

In both cases a diagnostic test as described in the Terrestrial Manual (Chapter 2.8.7) has to be used.

- b. The collection period is the period from the first day of semen collection of the donor boar up to, and including the last day of semen collection of the donor boar for the consignment of pig semen destined for export to New Zealand.

The definition for "collection period" will be added to Part D. Definitions of the IHS.

- c. Circulation of antibodies to the virus are detectable 14-21 days after infection based on indirect immunofluorescence test or ELISA (Nelson, E.A. et al. 1994).

Holding semen for at least 21 days (due to possible seroconversion occurring 14 to 21 days post infection) before the donor serology is undertaken is a sufficient period to reliably detect any seroconversion.to demonstrate freedom from PRRS.

**2.8. Swine vesicular disease (SVD): We support the risk management measures set out in 46 and 47. We do not support 48. This has the effect of accepting semen from a SVD positive country or zone on the basis of direct testing. We strongly recommend the appropriate requirements are those set out in the OIE Code.**

***MPI response:***

Option 48 has been removed. Recognised international standards exist to enable safe trade in porcine semen from either SVD-free<sup>7</sup> or SVD-infected<sup>8</sup> countries. Reflecting MPIs organisational strategy of adopting international standards where they exist<sup>9</sup>, options 46 and 47 (which reflect these international standards) will remain in the IHS.

**2.9. Leptospira: We have reservations about this risk management measure. More specificity would help (e.g. reference to specific antibiotics and inclusion rates). As stated this is too general to provide assurance of risk management unless also supported by direct testing.**

***MPI response:***

<sup>7</sup> See article 15.4.9 of the OIE Code

<sup>8</sup> See article 15.2.10 of the OIE Code

<sup>9</sup> See "Our strategy 2030" (weblink to 2030 strategy)



*Leptospira* are sensitive to a variety of antibiotics, and treatment of animals or inclusion of antibiotics in prepared semen has traditionally been used to prevent dissemination of *Leptospira* spp. by international trade. The OIE Chapter on collection and processing of bovine, small ruminant and porcine semen specifies which antibiotics can be used. Any of these antibiotics can be used, as long as effective against *Leptospira*.

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

### **3. New Zealand Pork Industry Board (Second Submission)**

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#### **3.1. Part D: Specific Requirements**

**Part D refers to diseases when the rest of the IHS (draft) considers risk management measures for risk organisms.**

**MPI response:** To be consistent within the document Part D could be amended to state risk organisms but diseases are a subset of risk organisms, which is appropriate given the specificity of section C. The term disease is also consistent with the OIE Code.

#### **3.2. General: Paragraph 27**

**It is not clear from assessing all the background the basis on which this list is made. It appears to be a sub-group of diseases which were not considered to require full assessment in the risk analysis, because they were not transmitted in semen.**

**Our recommendations are:**

**Blue eye disease has only ever been recorded in Mexico. It is caused by a rubulavirus which belongs in the paramyxovirus group. However closely related paramyxoviruses have been recorded in Australia, Canada, Japan and Israel. The clinical manifestations of the disease are much wider than blue eyes (corneal opacity), and the name is not an informative one. We recommend the disease is better termed La-Piedad Michoacan paramyxovirus disease, which links it to the causal agent. The agent causes orchitis in boars and reduced semen quality, so presumably is transmissible in semen, but we are not aware of evidence either way.**

**Teschovirus serotype 1 has caused severe outbreaks of encephalitis in several European countries, known as Teschen disease, but the disease has largely disappeared as the virulent form of the virus has been replaced by low path strains. Some of these mild strains are still circulating with uncertain distribution, so we recommend the listing should be Encephalitis caused by Teschovirus serotype 1, rather than just the virus name. The virus is unlikely to enter in semen.**

**Nipah virus is listed, but Menangle virus, a closely linked bat virus, is not listed although it is considered to be a hazard, and is included in the risk analysis. Menangle virus has only occurred in a piggery on one occasion, in Australia, but the virus is endemic in fruit bats. It caused severe reproductive disease in the affected piggery when it occurred in NSW. We recommend that**

Menangle virus as well as Nipah virus should be in the list of diseases in Para 27 for which there should be no outbreaks in the previous 12 months.

We do not understand the rationale for including Venezuelan encephalitis and Vesicular exanthema in Para 27, because neither of these diseases is a risk in this context:

Venezuelan (equine) encephalitis (VEE) can infect pigs, although we are not aware of evidence that the virus can be transmitted in semen. It is closely related to both Eastern and Western equine encephalitis, both of which are endemic in North America. They are considered and concluded not to be a risk in pig semen. Venezuelan encephalitis is endemic in South America but is a virus of wild birds which is spread by mosquitoes to horses and less commonly to pigs. Non-pathogenic VEE viruses circulate in Central and South America, and southern parts of the United States. Virulent strains emerge periodically and cause occasional outbreaks in Central and South America, and rarely in the southern United States. We do not understand why VEE has been specified in this list, when EEE and WEE are not considered relevant risks. We recommend that VEE is removed from Para 27.

Our view is that Vesicular exanthema is an inappropriate disease to include in Para 27. The virus naturally circulates in fish and marine mammals, and is now usually called San Miguel sea lion virus. Outbreaks occurred on the west coast of the US in the 1950s due to feeding of marine mammal meat to pigs, but the disease has not been seen since and is most unlikely to occur because the source of the risk is known. However the virus circulates widely off the US west coast, and elsewhere. The US and Canada are free of the disease on land, but have the virus off-shore. There seems no value in including the disease, and our recommendation is that it is dropped from Para 27.

#### **MPI response:**

The recommendation that Blue Eye disease is better termed La-Piedad Michoacan paramyxovirus disease, and Teschovirus serotype 1 is better termed Encephalitis caused by Teschovirus serotype 1 has been noted.

This series of comments in relation to Paragraph 27 was not included in the original submission on the draft IHS made by NZ Pork.

The RMP that formed part of the consultative package **at the time** stated:

*"This list differs from the IRA, since the IRA has assessed the risk of imported pig semen from only a number of specified countries (Australia, the USA, Canada, the EU and Norway).*

*When drafting the RMP and the IHS, MPI sought to create a fully generic approach (i.e. all hazards, all countries). Consequently, some diseases are included in the RMP and IHS that have been excluded in the IRA solely because they are not endemic to the countries assessed in the IRA.*

*In order to be able to issue generic risk measures for pig semen from all countries, measures for the following diseases have therefore been included:*

*African swine fever (ASF) has been included to align New Zealand's standards with the internationally accepted standards described in The World Organisation for Animal Health Terrestrial Animal Health Code (OIE Code).*

*Foot and mouth disease (FMD) was also included in this RMP. Measures for FMD are in line with New Zealand's IHS for bovine semen.*

*A further 5 organisms were identified in the IRA as organisms of potential concern, but since Australia, the USA, Canada, the European Union and Norway claim*

*freedom for these diseases, no further risk management measures are required for imports into New Zealand from these approved countries.*

*These organisms were:*

*Blue eye disease virus*

*Nipah virus*

*Teschovirus serotype 1*

*Venezuelan encephalitis virus*

*Vesicular exanthema virus*

*Other countries requesting approval under the IHS will either need to be free of these 5 diseases or further risk management measures may need to be determined following a formal risk assessment process”*

Since then, there has been a further risk analysis of these 5 diseases and subsequent minor amendment of the IHS.

The final version of the risk analysis (December 2012) also contains chapters assessing the risks associated with blue eye disease virus, foot and mouth disease virus, Nipah virus, Teschovirus serotype 1, Venezuelan encephalitis virus, and vesicular exanthema virus. Out of these six diseases foot and mouth disease and blue eye disease were concluded to be hazards in porcine semen.

Measures for blue eye disease are included in the RMP and have been incorporated into the IHS.

### 3.3. African swine fever (ASF)

The OIE protocol for SF is very weak. The troubling issue for NZPork is the movement of ASF across Russia, which is now posing a possible threat to the EU. The problem with ASF is the relatively poor diagnostic techniques, which makes inclusion of a testing requirement problematical. Hence the OIE Code section on ASF is much weaker than for other somewhat less serious diseases, and relies entirely on detection of clinical disease. The procedures implicit in 29 would provide little protection in reality, because of the nature of this disease. Our recommendation is to delete Para 29, and only import from ASF-free countries, which will be the reality anyway.

**MPI Response:** The original submission from NZPork made no comment on ASF. The IRA for pig semen noted that there is no evidence that ASF is found in semen of infected boars. MPI considers the OIE code to be adequate.

### 3.4. Aujeszky's disease (AD)

The protocol for Aujeszky's disease in the OIE Code requires four-monthly testing of all boars in the AI Centre with negative results, plus testing of donor boars within 10 days before collection or up to 21 days afterwards. Our recommendation is that the requirement is changed to 21 to 50 days afterwards to provide a more effective risk management measure because this will enable identification of any boar that is viraemic at time of semen collection. It also provides consistency with the testing requirement for other diseases (e.g. PRRS).

**MPI response:** The original submission from NZPork recommended that the third option in the HIS be removed and indicated strong support for the first 2 options, which reflect the OIE

code. MPI agrees. MPI considers that this new submission does not present adequate justification for imposing measures over and above the OIE code. There is nothing to prevent semen collection centres aligning the timing of testing for AD with that for PRRS as indicated

### **3.5. Bovine viral diarrhoea (BVD-2)**

**The protocol for BVD-2 requires national freedom from BVD2 or testing at least 21 days after collection of the semen batch for NZ, with negative results. Our recommendation is that the testing period be 21 to 50 days, as for AD and PRRS, for the reasons covered above - to set a range during which any animals infected and excreting virus at the time of semen collection would become seropositive.**

**MPI response:** The original submission from NZPork did not make any comment on measures for BVD. By stipulating measures for BVD-2, the IHS already goes above the OIE code, based on the risk analysis. There is nothing to prevent semen collection centres aligning the timing of testing for BVD with that for PRRS as indicated.

### **3.6. Foot and Mouth Disease (FMD)**

**The draft risk management measure permits semen to be collected from a zone which is FMD-free without vaccination, within a FMD-infected the country. Our recommendation is to delete "or zone" from Para 36, and require Para 37 to be used for such zones.**

**MPI response:** This comment was not included in the original submission. MPI supports the OIE process for determining zone freedom from FMD without vaccination.

### **3.7. Japanese encephalitis (JE)**

**JE is an insect-borne virus which is widespread in Asia and has occurred in the northern tip of Australia. Our recommendation is that the risk management measure in Para 38 is re-worded to be "Donor boars have been resident for their entire lives in a country or zone that is free from JE". This is because there is no recognition of the term "region" in the OIE code.**

**MPI response:** This comment was not included in the original submission from NZPork. The risk analysis discussed the rare occurrence of this virus in some parts of northern Australia, and the word 'region' was used in that context. However as 'zone' does have an official meaning under the OIE it may be a more appropriate word to use. MPI accepts this comment.

### **3.8. Porcine myocarditis (Bungowannah virus)**

**Bungowannah virus is a challenge because its origin is unknown. It has only been identified in pig herds in southern NSW in Australia (in 2003), where it caused mortality in unweaned piglets and stillbirths. A recent (2012) experimental study of infection in weaned pigs produced minimal clinical signs in the pigs, so the disease could occur unnoticed in a herd. We are not aware of any work to determine prevalence of infection by this virus outside the known infected group of herds and those receiving semen from them. Information provided from Australia by way of a letter (March 2010) suggests**

it is extremely unlikely that the virus can be spread in semen, and indicates that eradication of the infection from the affected herds was expected to be complete by the end of 2011. This was apparently not achieved.

Our recommendations for risk management measures are to retain Para 39 as stated, delete Para 41 as inconsistent with effective risk management and include a modified Para 40, modified to read: "Donor boars which provide semen are resident in a semen collection centre which does not have boars sourced from a herd which has had evidence of the presence of Bungowannah virus or porcine myocarditis within the last three years."

**MPI response:** It should be noted that pig semen has been imported from Australia for almost 10 yrs since the discovery of this virus, without any measures. As discussed with Frances Clement on 12<sup>th</sup> October 2012 as a result of the first submission from NZPork dated 14<sup>th</sup> May 2012, MPI decided to remove paragraph 42 from the draft HIS. This was made clear in the draft review of that NZPork submission which was given to NZPork at that meeting. MPI also gave NZPork an electronic copy of the revised IHS which unfortunately still contained that paragraph that had been earmarked for deletion (now labelled 39 as a result of other changes) Therefore the comment in 5<sup>th</sup> October NZPork submission referring to paragraph 40 was in fact referring to a paragraph that was removed on the basis of the first PIB submission.

In the first submission NZPork did not support paragraph 42 in isolation and suggested adding a further test. MPI instead added the extra test to 43 as a result of the submission by Bruce Welsh, which NZPork did not support in their first submission.

### 3.9. Porcine reproductive and respiratory syndrome (PRRS)

The requirements for donors from infected countries require clarification because the OIE Code does not specify whether pre-entry tests are to detect antigen or antibody. We recommend that Para 45a should specify that the testing is by a multivalent serum ELISA for PRRS antibodies for both type 1 and 2 strains (i.e. European and American strains), (as is currently specified for Para 45c.)

**MPI response:** This comment was not included in the original submission from NZPork. However MPI agrees and will specify the same multivalent serum ELISA with EU and American antigens for both pre-entry testing (45a) and post-collection testing (45c).

### 3.10. Swine vesicular disease (SVD)

The measure imposed will cause some difficulty in determining national disease status within Europe, because Italy in particular is infected with SVD (several outbreaks in 2012). In Europe it is not easy to determine whether Para 46 can realistically be satisfied, with free movement of pigs. With regard to Para 47: Article 15.4.10 does not provide very effective protection and our recommendation is that Para 47 is deleted, and replaced with an adaptation of Option 3 in the Risk Management Proposal, as follows:

"Where the requirements of paragraph 46 cannot confidently be satisfied, at least one semen sample from every donor boar be tested by a MAF approved PCR, with a negative result required".

**MPI response:** This comment was not included in the original submission and contravenes NZ Pork's earlier submission which supported options 46 and 47 but not 48 (which MPI removed). Country freedom in accordance with the OIE code requires demonstration that SVD has not been present for two years. If the exporting competent authority cannot reliably attest this outcome then option 47 applies.

### 3.11. Transmissible gastroenteritis virus (TGE)

The IHS requires in Para 21 that semen must be collected etc in accordance with the OIE Code. Part D requires compliance with Chapters 4.5 and 4.6 of the OIE Terrestrial Code in relation to a number of diseases, but no mention is made of TGE. However Article 4.6.4 requires risk management measures to be implemented for TGE in accordance with Article 15.5.4, if the country or zone is not free of TGE. Article 15.5.4 requires (inter alia) testing for TGE at least 14 days after collection for frozen semen, unless TGE is notifiable and no clinical disease has been recorded for the last three years. The risk analysis reports TGE as present in USA, Canada and Europe, and therefore the testing requirement would apply unless specifically excluded. The risk analysis concludes (on the absence of evidence rather than evidence of absence) that TGE virus is not transmitted in semen, and therefore no risk management measures are required.

TGE is a serious disease. At present the draft IHS implicitly requires TGE testing for boars in infected exporting countries in order to comply with Article 4.6 of the Code, but does not make this explicit. Our recommendation is that that TGE testing for donor boars is made explicit, by requiring that the TGE protocol in 15.5.4 in the OIE Code is followed.

#### **MPI response:**

This comment was not included in the original submission from NZPork.

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

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

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

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

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

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

## **4. Australian Government, Department of Agriculture, Fisheries and Forestry**

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### **4.1 Laboratory approved or endorsed by the Competent Authority**

**The Australian Government Department of Agriculture, Fisheries and Forestry (DAFF) (the competent authority certifying the export) does not approve or endorse laboratories. As an alternative, the National Association of Testing Authorities (NATA) accreditation is suggested.**

#### ***MPI response:***

When veterinary certificates are discussed during bilateral negotiations MPI will adopt the wording as per the veterinary certificates for bovine germplasm from Australia “All required laboratory testing must be conducted at a laboratory accredited by the National Association of Testing Authorities (NATA)”, provided these laboratories are accredited for export testing.

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

**Australia seeks clarification about the requirement “in accordance with the OIE Code”, noting that the OIE Code includes the testing requirement of donor boars in Section 4.6.4 for all the diseases listed. Australia would suggest that certification of country freedom should preclude testing for diseases not present in Australia.**

#### ***MPI response:***

MPI accepts that requirements for testing in accordance with the OIE Code Chapter 4.6.4 will be excluded when a country freedom claim is recognised for a specific disease. Other requirements for semen collection, processing, storage and transport need to comply with the OIE Code chapter 4.5 and 4.6.

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

**Australia notes that previously the IHS had detailed requirements for semen collection location, standards, approval and operation. These appear to be replaced by references to in accordance with the OIE Code. Australia will need clarification of specific requirements before finalising veterinary certificates based on this IHS.**

#### ***MPI response:***

In line with the import health standards for bovine germplasm, certification of requirements in accordance with the OIE Code is required. Where these requirements cannot be met and equivalence is required, MPI will consider approval of similar systems or measures or more detailed requirements in the bilateral negotiation phase of veterinary certificates.

### **4.4 Country freedom from blue eye disease**

**This disease has only been reported from Mexico and is therefore not present in countries approved to export pig semen to New Zealand. It was not identified as a hazard in the New Zealand Import risk analysis: Pig semen from Australia, the USA, Canada, the European Union, and Norway (January 2011). The disease is not notifiable in Australia and it is suggested that the disease is deleted from this clause.**

***MPI response:***

MPI accepts freedom from this disease in Australia and will not incorporate this requirement in the negotiated veterinary certificate for importation of pig semen from Australia to New Zealand.

**4.5 Regional freedom from Japanese encephalitis**

**As part of bilateral negotiations Australia will certify to State/Territory freedom as the basis of regional freedom.**

***MPI response:***

Noted

## **5. Canada - CFIA**

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**5.1 As currently drafted, the cumulative effect of the testing required to meet New Zealand's Import Health Standard would be prohibitive for the Canadian Industry.**

***MPI response:***

Noted. MPI believes that the risk management measures proposed for the IHS manage, to an acceptable level, the biosecurity risks posed by the import of pig semen into New Zealand

**5.2 See Appendix 1 for full text.**

**Teschovirus type I: As a result of the pervasive nature of this disease, Canada suggests that New Zealand remove the requirement for the exporting country to remain free from Teschovirus type I for the past 12 months.**

**In addition, Canada seeks clarification as to whether serological surveys have been performed in New Zealand to determine its status of PTV-1, including any risk analysis, and/or national control/eradication programs that may have been implemented.**

***MPI response:***

MPI accepts this disease is of no concern in Canada and will not incorporate this requirement in the veterinary certificate for importation of pig semen from Canada to New Zealand.

**5.3 See Appendix 1 for full text.**

**Canada requests that New Zealand not require Canada to test for B.suis biovars 1, 2 and 3 prior to export.**

***MPI response:***

All equivalences and disease freedom claims will be assessed during country-country bilateral negotiations of the approved veterinary/export certificate.

**5.4 See Appendix 1 for full text.**

**Canada suggests that New Zealand consider adding the requirement that "Boars are housed in closed barn systems with adequate biosecurity protocols that prevent the transmission of BVDV-2 from the ruminant" as an**



option in the Import Health Standard. Canada would be pleased to provide more information on the biosecurity measures in place in Canada to prevent the transmission of BVDV-2 to boars should New Zealand find this helpful. Canada also seeks clarification as to whether serological surveys have been performed in New Zealand to determine its status of BVD-2, including any risk analysis, and/or national control/eradication programs that may have been implemented.

***MPI response:***

All equivalences and disease freedom claims will be assessed during country-country bilateral negotiations of the approved veterinary/export certificate.

Please see response 1.5.

**5.5 See Appendix 1 for full text.**

Canada believes that the test requirements proposed by New Zealand for PRRS are excessive and go beyond what is necessary when sourcing swine from PRRS-free herds. Canada requests that New Zealand include a combination of biosecurity/herd health and Government verification as an option for export to New Zealand. Canada would be pleased to provide more information on the programs in place to ensure herd health should New Zealand find this helpful.

***MPI response:***

All equivalences and disease freedom claims will be assessed during country-country bilateral negotiations of the approved veterinary/export certificate.

The draft documents that went out for targeted consultation contained considerably stricter measures than we currently propose. After stakeholders had commented during targeted consultation on the daily testing of all boars in the semen collection centre, we took that requirement out. We have also changed the daily testing of donor boars to twice while in the semen collection centre. We have reduced the period post collection to 21 to 50 days.

## **6. PIC New Zealand**

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### **6.1 Role of the Certifying Herd Veterinarian**

In previous IHS's for New Zealand there used to be a Veterinary Certificate A and B to be completed. This required both the official certifying veterinarian and the herd veterinarian (who is familiar with the herd of origin and the species in question) to provide a degree of certification with respect to the absence of clinical disease in the donor sow herds supplying boars to the boar stud. We note that this is not included in the current Draft IHS. We consider this to be a backwards step. We do not believe that any less emphasis should be placed on the official veterinarian's certification or testing regime, but we do believe that the herd veterinarian provides further confidence with respect to disease freedom, particularly with reference to PRRS and most certainly with respect to pigs which are a specialised species. Laboratory testing is not infallible for a number of reasons so an experienced professional assessment of a herd's health status all helps to

**increase the level of confidence in disease freedom and the risks of that not being the case. The donor herd is one of the most likely routes of entry of PRRS or other infectious agents into the stud and this risk could easily be managed better.**

***MPI response:***

Point 17 of the draft IHS states:

“Pig semen must be collected, handled, prepared, processed and stored at semen collection centres approved for export by the Competent Authority. Semen collection centres must be subject to regular inspection by an Official Veterinarian and must be under the supervision of a semen collection centre veterinarian approved by the Competent Authority. The name and approval numbers of these semen collection centres must be recorded on the veterinary certificate”.

Point 20 of the draft IHS states:

“The approved semen collection centre veterinarian is responsible for ensuring that, on the day(s) of collection of the semen, the health status of each donor is monitored and recorded, and the donor does not show any clinical evidence of infectious diseases transmissible in semen”.

Point 21 of the draft IHS states:

“Semen must be collected, handled, prepared, processed and stored under the supervision of the approved semen collection centre veterinarian and in accordance with the World Organisation for Animal Health Terrestrial Animal Health Code (OIE Code)”.

The above clauses in the draft IHS require both the semen collection centre veterinarian and the official veterinarian to be involved in ensuring only healthy donor animals enter the semen collection centre.

## **6.2 Porcine Myocarditis (Bungowannah Virus)**

**This is a relatively new disease caused by a novel pestivirus around which there is very little understanding at the time of writing. This disease, when it enters a naïve herd, brings very substantial economic losses. During the acute phase piglet losses have been very large and, as we understand it, they ensue if the naïve sow is infected at most stages of gestation. Even in the endemically stable herd a low incidence of the disease persists and results in elevated piglet mortality on an ongoing basis.**

**We note that you consider use of antibody positive antigen negative boars as donors to be adequate risk mitigation. We consider this to be a premature position to take with this relatively poorly understood disease. Field evidence from one infected supplier of semen in Australia is not adequate science to support this position, albeit over a large number of semen doses supplied from the infected herd to negative farms. Failure to transmit the virus in this model may be partly due to good fortune rather than proof of concept. There are still too many unanswered questions such as whether the disease can transmit in semen from a viraemic boar (other pestiviruses do), whether recrudescence and further viral shedding could occur if the boars became immunosuppressed for any reason (e.g. a mycotoxin or nutritional challenge), test sensitivity and specificity (and ongoing validation of the test), errors in administration and recording of individual pigs entering stud and their laboratory results etc. Until there is robust science around these**

issues we do not believe that MAF should take this unnecessary risk. If the currently infected company wish to send semen to New Zealand (they have always been able to and have not done so) they may be able to source semen from negative breeding populations. There is no benefit to anyone from MAF taking this uncertain and unnecessary risk at this time.

**MPI response:**

Please also see response 2.6, 3.8 and 7.1

## **7. Bruce Welch (PVS Ltd)**

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- 7.1** Attached is a recent publication on the above virus (see Appendix 1). I note that in chronically infected pigs (infected in utero during certain periods of gestation) seroconversion can occur as late as 6 months of age and virus shedding can continue for 2-5 months after that. This coincides with the age of boars going into stud and getting collected for commercial semen production.

The risk that this virus shedding could be intermittent towards the end cannot be discounted. Also do we know the sensitivity or limit of detection of the current antigen test? Several other viruses are infective below the limit of detection (such as PRRS as you would be well aware). Such animals would be tested as “antigen negative” and make it into stud under your proposed protocol and if this pestivirus has similarities with CSF then it may well transmit in semen.

It seems to me that building an import protocol around anecdotal field evidence and a letter from another state Veterinarian is excessively and unnecessarily risky in this situation and does not consider the fact that understanding of the epidemiology of this virus is still very much in its infancy. Hence I believe you should re-consider your position on “antigen negative antibody positive boars” as suitable donors to send semen to NZ. If you insist on keeping this open perhaps the IHS should require that any donor boar should have had at least 3 tests over the 6 month period before collection with all 3 of them showing that he is antigen negative, antibody positive. Personally I think the knowledge gap is too big to take risks with it.

**MPI response:**

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) shows that long term carriage is possible It illustrates that PMC can be considered very similar in behaviour to other pestiviruses (eg. BVD, CSF).

Finlaison (2012 and 2009) 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.”*

PROVISIONAL

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# Appendix 1: Copies of Submissions

## European Union

Sent: Saturday, 5 May 2012 1:25 a.m.

Subject: EU comments on G/SPS/N/NZL/474

### COMMENTS OF THE EUROPEAN UNION TO THE NOTIFICATION G/SPS/N/NZL/474 SUBMITTED BY NEW ZEALAND RELATED TO IMPORT HEALTH STANDARD FOR PORCINE SEMEN.

The European Union (EU) would like to thank New Zealand for notification G/SPS/N/NZL/474 and for the opportunity to comment on the Import Health Standard for porcine semen.

The EU would like to transmit the following comments and questions on the content of the aforementioned text on the basis of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE Code) and the arrangements laid down in the EU-New Zealand Agreement ("Agreement between the European Community and New Zealand on sanitary measures applicable to trade in live animals and animal products"<sup>1</sup>, as approved by Council Decision 97/132/EC<sup>2</sup>).

#### COMMENTS ON PORCINE SEMEN:

| NZ Import Health Standard on porcine semen   | OIE Code/EU-NZ Agreement   | EU request to NZ   |
|--|--|--|
| Part A, Point 4<br>Scope of the Import Health Standard   |  | <ul style="list-style-type: none"><li>to delete requirements concerning post collection testing for BVD-2 and PRRS in Part C or provide options waiving those requirements in case of fresh semen.</li></ul> Or <ul style="list-style-type: none"><li>to change the scope of the Import Health Standard.</li></ul> <p><u>Rationale:</u><br/>Porcine semen is mostly traded as fresh semen. Therefore requirements concerning post-collection testing, restrict exports of porcine semen to New Zealand to frozen semen only.</p> |
| Part B, Point 12(c)<br>Documentation accompanying the consignment  | Annex V to the EU-NZ Agreement   | <ul style="list-style-type: none"><li>to delete the requirement as it creates huge administrative burden.</li></ul> <p><u>Rationale:</u><br/>Based on the principles of the EU-NZ Agreement</p>  |
| Part B, Point 16.<br>Donor eligibility   | EU-NZ Agreement  | <ul style="list-style-type: none"><li>to change "in the exporting country for at least 90 days" for "within the European Union for at least 90 days".</li></ul> <p><u>Rationale:</u><br/>The recognition of the EU as whole in the EU-NZ Agreement.</p>  |
| Part C, Point 27.<br>Country freedom <ul style="list-style-type: none"><li>Blue eye disease</li><li>Teschovirus serotype 1</li><li>Vesicular exanthema</li></ul> | The OIE Code does not provide any requirements as regards those diseases | <ul style="list-style-type: none"><li>to delete blue eye disease, Teschovirus serotype 1 and vesicular exanthema.</li></ul> <p><u>Rationale:</u></p> <ul style="list-style-type: none"><li>OIE does not consider those diseases to be a risk;</li><li>Not in the OIE listed diseases.</li></ul>  |
| Part C, Points 33-34.<br>Bovine viral diarrhoea  | The OIE Code does not provide any standards for trade in                 | <ul style="list-style-type: none"><li>to delete from Point 35 the requirement concerning country freedom of BVD-2;</li></ul>   |

<sup>1</sup> OJ L 57, 26.2.1997, p. 5.

<sup>2</sup> OJ L 57, 26.2.1997, p. 4.

| NZ Import Health Standard on porcine semen                                    | OIE Code/EU-NZ Agreement   | EU request to NZ   |
|---|--|--|
| (BVD-2)   | domestic pigs and semen of domestic pigs as regards this disease<br><br>Annex V to the EU-NZ Agreement       | <ul style="list-style-type: none"> <li>to delete Point 37 concerning testing for BVD-2.</li> </ul> <p><u>Rationale:</u></p> <ul style="list-style-type: none"> <li>OIE does not consider this disease to be a risk as regards pigs;</li> <li>Not an OIE listed disease as regards pigs;</li> <li>OIE Code does not require testing of pigs for BVD-2.</li> <li>NZ should provide information on the presumption that NZ is free of the BVD-2 in pigs.</li> </ul>   |
| Part C, Points 44-45.<br>Porcine reproductive and respiratory syndrome (PRRS) | No Chapter in the OIE Code setting up standards as regards that disease<br><br>Article 4.6.4 of the OIE Code | <ul style="list-style-type: none"> <li>criteria for country freedom should be provided;</li> <li>to delete point 45(c);</li> <li>to add the following option:<br/><br/>"Or<br/>Semen originates from a semen collection centre that complies with OIE Code Chapters 4.5 and 4.6."</li> </ul> <p><u>Rationale:</u></p> <ul style="list-style-type: none"> <li>No Chapter on that disease the OIE Code;</li> <li>Article 4.6.4 of the OIE Code provides that boars shall be tested negative for PRRS using a test compliant with the standards of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual) during the quarantine period of at least 28 days and, at least 21 days after entering the quarantine station, followed by an annual test on resident boars in the semen collection centre.</li> </ul> |

The EU would like to thank New Zealand for the opportunity to comment on its Import Health Standard and asks for its comments to be taken into consideration.

# New Zealand Pork Industry Board (First submission)

Sent: Mon 14/05/2012 4:58 p.m.

Subject: Pig semen draft border standards



14 May 2012

Animal Imports: Pig Semen Consultation  
Animal & Animal Products Directorate  
Standards Branch  
Ministry for Primary Industries  
PO Box 2526  
WELLINGTON

Via email: [animalimports@maf.govt.nz](mailto:animalimports@maf.govt.nz)

Dear Sirs

## Pig Semen Consultation

### Reason for making submission

The New Zealand Pork Industry Board (NZPork) is a producer board funded by pork producers (farmers) in New Zealand.

NZPork's activities are governed by the Pork Industry Board Act 1997.

NZPork's object is set out in Section 5 of that Act. This section requires the Board to:

- "Help in the attainment, in the interests of pig farmers, of the best possible net on-going returns for pigs, pork products and co-products.
- In pursuing its object the Board must have regard to the desirability of the pork industry's making the best possible net on-going contribution to the economy."

As required by its statutory responsibility to act in the interests of pig farmers to assist in their attainment of best possible net on-going returns, NZPork must carefully assess the impact of imported semen on the health status of its pig herd.

### Submission

The current consultation step follows on from earlier consultations.

This consultation step concerns the suite of documents described as:

- Draft Import Risk Analysis: Pig semen from Australia, the USA, Canada, the European Union, and Norway (January 2011)
- (Draft) Risk Management Proposal for Pig Semen (9 March 2012)
- (Draft) Guidance document for Importing Pig Semen (9 March 2012)
- (Draft) Import Health Standard for Pig Semen (9 March 2012)

NZPork has provided earlier input in particular: in regard to draft IRA (November 2009) and in regard to proposed risk management options (February 2010).

Our comments overleaf pertain to the risk management options presented within the (Draft) Import Health Standard for Pig Semen.

New Zealand Pork Industry Board

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PROVISIONAL

## **Part B. General Requirements**

### ***Approved Countries***

Countries are listed in the (Draft) Guidance Document based on claim of freedom from a number of hazards. The competent authority is required to attest freedom from these hazards within a Veterinary Certificate accompanying pig semen to be imported into New Zealand. We support this requirement.

How does MPI verify that the list with claims of freedom is current? What requirements are in place to require potential source countries to notify New Zealand of change in their health status?

### ***Laboratory testing, Donor eligibility, Semen collection centre requirements, Donor and semen collection centre health status, Semen collection, processing, storage and transport***

Is the effect of these general requirements to ensure that boar collection centres meet all the requirements of the OIE Code for collection centres? We recommend that this is the requirement and it should be stated as such.

We support the requirement for supervision at the collection centre by a semen collection centre veterinarian in addition to regular inspection by an Official Veterinarian.

## **Part C. Specific Requirements**

### ***Aujeszky's Disease***

We support the risk management measures set out in 30 and 31.

We do not support 32. We strongly recommend the appropriate requirements are those set out in OIE chapters 4.5 and 4.6; which are shown as 30 and 31.

### ***Classical Swine Fever***

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.

### ***Porcine myocarditis***

We support the risk management measure set out in 41.

We do not support 42 in isolation: this has the effect of accepting semen from animals whose health status is unknown. Absence of clinical disease is not an acceptable risk management strategy. We strongly recommend 42 requires the addition of negative testing prior to entry into the boar stud as per the OIE schedule for CSF.

We do not support 43.

### ***Porcine reproductive and respiratory syndrome***

We support the risk management measure set out in 44.

In regard to the risk management measure set out in 45:

- a. This needs to better clarify that it is the semen collection centre that is described in chapter 4.6 of the OIE Code. What is the test referred to, to demonstrate PRRS freedom prior to entry to the semen collection centre? There is no reference to tests in the OIE Code.
- b. What does 'collection' period mean?
- c. Requires a minimum of 30 days to provide appropriate assurance of PRRS freedom, given the acknowledged challenge to keep sites free from PRRS.

*Swine vesicular disease (SVD)*

We support the risk management measures set out in 46 and 47.

We do not support 48. This has the effect of accepting semen from a SVD positive country or zone on the basis of direct testing. We strongly recommend the appropriate requirements are those set out in the OIE Code.

*Leptospira*

We have reservations about this risk management measure. More specificity would help (e.g. reference to specific antibiotics and inclusion rates). As stated this is too general to provide assurance of risk management unless also supported by direct testing.

Thank you for the opportunity to contribute.

Regards



Frances Clement  
Policy and Issues Manager

# New Zealand Pork Industry Board (Second submission)

Sent: Friday 05/10/2012.



October 5 2012

## Response to Pig Semen IHS (draft) and Review of NZPork Submission (draft)

Thank you for the opportunity to review these documents. We have a number of comments covered here, based on careful review by our technical advisers. We apologise that this review and comments was not provided during the earlier consultation – due to the unavailability of one of our advisers at that time.

Our comments are:

### Part D: Specific Requirements

Part D refers to diseases when the rest of the IHS (draft) considers risk management measures for risk organisms.

### General Para 27

It is not clear from assessing all the background the basis on which this list is made. It appears to be a sub-group of diseases which were not considered to require full assessment in the risk analysis, because they were not transmitted in semen.

Our recommendations are:

- Blue eye disease has only ever been recorded in Mexico. It is caused by a rubulavirus which belongs in the paramyxovirus group. However closely related paramyxoviruses have been recorded in Australia, Canada, Japan and Israel. The clinical manifestations of the disease are much wider than blue eyes (corneal opacity), and the name is not an informative one. We recommend the disease is better termed La-Piedad Michoacan paramyxovirus disease, which links it to the causal agent. The agent causes orchitis in boars and reduced semen quality, so presumably is transmissible in semen, but we are not aware of evidence either way.
- Teschovirus serotype 1 has caused severe outbreaks of encephalitis in several European countries, known as Teschen disease, but the disease has largely disappeared as the virulent form of the virus has been replaced by low path strains. Some of these mild strains are still circulating with uncertain distribution, so we recommend the listing should be Encephalitis caused by Teschovirus serotype 1, rather than just the virus name. The virus is unlikely to enter in semen.
- Nipah virus is listed, but Menangle virus, a closely linked bat virus, is not listed although it is considered to be a hazard, and is included in the risk analysis. Menangle virus has only occurred in a piggery on one occasion, in Australia, but the virus is endemic in fruit bats. It caused severe reproductive disease in the affected piggery when it occurred in NSW. We recommend that Menangle virus as well as Nipah virus should be in the list of diseases in Para 27 for which there should be no outbreaks in the previous 12 months.

- We do not understand the rationale for including Venezuelan encephalitis and Vesicular exanthema in Para 27, because neither of these diseases is a risk in this context:
  - Venezuelan (equine) encephalitis (VEE) can infect pigs, although we are not aware of evidence that the virus can be transmitted in semen. It is closely related to both Eastern and Western equine encephalitis, both of which are endemic in North America. They are considered and concluded not to be a risk in pig semen. Venezuelan encephalitis is endemic in South America but is a virus of wild birds which is spread by mosquitoes to horses and less commonly to pigs. Non-pathogenic VEE viruses circulate in Central and South America, and southern parts of the United States. Virulent strains emerge periodically and cause occasional outbreaks in Central and South America, and rarely in the southern United States. We do not understand why VEE has been specified in this list, when EEE and WEE are not considered relevant risks. We recommend that VEE is removed from Para 27.
  - Our view is that Vesicular exanthema is an inappropriate disease to include in Para 27. The virus naturally circulates in fish and marine mammals, and is now usually called San Miguel sea lion virus. Outbreaks occurred on the west coast of the US in the 1950s due to feeding of marine mammal meat to pigs, but the disease has not been seen since and is most unlikely to occur because the source of the risk is known. However the virus circulates widely off the US west coast, and elsewhere. The US and Canada are free of the disease on land, but have the virus off-shore. There seems no value in including the disease, and our recommendation is that it is dropped from Para 27.

#### **African swine fever (ASF)**

The OIE protocol for ASF is very weak.

The troubling issue for NZPork is the movement of ASF across Russia, which is now posing a possible threat to the EU. The problem with ASF is the relatively poor diagnostic techniques, which makes inclusion of a testing requirement problematical. Hence the OIE Code section on ASF is much weaker than for other somewhat less serious diseases, and relies entirely on detection of clinical disease. The procedures implicit in 29 would provide little protection in reality, because of the nature of this disease. Our recommendation is to delete Para 29, and only import from ASF-free countries, which will be the reality anyway.

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

The protocol for Aujeszky's disease in the OIE Code requires four-monthly testing of all boars in the AI Centre with negative results, plus testing of donor boars within 10 days before collection or up to 21 days afterwards. Our recommendation is that the requirement is changed to 21 to 50 days afterwards to provide a more effective risk management measure because this will enable identification of any boar that is viraemic at time of semen collection. It also provides consistency with the testing requirement for other diseases (e.g. PRRS).

#### **Bovine viral diarrhoea (BVD-2)**

The protocol for BVD-2 requires national freedom from BVD2 or testing at least 21 days after collection of the semen batch for NZ, with negative results. Our recommendation

is that the testing period be 21 to 50 days, as for AD and PRRS, for the reasons covered above - to set a range during which any animals infected and excreting virus at the time of semen collection would become seropositive.

#### **Foot and Mouth Disease (FMD)**

The draft risk management measure permits semen to be collected from a zone which is FMD-free without vaccination, within a FMD-infected the country. Our recommendation is to delete "or zone" from Para 36, and require Para 37 to be used for such zones.

#### **Japanese encephalitis (JE)**

JE is an insect-borne virus which is widespread in Asia and has occurred in the northern tip of Australia. Our recommendation is that the risk management measure in Para 38 is re-worded to be "Donor boars have been resident for their entire lives in a country or zone that is free from JE". This is because there is no recognition of the term "region" in the OIE code.

#### **Porcine myocarditis (Bungowannah virus)**

Bungowannah virus is a challenge because its origin is unknown. It has only been identified in pig herds in southern NSW in Australia (in 2003), where it caused mortality in unweaned piglets and stillbirths. A recent (2012) experimental study of infection in weaned pigs produced minimal clinical signs in the pigs, so the disease could occur unnoticed in a herd. We are not aware of any work to determine prevalence of infection by this virus outside the known infected group of herds and those receiving semen from them. Information provided from Australia by way of a letter (March 2010) suggests it is extremely unlikely that the virus can be spread in semen, and indicates that eradication of the infection from the affected herds was expected to be complete by the end of 2011. This was apparently not achieved.

Our recommendations for risk management measures are to retain Para 39 as stated, delete Para 41 as inconsistent with effective risk management and include a modified Para 40, modified to read: "Donor boars which provide semen are resident in a semen collection centre which does not have boars sourced from a herd which has had evidence of the presence of Bungowannah virus or porcine myocarditis within the last three years."

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

The requirements for donors from infected countries require clarification because the OIE Code does not specify whether pre-entry tests are to detect antigen or antibody. We recommend that Para 45a should specify that the testing is by a multivalent serum ELISA for PRRS antibodies for both type 1 and 2 strains (i.e. European and American strains), (as is currently specified for Para 45c.)

#### **Swine vesicular disease (SVD)**

The measure imposed will cause some difficulty in determining national disease status within Europe, because Italy in particular is infected with SVD (several outbreaks in 2012). In Europe it is not easy to determine whether Para 46 can realistically be satisfied, with free movement of pigs. With regard to Para 47: Article 15.4.10 does not provide very effective protection and our recommendation is that Para 47 is deleted, and replaced with an adaptation of Option 3 in the Risk Management Proposal, as follows:

"Where the requirements of paragraph 46 cannot confidently be satisfied, at least one semen sample from every donor boar be tested by a MAF approved PCR, with a negative result required".

#### **Transmissible gastroenteritis virus (TGE)**

The IHS requires in Para 21 that semen must be collected etc in accordance with the OIE Code. Part D requires compliance with Chapters 4.5 and 4.6 of the OIE Terrestrial Code in relation to a number of diseases, but no mention is made of TGE. However Article 4.6.4 requires risk management measures to be implemented for TGE in accordance with Article 15.5.4, if the country or zone is not free of TGE. Article 15.5.4 requires (inter alia) testing for TGE at least 14 days after collection for frozen semen, unless TGE is notifiable and no clinical disease has been recorded for the last three years. The risk analysis reports TGE as present in USA, Canada and Europe, and therefore the testing requirement would apply unless specifically excluded. The risk analysis concludes (on the absence of evidence rather than evidence of absence) that TGE virus is not transmitted in semen, and therefore no risk management measures are required.

TGE is a serious disease. At present the draft IHS implicitly requires TGE testing for boars in infected exporting countries in order to comply with Article 4.6 of the Code, but does not make this explicit. Our recommendation is that that TGE testing for donor boars is made explicit, by requiring that the TGE protocol in 15.5.4 in the OIE Code is followed.

## Australian Government

Sent: Monday, 14 May 2012 4:31 p.m

Subject: Australian comments on G/SPS/N/NZL/474



## Australian Government

### **Comments from the Australian Government on New Zealand's proposed revision of *Import Health Standard for Pig Semen***

The Australian Government welcomes the opportunity to provide comments on New Zealand's proposed revisions to *Import Health Standard for Pig Semen* as notified by the World Trade Organization notification (G/SPS/N/NZL/474) dated 15 March 2012.

#### **General comments**

Australia notes the proposed revisions are generic and that a veterinary certificate based these measures will be negotiated.

#### **Specific comments on the import health standard for pig semen**

##### **14. Laboratory approved or endorsed by the Competent Authority**

The Australian Government Department of Agriculture, Fisheries and Forestry (DAFF) (the competent authority certifying the export) does not approve or endorse laboratories. As an alternative, the National Association of Testing Authorities (NATA) accreditation is suggested.

##### **21. Semen collection, processing, storage and transport**

Australia seeks clarification about the requirement "in accordance with the OIE Code", noting that the OIE Code includes the testing requirement of donor boars in Section 4.6.4 for all the diseases listed. Australia would suggest that certification of country freedom should preclude testing for diseases not present in Australia.

##### **21.-26. Semen collection, processing, storage and transport**

Australia notes that previously the IHS had detailed requirements for semen collection location, standards, approval and operation. These appear to be replaced by references to in accordance with the OIE Code. Australia will need clarification of specific requirements before finalising veterinary certificates based on this IHS.

##### **27. Country freedom from blue eye disease**

This disease has only been reported from Mexico and is therefore not present in countries approved to export pig semen to New Zealand. It was not identified as a hazard in the New Zealand *Import risk analysis: Pig semen from Australia, the USA, Canada, the European Union, and Norway (January 2011)*. The disease is not notifiable in Australia and it is suggested that the disease is deleted from this clause.

##### **40. Regional freedom from Japanese encephalitis**

As part of bilateral negotiations Australia will certify to State/Territory freedom as the basis of regional freedom.



## Canada

Sent: Tuesday, 15 May 2012 4:25 a.m

Subject: Canadian Comments on SPS/NZL/474

 Canadian Food Inspection Agency    Agence canadienne d'inspection des aliments  
1400 Merivale Rd  
Ottawa, ON K1A 0Y9  
Canada

May 14, 2012

Mrs. Sally Jennings  
Coordinator, SPS New Zealand  
PO Box 2526  
Wellington, New Zealand

**Subject: Government of Canada Comments on World Trade Organization (WTO) G/SPS/N/NZL/474 Import Health Standard for Pig Semen; Risk Management Proposal for Pig Semen**

Dear Mrs. Jennings,

The Government of Canada thanks New Zealand for the opportunity to comment on the above notification, dated March 15, 2012, concerning New Zealand's proposed Import Health Standard and Risk Management Proposal for pig semen.

As you may be aware, Canada provided feedback on the Ministry of Agriculture and Forestry's draft risk assessment in August 2011. Our comments below reflect those that were provided on the draft risk assessment.

As currently drafted, the cumulative effect of the testing required to meet New Zealand's Import Health Standard would be prohibitive for the Canadian Industry.

Teschovirus type 1:

The OIE decision to remove Teschovirus from the Terrestrial Animal Health Code was based on the migration of the pathogenicity of Teschen disease to a less virulent strain of PTV-1. Although initially limited to parts of Europe in the early 1900's, porcine teschoviruses, including PTV-1, are now considered ubiquitous worldwide and conventional pig herds, although clinically free, are unlikely to be serologically free of PTV. Historically, clinical signs of PTV-1 Teschen Disease have never been reported in Canada. However, serological surveys have not been implemented in Canada to search for serotypes of PTV and it is unlikely that these surveys will be implemented in the near future.

As a result of the pervasive nature of this disease, Canada suggests that New Zealand remove the requirement for the exporting country to remain free from Teschovirus type 1 for the past 12 months.



1 of 3

In addition, Canada seeks clarification as to whether serological surveys have been performed in New Zealand to determine its status of PTV-1, including any risk analysis, and/or national control/eradication programs that may have been implemented.

Brucella suis (B. suis):

Canada would like to further clarify our country's status for *B. suis*. *B. suis* biovar 4 (Rangiferine brucellosis), which does not cause brucellosis in swine, has been present in free-ranging caribou and reindeer herds in Arctic and sub-Arctic Canada for a number of decades and was detected for the last time in January 2009. These herds range in areas where livestock is not raised. *B. suis* biovars 1, 2 and 3, which are known to cause brucellosis in swine have never occurred in Canada. As such, Canada requests that New Zealand not require Canada to test for *B. suis* biovars 1, 2 and 3 prior to export.

BVDV-2:

The New Zealand risk analysis and the subsequent proposed Import Health Standard did not appear to take into consideration housing type or proximity of ruminant species that may be carriers of BVDV-2. The trend in Canada for the past 30 years has been to specialize in single species farms. Swine raised in Canada are housed in closed barn systems due to our harsh climate and to facilitate biosecurity protocols. Pigs selected to enter Canadian semen production centres are from high health herds where genetic improvement in their own barns occurs solely through the use of semen or embryos. Additionally, to facilitate biosecurity protocols and herd health, the swine sector prefers to locate their farms in remote locations, which is easily accomplished in Canada. The risk of transmission of BVDV-2 from the ruminant population to the Canadian swine herd is negligible. To address the above noted concern, Canada suggests that New Zealand consider adding the requirement that "Boars are housed in closed barn systems with adequate biosecurity protocols that prevent the transmission of BVDV-2 from the ruminant population" as an option in the Import Health Standard. Canada would be pleased to provide more information on the biosecurity measures in place in Canada to prevent the transmission of BVDV-2 to boars should New Zealand find this helpful.

Canada also seeks clarification as to whether serological surveys have been performed in New Zealand to determine its status of BVDV-2, including any risk analysis, and/or national control/eradication programs that may have been implemented.

PRRS:

Canada is not considered free of PRRS. As you know, large multi-national owned farms in Canada have biosecurity and herd health programs that are universal between their farms. These programs are developed based on the health status requirements of their clients in other countries. All of these companies have programs that include measures to maintain their herds free from PRRS. Canadian industry-owned nucleus herds have also adopted these measures with respect to biosecurity and herd health programs.

Canada takes additional steps to further evaluate (test) and verify freedom from PRRS (review herd program and test history) for donor boars whose semen will be exported to countries that claim PRRS freedom. This combination of on-farm biosecurity/herd health and verification by the Government of Canada has historically been very effective and has always been satisfactory to our trading partners.

Canada believes that the test requirements proposed by New Zealand for PRRS are excessive and go beyond what is necessary when sourcing swine from PRRS-free herds. Canada requests that New Zealand include a combination of biosecurity/herd health and Government verification as an option for export to New Zealand. Canada would be pleased to provide more information on the programs in place to ensure herd health should New Zealand find this helpful.

Canada thanks New Zealand for the opportunity to comment on their proposed Import Health Standard for Pig Semen and Risk Management Proposal for Pig Semen and looks forward to receiving a response to these questions prior to the implementation of the Import Health Standard.

Sincerely,



Daniel Burgoyne

A/Director, Bilateral Relations and Market Access, International Policy

# PIC New Zealand

Sent: Monday, 14 May 2012

Subject: PIC Submission on IHS for Semen 24 April 2012



## **PIC New Zealand**

24 April 2012

PIC New Zealand Ltd  
21 Jipcho Road  
P O Box 348  
Christchurch  
New Zealand  
Tel: +64-3-341 0220  
Fax: +64-3-343 7234  
www.picnz.co.nz

Dear Sir / Madam,

### **Re : Submission on Draft Import Health Standard for Porcine Semen**

PIC New Zealand holds the franchise for PIC International, which is the largest pig breeding company in the world. PIC Internationally places a very great emphasis on health assurance principles and the avoidance of transmission of disease via breeding material.

PIC welcomes MAF's approach to controlling risk while allowing importation of genetic material into New Zealand and the science-based approach taken. In a few areas, however, we would like to see the level of risk reduced.

Following are our concerns with respect to the aforementioned Draft IHS :-

### **Role of the Certifying Herd Veterinarian**

In previous IHS's for New Zealand there used to be a Veterinary Certificate A and B to be completed. This required both the official certifying veterinarian and the herd veterinarian (who is familiar with the herd of origin and the species in question) to provide a degree of certification with respect to the absence of clinical disease in the donor sow herds supplying boars to the boar stud. We note that this is not included in the current Draft IHS. We consider this to be a backwards step. We do not believe that any less emphasis should be placed on the official veterinarian's certification or testing regime, but we do believe that the herd veterinarian provides further confidence with respect to disease freedom, particularly with reference to PRRS and most certainly with respect to pigs which are a specialised species. Laboratory testing is not infallible for a number of reasons so an experienced professional assessment of a herd's health status all helps to increase the level of confidence in disease freedom and the risks of that not being the case. The donor herd is one of the most likely routes of entry of PRRS or other infectious agents into the stud and this risk could easily be managed better.

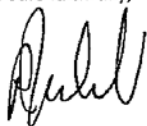
### **Porcine Myocarditis (Bungowannah Virus)**

This is a relatively new disease caused by a novel pestivirus around which there is very little understanding at the time of writing. This disease, when it enters a naive herd, brings very substantial economic losses. During the acute phase piglet losses have been very large and, as we understand it, they ensue if the naive sow is infected at most stages of gestation. Even in the endemically stable herd a low incidence of the disease persists and results in elevated piglet mortality on an ongoing basis.

We note that you consider use of antibody positive antigen negative boars as donors to be adequate risk mitigation. We consider this to be a premature position to take with this relatively poorly understood disease. Field evidence from one infected supplier of semen in Australia is not adequate science to support this position, albeit over a large number of semen doses supplied from the infected herd to negative farms. Failure to transmit the virus in this model may be partly due to good fortune rather than proof of concept. There are still too many unanswered questions such as whether the disease can transmit in semen from a viraemic boar (other pestiviruses do), whether recrudescence and further viral shedding could occur if the boars became immunosuppressed for any reason (e.g. a mycotoxin or nutritional challenge), test sensitivity and specificity (and ongoing validation of the test), errors in administration and recording of individual pigs entering stud and their laboratory results etc. Until there is robust science around these issues we do not believe that MAF should take this unnecessary risk. If the currently infected company wish to send semen to New Zealand (they have always been able to and have not done so) they may be able to source semen from negative breeding populations. There is no benefit to anyone from MAF taking this uncertain and unnecessary risk at this time.

We hope that these observations and concerns will be of value

Yours faithfully,



Peter MacDonald  
GENERAL MANAGER



Dr Bruce Welch  
CONSULTING VETERINARIAN

## **Bruce Welch (PVS Limited)**

*Sent: Friday, 15 June 2012*  
*Subject: Bungowannah virus*

Hi Ellen,

Attached is a recent publication on the above virus. I note that in chronically infected pigs (infected in utero during certain periods of gestation) seroconversion can occur as late as 6 months of age and virus shedding can continue for 2-5 months after that. This coincides with the age of boars going into stud and getting collected for commercial semen production.

The risk that this virus shedding could be intermittent towards the end cannot be discounted. Also do we know the sensitivity or limit of detection of the current antigen test ? Several other viruses are infective below the limit of detection (such as PRRS as you would be well aware). Such animals would be tested as "antigen negative" and make it into stud under your proposed protocol and if this pestivirus has similarities with CSF then it may well transmit in semen.

It seems to me that building an import protocol around anecdotal field evidence and a letter from another state Veterinarian is excessively and unnecessarily risky in this situation and does not consider the fact that understanding of the epidemiology of this virus is still very much in its infancy. Hence I believe you should re-consider your position on "antigen negative antibody positive boars" as suitable donors to send semen to NZ. If you insist on keeping this open perhaps the IHS should require that any donor boar should have had at least 3 tests over the 6 month period before collection with all 3 of them showing that he is antigen negative, antibody positive. Personally I think the knowledge gap is too big to take risks with it

If you are not aware how financially devastating this disease can be I would be happy to send you further information

Thanks and Regards

Bruce

**Dr. Bruce Welch**

Veterinarian

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**Experimental Bungowannah virus infections in weaner pigs and pregnant sows – virology and serology studies**DS Finlaison<sup>1</sup>, KR King<sup>1</sup>, PD Kirkland<sup>1</sup><sup>1</sup>*Virology Laboratory, Elizabeth Macarthur Agricultural Institute, Camden, NSW Australia  
deborah.finlaison@dpi.nsw.gov.au***Introduction**

Bungowannah virus is a pestivirus identified from an outbreak of disease on a piggery in New South Wales, Australia in June 2003<sup>1,2</sup>. The aims of the studies described in this paper were to compare viraemia levels, viral excretion and the serological response in pigs infected post-natally or *in utero* with Bungowannah virus, and determine if persistent or chronic infections occur.

**Materials and Methods**

During studies of post-natal and *in utero* infection with Bungowannah virus the host-pathogen interaction was also investigated<sup>1</sup>. Virus loads and virus excretion were monitored by real-time RT-PCR and serological responses by peroxidase linked assay and virus neutralisation test. In the first study, 30 weaner pigs were challenged with one of six doses of Bungowannah virus and the infectious dose determined. In the second study 23 pregnant pigs were challenged with Bungowannah virus at approximately 35, 55, 75 or 92 days gestation.

**Results**

Following infection of weaner pigs, viraemia and viral excretion were detected from 3 days post-inoculation and seroconversion from 10 days post-inoculation. Viral shedding was greatest and most frequently detected in oropharyngeal and nasal secretions, and generally detected in lower amounts and less frequently in conjunctival secretions and faeces. Seroconversion was associated with a marked reduction in viraemia and viral excretion and chronic infections like those seen in some cases of classical swine fever were not observed.

The foetuses from 20/23 of the challenged dams became infected. With the exception of one piglet, all foetuses within these 20 litters were infected and all foetuses were still viraemic at birth regardless of the stage of gestation at which infection had occurred or whether the foetus had mounted a humoral immune response to the virus. Few foetuses developed antibodies after infection at 35 days of gestation whereas all foetuses infected at 75 days were seropositive at birth. Post-natally, Bungowannah virus was cleared most rapidly from the progeny of dams infected at approximately 92 days gestation. Persistently and 'chronically' infected pigs were identified following infection of the dam at 35 and 55 days gestation respectively. The 'chronically' infected pigs seroconverted at a variable but lengthy time after birth (up to 180 days).

The mean viral load in serum and oropharyngeal fluid in piglets at birth following *in utero* infection was typically

≥100 times greater than the peak observed in post-natally infected pigs. Bungowannah virus was also detected at higher levels in faecal swabs of pigs infected *in utero*. Viral excretion was maintained at high levels in persistently infected pigs or until seroconversion in 'chronically' infected pigs. In persistently and 'chronically' infected pigs there was a decrease in the level of viraemia with the ingestion of maternal antibodies which subsequently increased again as maternal antibodies waned. After seroconversion in the 'chronically' infected pigs, viraemia and virus shedding reduced or ceased over a period of 2-5 months.

**Conclusions and Discussion**

These studies show that the course of infection following post-natal infection with Bungowannah virus is typical of most other pestiviruses with viraemia and viral excretion resolving after seroconversion. Following *in utero* infection prolonged infections are observed despite a serological response by the foetus. In addition, persistent and 'chronic' infections also occur following infection in early gestation. *In utero* infection, and the consequences of this, is the greatest source of environmental contamination by Bungowannah virus.

**Acknowledgements**

Funding was generously provided by Australian Pork Limited, the Australian Biosecurity Cooperative Research Centre for Emerging Infectious Disease and NSW Department of Primary Industries under Project No. 2188.

**References**

1. Finlaison DS et al.: 2012, these proceedings.
2. McOrist S et al.: 2004, Aust Vet J 82:509.