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

January 2017

Contact:

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

Contents

Introduction and background **3**
Introduction 3
Background 3
Concerns with generic approach **3**
OIE importation recommendations for porcine semen* **6**
Key features of OIE importation recommendations **7**
MPI list of recommendations for risk mitigation for non-OIE listed agents **13**
General concerns not included in tracked comments above **13**
Recommendations **15**
Appendix 1. Relevant OIE definitions from the Terrestrial Code **18**
Appendix 2. OIE Terrestrial Code relevant chapters **19**
Chapter 4.5: General hygiene semen collection and processing centres 19
Article 4.5.1. General considerations 19
Article 4.5.2. Conditions applicable to artificial insemination centres 19
Article 4.5.3. Conditions applicable to semen collection facilities 19
Article 4.5.4. Conditions applicable to semen laboratories 20
Article 4.5.5. Conditions applicable to the management of bulls, rams, bucks and boars 20
Chapter 4.6 Collection and processing of bovine, small ruminant and porcine semen 20
Article 4.6.1. General considerations 20
Article 4.6.2. Conditions applicable to testing of bulls and teaser animals 20
Article 4.6.3. Conditions applicable to testing of rams/bucks and teaser animals 22
Article 4.6.4. Conditions applicable to testing of boars 23
Article 4.6.5. General considerations for hygienic collection and handling of semen 24
Article 4.6.6. Conditions applicable to the collection of semen 24
Article 4.6.7. Conditions applicable to the handling of semen and preparation of semen samples in the laboratory 24

Introduction and background

Introduction

This submission is made by NZPork on behalf of New Zealand's commercial pig farmers, with technical input from and also on behalf of the industry's veterinarians, all of whom have substantial international experience with a number of the exotic diseases assessed in this suite of documents.

The New Zealand pig industry is a highly productive livestock sector, well integrated within New Zealand's primary production economic base. Its productivity is enhanced by New Zealand's high pig herd health and welfare status, and its focus on genetic improvement. Its high herd health and welfare status are very highly valued by the commercial industry, as evidenced by NZPork's early commitment to partner within GIA (Government Industry Agreement) with the over-arching goal of delivering better biosecurity for the industry and New Zealand. Pig semen importation is a significant pathway for incursion of an exotic disease into New Zealand, either within the commercial industry, where the industry structure would enable rapid dissemination within the commercial pig herd; or within the non-commercial sector where pig ownership is largely unknown and largely unregulated, and which exists geographically alongside the commercial herd, a significant proportion of which are outdoor breeding farms.

Background

As Ministry for Primary Industries (MPI) explained in its draft Risk Management Proposal, MPI's current strategy is to create a fully generic approach (i.e. all hazards, all countries) to import health standards. A generic IHS was completed for semen in 2013 (PIGSEMIC.GEN) but the OIE Terrestrial Animal Health Code (the Code) requirements for swine vesicular disease and Brucella spp. have since changed and MPI has also raised specific concerns with regard to risk management measures for bovine viral diarrhoea virus, necessitating a review of the IHS.

MPI has thus released a full suite of draft documents (draft risk management proposal, draft import health standard, draft guidance document, and draft guidance document on recognition of export controls and certification systems for animals and animal products) for consultation.

Note that despite the confirmation of PIGSEMIC.GEN in 2013, to date no veterinary certificates have been issued under PIGSEMIC.GEN and current trade in pig semen is only possible under previously existing IHSs:

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

Concerns with generic approach

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

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

- Not all exotic diseases important to New Zealand are OIE listed and therefore need to have specific requirements developed anyway.
- New Zealand is a committed member of OIE and supports its overall objectives for international animal health. But it does not always follow that New Zealand supports a particular OIE recommendation that has been confirmed by a majority process. This may be due to New Zealand's internationally very high animal health status which is critical economically for its ability to trade. For example, the consequences of an FMD

incursion on New Zealand's economy relative to the effect of the disease in other countries not dependent on dairy and meat is likely to be far higher. It may also be due to unique characteristics of the New Zealand landscape. For example, in New Zealand the population of backyard and non-commercial pigs is unknown and largely uncontrolled, is likely to feed food waste, and exists alongside the commercial pig herd.

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

Risk assessments in the IHS context must consider factors related to an agent as they pertain to:

- Release: the biological pathway(s) necessary for an importation activity to 'release' (that is, introduce) pathogenic agents into a particular environment (i.e. Biological factors, Country factors, and Commodity factors).
- Exposure: the biological pathway(s) necessary for exposure of animals and humans in the importing country to the hazards (in this case the pathogenic agents) released from a given risk source (Biological factors, Country factors, and Commodity factors).
- Consequence: the relationship between specified exposures to a biological agent and the consequences of those exposures (Direct consequences and Indirect consequences).

The OIE recommendations have been developed primarily based on risk factors related to Release with little to no focus on risk factors related to Exposure and/or Consequence. Thus, it is crucial that New Zealand's IHSs must be preceded by New Zealand's own risk assessment to ensure appropriate consideration is also given to Exposure and Consequence.

OIE is a complex organisation seeking to find consensus amongst a large number of countries, each attempting to balance their own perspectives with the available scientific evidence with regard to development of standards for ensuring safe international trade in animal products. Over time, these competing desires result in an accumulation of complexities and inconsistencies (i.e. negotiated work-arounds to facilitate specific trade situations) in the recommendations, usually through development of special conditions for a zone, compartment, artificial insemination (AI) centre, or establishment. Further, there is often 'nesting' of these various categories within the recommendations as well as 'disease specific variations' (see, for example, in Table 1 '+/- vaccination for FMD, 'provisionally free for Aujeszky's, etc.') making for a complex interpretation of the recommendations. The many and varied categories also make it difficult to compare recommendations amongst diseases, even for a specific commodity such as pig semen, to see if they are reasonably consistent.

In an effort to evaluate consistency in the approach to risk management among the disease recommendations for pig semen, we have undertaken to recast the relevant parts of the Code that have been cited by MPI into a matrix. Table 2 sets out the OIE risk management recommendations for pig semen to manage the risk of various diseases. This matrix enables a comparison across diseases. We have also included comments noting our concerns and queries regarding risk management of each disease and category.

This is not an approach we used in prior evaluations of the existing semen IHS's but we have found it exceedingly useful in our current analysis as it clearly illustrates the disparity in risk management approaches amongst the various diseases. Our view is that in a 'generic' approach to IHSs, diseases with similar epidemiology, routes of transmission, and pathophysiology should share similar risk mitigation strategies. Thus, identification of disparities amongst similar diseases in the current proposed recommendations have guided us in formulating our comments.

Reducing or eliminating these disparities wherever possible will provide a more sound epidemiological approach to managing semen risks, ease future review and modification of the IHS, simplify interpretation of the IHS by importers and exporters, and assist in New Zealand's ongoing obligation to review and comment on proposed changes to the OIE Terrestrial Code itself.

The logic behind the various disparities amongst the various 'agent x category' combinations shown in Table 2 is not obvious in many cases so we have looked across all the combinations, regardless of whether changes have been proposed in the generic IHS currently being proposed, versus the 2013 version currently in effect.

OIE importation recommendations for porcine semen*

* Applies equally to BOTH fresh and frozen unless specifically noted

Table 1. Overview of which diseases requiring risk management (according to MPI's rapid assessment) have importation recommendations described in the OIE Terrestrial Manual.

Category	Free					Infected	Any status
Agent	**Importation from free countries and zones**	**Importation from free countries, zones and compartments**	**Importation from provisionally free countries and zones**	**Importation from FMD free countries or zones where FMD vaccination is not practised, or FMD free compartments**	**Importation from FMD free countries or zones where FMD vaccination is practised**	**Importation from infected countries and zones**	
ASF	NO	YES	NO	NO	NO	YES	NO
AD	YES	NO	YES	NO	NO	YES	NO
BED	NO	NO	NO	NO	NO	NO	NO
BVD	NO	NO	NO	NO	NO	NO	NO
CSF	NO	YES	NO	NO	NO	YES	NO
FMD	NO	NO	NO	YES - Different for fresh vs frozen	YES - Frozen only	YES - Frozen only	NO
JE	NO	NO	NO	NO	NO	NO	NO
Bungowannah	NO	NO	NO	NO	NO	NO	NO
PRRS	NO	NO	NO	NO	NO	NO	NO
SVD	NO	NO	NO	NO	NO	NO	NO
TGE	NO	NO	NO	NO	NO	NO	YES
Brucellosis	NO	NO	NO	NO	NO	NO	YES
Lepto	NO	NO	NO	NO	NO	NO	NO
Salmonella	NO	NO	NO	NO	NO	NO	NO

Key features of OIE importation recommendations

Table 2 below sets out the OIE risk management recommendations for pig semen to manage the risk of various diseases. This matrix enables a comparison across diseases. We have also included comments noting our concerns and queries regarding risk management of each disease and category.

Table 2. Summary of importation requirements for semen according to OIE recommendations.

Category	Free					Infected	Any status
Agent	**Importation from free countries and zones**	**Importation from free countries, zones and compartments**	**Importation from provisionally free countries and zones**	**Free countries or zones where vaccination is not practised, or FMD free compartments**	**Free countries or zones where vaccination is practised**	**Importation from infected countries and zones**	
ASF	NO	• Kept in free c/z/com >=40d; • No clinsigns day of collection	NO	NO	NO	• Kept in free com >= 40d; • No clinsigns day of collection and for following 40d	NO
AD	• No clinsigns day of collection; • Kept in estab. or AI centre in AD free c/z at time of collection	NO	• Kept in AD free establishment for >=4m before entering AI centre; • Kept in AI centre >=4m having status of 'AD free', and where all boars tested by whole-virus AD serology every 4m (and found negative); • No clinsigns on day of collection	NO	NO	• Kept in AD free establishment for >=6m before entering AI centre; • Kept in AI centre >=4m having status of 'AD free', and where all boars tested by whole-virus AD serology every 4m (and found negative); • Were found negative on a single test between -10d and +21 relative to collection	NO
BED	NO	NO	NO	NO	NO	NO	NO
BVD	NO	NO	NO	NO	NO	NO	NO

Commented [A1]: In some respects, this standard is even less conservative than for AD as semen can be exported from free c/z/com with roughly the same requirements as AD has for only for free c/z.
No diagnostic testing requirement for ASF means complete reliant for identification on a virulent strain that produces pathognomonic signs; low virulence strains may not be detected by clinical signs in captive wild pigs (zoo, warthogs, EU wild boar, etc.) as we know at least the warthogs generally do not show clinical signs.

Commented [A2]: As above, the basis for disease detection is completely around clinical signs in the absence of any diagnostic testing.To their credit, there is at least a requirement that no clinical signs have occurred for 40d post collection.

NZ should not be importing semen from countries known to be infected with ASF. The outbreak is ongoing across the EU region with only scant evidence that the regionalizaiton efforts are working. Incursions into uninfected zones continue as well as incursions into domestic herds.

It is unclear whether the ASF zoning that is occurring actually constitutes some kind of "OIE zone or compartment' and we would like clarification around this. In any event, the zoning does not appear to be stopping spread of the disease. The epidemic is on-going within and between countries, and between zones.

Commented [A3]: Generally OK.

Commented [A4]: Generally OK. Our suspicion is this classification is generally used by countries such as the US that have eradicated AD from domestic, but not feral pigs. It also provides some flexibility in that countries can make use of diagnostic tests that can differentiate between vaccine and wild exposure. We are unsure why 'compartment' was not used in this context but instead OIE has used 'provisional'.

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

Commented [A5]: NZ should not be importing from countries known to be infected with AD. However, compartmentalisation does provide a means to export semen under specific conditions.

While we support the before and after testing regime, it is not clear why the post-collection testing period has been extended to include -10d from collection; we would like clarification on this matter ... [1]

Category	Free					Infected	Any status
Agent	**Importation from free countries and zones**	**Importation from free countries, zones and compartments**	**Importation from provisionally free countries and zones**	**Free countries or zones where vaccination is not practised, or FMD free compartments**	**Free countries or zones where vaccination is practised**	**Importation from infected countries and zones**	
CSF	NO	• Kept in a free c/z/com >=3m; • No clinsigns day of collection	NO	NO	NO	• Kept in free com. >=3m; • No clinsigns between 0d and +40d from collection, and one of the following: ○ not vax and neg serological test >=21d after collection; or ○ vax plus prove pos was due to vax; or ○ vax and found to be 'virus neg' on day of collection.	NO

Commented [A6]: No diagnostic testing requirement for CSF means they are completely reliant on a virulent strain that produces pathognomonic signs; low virulence strains may not be detected by clinical signs.

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

Commented [A7]: NZ should not be importing from countries known to be infected with CSF. However, compartmentalisation does provide a means to export semen under specific conditions.

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

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

FMD	NO	NO	NO	Fresh • No clinsigns day of collection • Kept >=3m in free c/z where vax not practised, or an FMD free com. • Kept in AI centre where no animals had hx of FMD infection Frozen • No clinsigns between d0 and +30d of collection; • Kept >=3m in free c/z where vax not practised, or an FMD free com.	Frozen only • No clinsigns between d0 and +30d of collection; • Kept >=3m in free c/z where vax is practised, and one of the following: ○ Vax 2x with last vax between -1m and -6m prior to collection, unless protective immunity has been demonstrated for >6m; or ○ Negative antibody test >21d after collection. • Semen must be stored in country of origin for >=1m, and during this period no animals on establishment showed clinsigns	Frozen only • No clinsigns between d0 and +30d of collection; • Kept in AI centre where no animals have been added in last 30d, and that FMD not occurred within a 10km radius between -30d and +30d of collection, and either: ○ Vax 2x with last vax between -1m and -6m prior to collection, unless protective immunity has been demonstrated for >6m; or ○ Negative antibody test >21d after collection. • Semen tested negative for 'evidence of FMD' if donor has been vax in the prior 12m; • Semen must be stored in country of origin for >=1m, and during this period no animals on establishment showed clinsigns	NO

Commented [A8]: It is not clear why the fresh and frozen standards are different. Please explain.

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

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

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

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

Commented [A9]: New Zealand should not be importing from vaccinated animals, regardless of their serostatus.

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

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

Commented [A10]: New Zealand should not be importing semen from infected countries and zones.

Category	Free					Infected	Any status
Agent	Importation from free countries and zones	Importation from free countries, zones and compartments	Importation from provisionally free countries and zones	Free countries or zones where vaccination is not practised, or FMD free compartments	Free countries or zones where vaccination is practised	Importation from infected countries and zones	
JE	NO	NO	NO	NO	NO	NO	NO
Bungowannah	NO	NO	NO	NO	NO	NO	NO
PRRS	NO	NO	NO	NO	NO	NO	NO
SVD	NO	NO	NO	NO	NO	NO	NO

Category	Free					Infected	Any status
Agent	**Importation from free countries and zones**	**Importation from free countries, zones and compartments**	**Importation from provisionally free countries and zones**	**Free countries or zones where vaccination is not practised, or FMD free compartments**	**Free countries or zones where vaccination is practised**	**Importation from infected countries and zones**	
TGE	NO	NO	NO	NO	NO	NO	• No clinsigns on day of collection; and either of: o Kept >=40d in AI centre in which all animals in centre were free of clinsigns for >=12m; i. Fresh – 'dx test' between -30d and 0d prior to collection ; ii. Frozen - 'dx test' between 0d and 14d after collection o Kept in country in which TGE is officially reportable and no clinical case has been recorded in previous 3y.

Commented [A11]: The need for different requirements for fresh and frozen is not clear; please explain.

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

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

Category	Free					Infected	Any status
Agent	**Importation from free countries and zones**	**Importation from free countries, zones and compartments**	**Importation from provisionally free countries and zones**	**Free countries or zones where vaccination is not practised, or FMD free compartments**	**Free countries or zones where vaccination is practised**	**Importation from infected countries and zones**	

Brucellosis	NO	NO	NO	NO	NO	NO	• No clinsigns on day of collection;
							• Not vax and either:
							  ○ kept in AI centre complying with OIE4.5/4.6, or
							  ○ kept in free herd that is 'tested' every 6m

Lepto	NO	NO	NO	NO	NO	NO	NO
Salmonella	NO	NO	NO	NO	NO	NO	NO

Commented [A12]: New Zealand should not be importing semen from countries infected with brucellosis, particularly in the absence of any testing scheme.

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

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

MPI list of recommendations for risk mitigation for non-OIE listed agents

For those diseases for which OIE chapters exist, New Zealand proposes to accept all OIE recommendations, as described above.

For diseases for which no OIE chapter exists, New Zealand proposes the following:

1) Blue eye disease (apparently only occurs in Mexico)
   a) Kept their entire lives in a free country; OR
   b) Found negative on a serological test
2) BVD
   a) No risk management considered to be necessary
3) JE
   a) Kept entire lives in c/z free from JE
4) Bungowannah virus
   a) Kept their entire lives in a free c/z/com; or
   b) Originate from properties where porcine myocarditis has been diagnosed were isolated and subjected to tests listed in MPI-STD-TVTL to demonstrate they were seropositive for porcine myocarditis virus and negative for porcine myocarditis virus RNA before entering the semen collection centre; and
      i) An aliquot of each batch of semen for export was subjected to a RT-PCR test listed in MPI-STD-TVTL, with negative results.
5) PRRS
   a) Kept their entire lives in a country free from PRRS; or
   b) Were sourced from herds that are not vaccinated against PRRS, and were tested using a multivalent serum ELISA for PRRS antibodies that uses both European and American strain antigens listed in MPI-STD-TVTL, with negative results before entering the semen collection centre; and
      i) On two occasions, the first occasion at the start of the collection period and the second occasion no less than 30 days subsequent to the first occasion, donors were tested for PRRS virus using a serum PCR test listed in MPI-STD-TVTL, with negative results; and
      ii) Twenty-one to 50 days after the final semen collection, donors were tested using a multivalent serum ELISA for PRRS antibodies that uses both European and American strain antigens listed in MPI-STD-TVTL, with negative results.
6) SVD
   a) No risk management considered to be necessary
7) Leptospirosis
   a) Antibiotics effective against Leptospira spp. as listed in MPI-STD-TVTL, were added to the semen
8) Salmonella
   a) No risk management considered to be necessary

General concerns not included in tracked comments above

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

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

   The MPI-STD-TVTL can be downloaded from http://www.mpi.govt.nz/document-vault/2040.

Commented [A13]: We are not aware of any commercially available or validated diagnostic tests for this disease. Aside from meaning that essentially no country can therefore unequivocally generate proof of freedom (aside from a lack of clinical signs), it creates an obvious compliance issue for the IHS.

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

Commented [A14]: NZPork is not particularly concerned about BVD-2 per se. However, several pestiviruses (that cause disease in pigs) have emerged/been discovered in the last 5-10 years (Bungowannah, border disease variants, CSF variants, atypical porcine pestivirus 'tremors') and the IHS does not deal with many of these. We would encourage MPI to investing in a more comprehensive review of porcine Pestiviruses and ensure any important risks are identified and managed.

Commented [A15]: JE is associated with infertility in boars and may lead to edematous, congested testicles resulting in lowered motile sperm counts and abnormal spermatozoa.

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

We agree with the proposed risk mitigation strategy.

Commented [A16]: Bungowannah is a known disease causing virus in Australia and continues to circulate in some parts of the country. As discussed in the Section below entitled 'General concerns not included in tracked comments above', point (2), a structured compartment established and managed using the principles laid out in OIE Code in order to permit the importation of semen from Australia.

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

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

Commented [A17]: The stated requirements are reasonable in terms of the correct test selection and the correct timing periods.

However, as described above for Bungowannah virus, 'OIE-like' compartments should be established to incorporate the AI Centres in these infected countries.

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

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

Commented [A18]: No comment

Commented [A19]: OK

Commented [A20]: OK

2) OIE's guidelines recommends standards by which semen and genetic material from countries and zones infected with diseases can be traded through establishment of disease free zones or compartments.

The OIE Code Chapter 4.3. Zoning and compartmentalisation, Article 4.3.1. Introduction reminds us that 'Establishing and maintaining a disease free status throughout the country should be the final goal for Member Countries.' and therefore one might consider it against the spirit of the code to establish a disease free zone or compartment when there is no active, conscious effort to eradicate the disease in question from the country. However, there is a long history of using zoning and compartmentalisation to permit trade in animal products from countries endemically infected with agents that are not present in their trading partners: Export of semen from AI centres located in countries infected with PRRS (domestic and wild), and/or CSF and AD (primarily in wild boars) has been occurring for several years. It is critical to remember however, that compartmentalisation has failed to stop disease transmission in a number of recent instances including repeated incursions of PRRS into Switzerland from AI centres in Germany, ASF into uninfected wild and domestic herds from infected zones in several countries in Eastern Europe, and AD into 'transitional' herds as a result of contact with wild pigs in their infected feral compartment. International spread of pig diseases remains active.

While zoning applies to an animal subpopulation defined primarily on a geographical basis (using natural, artificial or legal boundaries), compartmentalisation applies to an animal subpopulation defined primarily by management and husbandry practices related to biosecurity. In practice, spatial considerations and good management including biosecurity plans play important roles in the application of both concepts. OIE Code Article 4.3.3. of the Code describes the principles for defining and establishing a zone or compartment.

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

- Control of risk material into the compartment for an extended period of time prior to (and after) its official establishment
- Surveillance for the disease in and around the compartment, prior to its establishment and on an ongoing basis. A control program should be established in the event the disease is detected.
- Implementation of measures to prevent transmission of the disease to/from wild pigs
- Control by the Veterinary Authority
- Absence of vaccination for the disease and no presence of antibody (sic vaccine titers) in the pigs in the compartment

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

Diseases such as PRRS and Bungowannah that

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

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

3) To manage the issues related to a boar being in the pre-clinical and/or prodromal phases of an infection (yet circulating and possibly shedding the agent), a strategy combining testing of the boar (or semen) at the time of collection for presence of the agent and post-collection serology are recommended for some but not all of the OIE list diseases. We strongly support the approach for all of the diseases, but particularly for those situations that involve the AI centre being geographically located in an infected country, zone, or compartment. In addition, the semen should be held in the country of origin until all test results have been returned and found to be negative. Retention of semen in the country of origin appears only to be required for FMD, TGE and Brucellosis in the current recommendations. Because this requirement would essentially require that semen be frozen (and noting that porcine semen does not freeze particularly well), this creates a potential problem. However, input from industry stakeholders on this matter indicates that it is manageable with available technology, semen extenders, and insemination protocols.
4) There should always be a component of population based diagnostic testing in the source population, in addition to individual testing when required. The tests referred to for these diseases are not adequate for use in individual animals and this principle extends also to PCR, not just serology.
5) The requirements for establishment and management of an 'AI centre' are different for each disease. In particular, it appears that there are potentially important differences in requirements such setback distances from other pigs/farms/feral populations, diagnostic testing requirements inside the centre (routine? periodic? maintenance of status? related to individuals whose semen is destined for export? etc.), and diagnostic testing requirements for animals in the surrounding population (external to the AI centre).
6) Use of clinical signs as the only indicator of disease status or occurrence is inadequate.
7) Except for Aujeszky's Disease, serologic tests are not currently available that can differentiate the presence of antibodies due to vaccination versus exposure to infection. PCR and genomic sequencing are not sufficiently specific enough to differentiate whether detected nucleic acids are from vaccine or infection.

Recommendations

1) Disease specific comments and recommendations of NZPork are inserted as 'Word comments' in the Sections above entitled 'Key features of OIE importation recommendations' and 'MPI list of recommendations for risk mitigation for non-OIE listed agents'. Most comments includes specific requests for action by MPI.
2) General concerns about the IHS and principles underlying development of the standards are described in Section 'General concerns not included in tracked comments above'. Most comments includes specific requests for action by MPI.
3) Senecavirus A, a picornavirus related to FMD, has occurred widely in the North American pig industry during 2016. While the virus has been known to occur in the region previously, the reason(s) for the current outbreak (which causes clinical signs similar to FMD infection simultaneously among a large number of animals in an infected group) have not been explained. Until such information becomes available, the current situation meets the definition of an emerging or re-emerging disease as indicated by OIE:

> An emerging disease is defined as a new infection resulting from the evolution or change of an existing pathogen or parasite resulting in a change of host range, vector, pathogenicity or strain; or the occurrence of a previously unrecognised infection or disease. A re-emerging disease is considered an already known disease that either shifts its geographical setting or expands its host range, or significantly increases its prevalence (link to source).

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

The scientific literature related to the outbreak is growing rapidly. An epidemiological study published in 2017 in Transboundary and Emerging Disease (link to source) and a comprehensive recent factsheet is also available from the Swine Health Information Center (link to source). At least one study appears to be underway to determine the potential for transmitting the virus through semen (link to source); funding by the Minnesota Rapid Agricultural Response program). No systematic or official surveillance information on

Senecavirus in the US could be located but National Pork Board through their Swine Health Monitoring Project published the results of sampling in sentinel herds in December 2016 (Figure 1); the disease is not reportable in the US. The data clearly supports a significant change in prevalence as only seven cases were reported from US pigs during the period of 2008 to 2012.

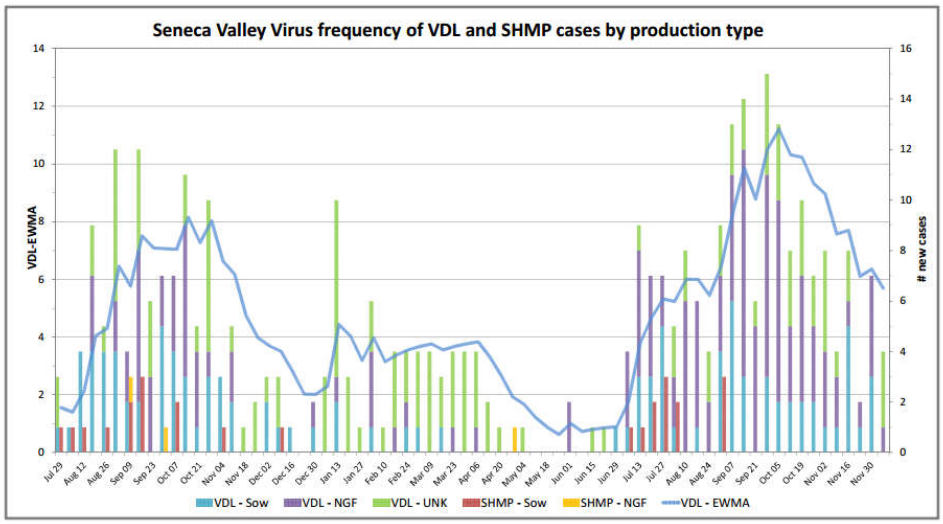

Figure 1. Results of voluntary surveillance on sentinel herds in the US based Swine Health Monitoring Project, reported December 2016. Data is reported from July 29, 2015 to November 30, 2016.

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

4) Requirements related to TGE should be extended to include PED. Much of the pig producing world experience a re-emergence of this disease in 2013-14 and the disease continues. PED is very similar to TGE in virtually all respects and should therefore be subject to risk mitigation. PED is known to become viremic at higher levels and for a longer period than TGE and therefore represents an even higher risk than TGE. Limited studies have been done to investigate PED and risk to semen but at least one controlled study has shown the virus to be present in semen of infected boar though whether it was due directly to the infection or as a result of contamination of the semen was not clear (Reicks, et al. Detection of economically important viruses in boar semen by quantitative real-time PCR technology. 2015 Annual mtg of the AASV.); in either event the risk is tangible. Similarly, the requirements for TGE should also be extended to include porcine Deltacoronavirus as its emergence in US pigs has also led to a large outbreak of a new disease.
5) A particular concern we have over MPI's strategy to create fully generic IHSs is how to monitor (and manage as required) the occurrence of emerging and re-emerging agents. Under the previous IHS system, both MPI and the pig industry could focus their attention on agents that were emerging in those countries for which trade was permitted. Under the new philosophy, MPI and the pig industry must closely monitor the emergence and re-emergence of agents in all countries of the world as they are all covered under the generic IHS. As an example, there is currently widespread emergence of novel influenza strains in India

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

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

Appendix 1. Relevant OIE definitions from the Terrestrial Code

ARTIFICIAL INSEMINATION CENTRE

means a facility approved by the Veterinary Authority and which meets the conditions set out in the Terrestrial Code for the collection, processing and/or storage of semen.

CAPTIVE WILD ANIMAL

means an animal that has a phenotype not significantly affected by human selection but that is captive or otherwise lives under direct human supervision or control, including zoo animals and pets.

COLLECTION CENTRE

means a facility approved by the Veterinary Authority for the collection of embryos/ova and used exclusively for donor animals which meet the conditions of the Terrestrial Code.

EPIDEMIOLOGICAL UNIT

means a group of animals with a defined epidemiological relationship that share approximately the same likelihood of exposure to a pathogen. This may be because they share a common environment (e.g. animals in a pen), or because of common management practices. Usually, this is a herd or a flock. However, an epidemiological unit may also refer to groups such as animals belonging to residents of a village, or animals sharing a communal animal handling facility. The epidemiological relationship may differ from disease to disease, or even strain to strain of the pathogen.

ESTABLISHMENT

means the premises in which animals are kept.

FREE COMPARTMENT

means a compartment in which the absence of the animal pathogen causing the disease under consideration has been demonstrated by all requirements specified in the Terrestrial Code for free status being met.

FREE ZONE

means a zone in which the absence of the disease under consideration has been demonstrated by the requirements specified in the Terrestrial Code for free status being met. Within the zone and at its borders, appropriate official veterinary control is effectively applied for animals and animal products, and their transportation.

NOTIFIABLE DISEASE

means a disease listed by the Veterinary Authority, and that, as soon as detected or suspected, should be brought to the attention of this Authority, in accordance with national regulations.

VACCINATION

means the successful immunisation of susceptible animals through the administration in accordance with the manufacturer's instructions and the Terrestrial Manual, where relevant, of a vaccine comprising antigens appropriate to the disease to be controlled.

ZONE/REGION

means a clearly defined part of a territory containing an animal subpopulation with a distinct health status with respect to a specific disease for which required surveillance, control and biosecurity measures have been applied for the purpose of international trade.

Appendix 2. OIE Terrestrial Code relevant chapters

Chapter 4.5: General hygiene semen collection and processing centres

Article 4.5.1. General considerations

Observation of the recommendations described in the articles below will very significantly reduce the likelihood of the semen being contaminated with common micro-organisms some of which are potentially pathogenic.

Article 4.5.2. Conditions applicable to artificial insemination centres

1) The artificial insemination centre is comprised of:
   a) animal accommodation areas (including one isolation facility for sick animals) and a semen collection room, these two premises hereon designated as semen collection facilities; accommodation areas should be species specific where relevant;
   b) a semen laboratory and semen storage areas;
   c) administration offices;
   d) a pre-entry isolation facility which is not compulsory in case of horses.
2) The centre should be under the direct supervision and control of a centre veterinarian.
3) Only animals associated with semen production should be permitted to enter the centre. Other species of livestock may exceptionally be resident on the centre, provided that they are kept physically apart from these animals.
4) Donors and teasers on the centre should be adequately isolated from farm livestock on adjacent land or buildings for instance by natural or artificial means.
5) The entry of visitors should be strictly controlled. Personnel at a centre should be technically competent and observe high standards of personal hygiene to preclude the introduction of pathogenic organisms. Protective clothing and footwear for use only on the centre should be provided.
6) Individual semen containers and storage rooms should be capable of being disinfected.
7) The centre should be officially approved by the Veterinary Authority.
8) The centre should be under the supervision and control of the Veterinary Services which will be responsible for regular audits, at an interval of no more than 12 months, of protocols, procedures and records on the health and welfare of the animals in the centre and on the hygienic production, storage and dispatch of semen.

Article 4.5.3. Conditions applicable to semen collection facilities

1) The semen collection facilities should include separate and distinct areas for accommodating resident animals, for semen collection, for feed storage, for manure storage, and for the isolation of animals suspected of being infected.
2) Only animals associated with semen production should be permitted to enter the semen collection facilities. Other species of animals may be resident at the centre, if necessary for the movement or handling of the donors and teasers or for security, but contact with the donors and teasers should be minimised. All animals resident at the semen collection facilities should meet the minimum health requirements for donors.
3) The donors and teasers should be adequately isolated to prevent the transmission of diseases from farm livestock and other animals. Measures should be in place to prevent the entry of wild animals susceptible to ruminant and swine diseases transmissible via semen.
4) Personnel at the centre should be technically competent and observe high standards of personal hygiene to preclude the introduction of pathogenic organisms. Special protective clothing and footwear for use only at the semen collection facilities should be provided and worn at all times inside.
5) Visitors to the semen collection facilities should be kept to a minimum, and visits should be subject to formal authorisation and control. Equipment for use with the livestock should be dedicated to the semen collection facilities or disinfected prior to entry. All equipment and tools brought on to the premises should be examined and treated if necessary to ensure that they cannot introduce disease.
6) Vehicles used for transport of animals to and from the semen collection facilities should not be allowed to enter the facilities.
7) The semen collection area should be cleaned daily after collection. The animals' accommodation should be kept clean.

8) Fodder introduction and manure removal should be done in a manner which poses no significant animal health risk.

Article 4.5.4. Conditions applicable to semen laboratories

1) The semen laboratory should be physically separated from the semen collection facilities, and include separate areas for artificial vagina cleaning and preparation, semen evaluation and processing, semen pre-storage and storage. Entry to the laboratory should be prohibited to unauthorised personnel.
2) The laboratory personnel should be technically competent and observe high standards of personal hygiene to preclude the introduction of pathogenic organisms during semen evaluation, processing and storage.
3) Visitors to the laboratory should be kept to a minimum, and visits should be subject to formal authorisation and control.
4) The laboratory should be constructed with materials that permit effective cleaning and disinfection.
5) The laboratory should be regularly cleaned. Work surfaces for semen evaluation and processing should be cleaned and disinfected at the end of each workday.
6) The laboratory should be treated against rodents and insects on a regular basis as needed to control these pests.
7) The storage rooms and individual semen containers should be easy to clean and disinfect.
8) Only semen collected from donors having a health status equivalent to or better than the donors at the semen collection facilities should be processed in the laboratory.

Article 4.5.5. Conditions applicable to the management of bulls, rams, bucks and boars

The objective is to keep the animals in a satisfactory state of cleanliness, particularly of the lower thorax and abdomen.

1) Whether on pasture or housed, the animal should be kept under hygienic conditions. If housed, the litter should be kept clean and renewed as often as necessary.
2) The coat of the animal should be kept clean.
3) For bulls, the tuft of hairs at the preputial orifice, which is often soiled, should be cut to about 2 cm. The hair should not be removed altogether, because of its protective role. If cut too short, irritation of the preputial mucosa may result because these hairs aid the drainage of urine.
4) The animal should be brushed regularly, and where necessary on the day before semen collection, paying special attention to the underside of the abdomen.
5) In the event of obvious soiling, there should be careful cleaning, with soap or a detergent, of the preputial orifice and the adjoining areas, followed by thorough rinsing and drying.
6) When the animal is brought into the collection area, the technician should make sure that it is clean, and that it is not carrying any excessive litter or particles of feed on its body or its hooves.

Chapter 4.6 Collection and processing of bovine, small ruminant and porcine semen

Article 4.6.1. General considerations

The purposes of official sanitary control of semen production are to:

1) maintain the health of animals on an artificial insemination centre at a level which permits the international distribution of semen with a negligible risk of infecting other animals or humans with pathogens transmissible by semen;
2) ensure that semen is hygienically collected, processed and stored.

Artificial insemination centres should comply with recommendations in Chapter 4.5.

Standards for diagnostic tests are described in the Terrestrial Manual.

Article 4.6.2. Conditions applicable to testing of bulls and teaser animals

Bulls and teaser animals should enter an artificial insemination centre only when they fulfil the following requirements.

1) Prior to entering pre-entry isolation facility
   The animals should comply with the following requirements prior to entry into isolation at the pre-entry isolation facility where the country or zone of origin is not free from the diseases in question.
   a) Brucellosis – Chapter 8.4.

b) Bovine tuberculosis – Point 3 or 4 of Article 11.5.5.
c) Bovine viral diarrhoea (BVD)
The animals should be subjected to:
i) a virus isolation test or a test for virus antigen, with negative results; and
ii) a serological test to determine the serological status of every animal.
d) Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
If the artificial insemination centre is to be considered as infectious bovine rhinotracheitis/infectious pustular vulvovaginitis free (IBR/IPV), the animals should either:
i) come from an IBR/IPV free herd as defined in Article 11.10.3.; or
ii) be subjected, with negative results, to a serological test for IBR/IPV on a blood sample.
e) Bluetongue
The animals should comply with Articles 8.3.7. or 8.3.8., depending on the bluetongue status of the country or zone of origin of the animals.

2) Testing in the pre-entry isolation facility prior to entering the semen collection facilities
Prior to entering the semen collection facilities of the artificial insemination centre, bulls and teaser animals should be kept in a pre-entry isolation facility for at least 28 days. The animals should be tested as described below a minimum of 21 days after entering the pre-entry isolation facility, except for Campylobacter fetus subsp. venerealis and Tritrichomonas foetus, for which testing may commence after 7 days in pre-entry isolation. All the results should be negative except in the case of BVD antibody serological testing (see point 2b)i) below).
a) Brucellosis
The animals should be subjected to a serological test with negative results.
b) BVD
i) The animals should be subjected to a virus isolation test or a test for virus antigen, with negative results. Only when all the animals in pre-entry isolation have had negative results, may the animals enter the semen collection facilities.
ii) All animals should be subjected to a serological test to determine the presence or absence of BVD antibodies.
iii) Only if no seroconversion occurs in the animals which tested seronegative before entry into the pre-entry isolation facility, may any animal (seronegative or seropositive) be allowed entry into the semen collection facilities.
iv) If seroconversion occurs, all the animals that remain seronegative should be kept in pre-entry isolation until there is no more seroconversion in the group for a period of three weeks. Serologically positive animals may be allowed entry into the semen collection facilities.
c) Campylobacter fetus subsp. venerealis
i) Animals less than six months old or kept since that age only in a single sex group prior to pre-entry isolation should be tested once on a preputial specimen, with a negative result.
ii) Animals aged six months or older that could have had contact with females prior to pre-entry isolation should be tested three times at weekly intervals on a preputial specimen, with a negative result in each case.
d) Tritrichomonas foetus
i) Animals less than six months old or kept since that age only in a single sex group prior to pre-entry isolation, should be tested once on a preputial specimen, with a negative result.
ii) Animals aged six months or older that could have had contact with females prior to pre-entry isolation should be tested three times at weekly intervals on a preputial specimen, with a negative result in each case.
e) IBR/IPV
If the artificial insemination centre is to be considered as IBR/IPV free, the animals should be subjected, with negative results, to a diagnostic test for IBR/IPV on a blood sample. If any animal tests positive, the animal should be removed immediately from the pre-entry isolation facility and the other animals of the same group should remain in pre-entry isolation and be retested, with negative results, not less than 21 days after removal of the positive animal.
f) Bluetongue

The animals should comply with the provisions referred to in Articles 8.3.6., 8.3.7. or 8.3.8., depending on the bluetongue status of the country or zone where the pre-entry isolation facility is located.

3) Testing programme for bulls and teasers resident in the semen collection facilities
All bulls and teasers resident in the semen collection facilities should be tested at least annually for the following diseases, with negative results, where the country or zone where the semen collection facilities are located is not free:
   a) Brucellosis
   b) Bovine tuberculosis
   c) BVD
      Animals negative to previous serological tests should be retested to confirm absence of antibodies. Should an animal become serologically positive, every ejaculate of that animal collected since the last negative test should be either discarded or tested for virus with negative results.
   d) Campylobacter fetus subsp. venerealis
      i) A preputial specimen should be tested.
      ii) Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a lay-off of more than six months should be tested not more than 30 days prior to resuming production.
   d) Bluetongue
      The animals should comply with the provisions referred to in Article 8.3.9. or Article 8.3.10.
   e) Tritrichomonas foetus
      i) A preputial specimen should be cultured.
      ii) Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a lay-off of more than six months should be tested not more than 30 days prior to resuming production.
   f) IBR/IPV
      If the artificial insemination centre is to be considered as IBR/IPV free, the animals should comply with the provisions in point 2c) of Article 11.10.3.
4) Testing for BVD prior to the initial dispatch of semen from each serologically positive bull
Prior to the initial dispatch of semen from BVD serologically positive bulls, a semen sample from each animal should be subjected to a virus isolation or virus antigen test for BVD. In the event of a positive result, the bull should be removed from the centre and all of its semen destroyed.
5) Testing of frozen semen for IBR/IPV in artificial insemination centres not considered as IBR/IPV free
Each aliquot of frozen semen should be tested as per Article 11.10.7.

Article 4.6.3. Conditions applicable to testing of rams/bucks and teaser animals

Rams/bucks and teaser animals should only enter an artificial insemination centre if they fulfil the following requirements.

1) Prior to entering pre-entry isolation facility
The animals should comply with the following requirements prior to entry into isolation at the pre-entry isolation facility where the country or zone of origin is not free from the diseases in question.
   a) Brucellosis – Chapter 8.4.
   b) Ovine epididymitis – Article 14.6.3.
   c) Contagious agalactia – Points 1 and 2 of Article 14.2.1.
   d) Peste des petits ruminants – Points 1, 2a) or 3 of Article 14.7.10.
   e) Contagious caprine pleuropneumonia – Article 14.3.7., depending on the CCPP status of the country or zone of origin of the animals.
   f) Paratuberculosis – Free from clinical signs for the past two years.
   g) Scrapie – Comply with Article 14.8.8. if the animals do not originate from a scrapie free country or zone as defined in Article 14.8.3.
   h) Maedi-visna – Article 14.5.2.
   i) Caprine arthritis/encephalitis – Article 14.1.2. in the case of goats.
   j) Bluetongue
      The animals should comply with Articles 8.3.7. or 8.3.8., depending on the bluetongue status of the country or zone of origin of the animals.

k) Tuberculosis – In the case of goats, a single or comparative tuberculin test, with negative results.

2) Testing in the pre-entry isolation facility prior to entering the semen collection facilities
Prior to entering the semen collection facilities of the artificial insemination centre, rams/bucks and teasers should be kept in a pre-entry isolation facility for at least 28 days. The animals should be tested as described below a minimum of 21 days after entering the pre-entry isolation facility, with negative results.
   a) Brucellosis – Chapter 8.4.
   b) Ovine epididymitis – Point 1d) of Article 14.6.4.
   c) Maedi-visna and caprine arthritis/encephalitis – Test on animals.
   d) Bluetongue
      The animals should comply with the provisions referred to in Articles 8.3.6., 8.3.7. or 8.3.8., depending on the bluetongue status of the country or zone where the pre-entry isolation facility is located.

3) Testing programme for rams/bucks and teasers resident in the semen collection facilities
All rams/bucks and teasers resident in the semen collection facilities should be tested at least annually for the following diseases, with negative results, where the country or zone where the semen collection facilities are located is not free:
   a) Brucellosis;
   b) ovine epididymitis;
   c) Maedi-visna and caprine arthritis/encephalitis;
   d) tuberculosis (for goats only);
   e) bluetongue.
      The animals should comply with the provisions referred to in Article 8.3.9. or Article 8.3.10.

Article 4.6.4. Conditions applicable to testing of boars

Boars should only enter an artificial insemination centre if they fulfil the following requirements.

1) Prior to entering pre-entry isolation facility
The animals should be clinically healthy, physiologically normal and comply with the following requirements within 30 days prior to entry into isolation at the pre-entry isolation facility where the country or zone of origin is not free from the diseases in question.
   a) Brucellosis – Chapter 8.4.
   b) Foot and mouth disease – Articles 8.8.10., 8.8.11. or 8.8.12.
   c) Aujeszky's disease – Article 8.2.9. or Article 8.2.10.
   d) Transmissible gastroenteritis – Article 15.4.2.
   e) African swine fever – Article 15.1.5. or Article 15.1.6.
   f) Classical swine fever – Article 15.2.7. or Article 15.2.8.
   g) Porcine reproductive and respiratory syndrome – Test complying with the standards in the Terrestrial Manual.

2) Testing in the pre-entry isolation facility prior to entering the semen collection facilities
Prior to entering the semen collection facilities of the artificial insemination centre, boars should be kept in a pre-entry isolation facility for at least 28 days. The animals should be subjected to diagnostic tests as described below a minimum of 21 days after entering the pre-entry isolation facility, with negative results.
   a) Brucellosis – Chapter 8.4.
   b) Foot and mouth disease – Articles 8.8.13., 8.8.14., 8.8.15. or 8.8.16.
   c) Aujeszky's disease – Articles 8.2.13., 8.2.14. or 8.2.15.
   d) Transmissible gastroenteritis – Article 15.4.4.
   e) African swine fever – Article 15.1.8. or Article 15.1.9.
   f) Classical swine fever – Article 15.2.10. or Article 15.2.11.
   g) Porcine reproductive and respiratory syndrome – The test complying with the standards in the Terrestrial Manual.

3) Testing programme for boars resident in the semen collection facilities
All boars resident in the semen collection facilities should be tested at least annually for the following diseases, with negative results, where the country or zone where the semen collection facilities are located is not free:
   a) Brucellosis – Chapter 8.4.
   b) Foot and mouth disease – Articles 8.8.13., 8.8.14., 8.8.15. or 8.8.16.

c) Aujeszky's disease – Articles 8.2.13., 8.2.14. or 8.2.15.
d) Transmissible gastroenteritis – Article 15.4.4.
e) African swine fever – Article 15.1.8. or Article 15.1.9.
f) Classical swine fever – Article 15.2.10. or Article 15.2.11.
g) Porcine reproductive and respiratory syndrome – The test complying with the standards in the Terrestrial Manual.

Article 4.6.5. General considerations for hygienic collection and handling of semen

Observation of the recommendations described in the Articles below will very significantly reduce the likelihood of the semen being contaminated with common bacteria which are potentially pathogenic.

Article 4.6.6. Conditions applicable to the collection of semen

1) The floor of the mounting area should be clean and provide safe footing. A dusty floor should be avoided.
2) The hindquarters of the teaser, whether a dummy or a live teaser animal, should be kept clean. A dummy should be cleaned completely after each period of collection. A teaser animal should have its hindquarters cleaned carefully before each collecting session. The dummy or hindquarters of the teaser animals should be sanitized after the collection of each ejaculate. Disposable plastic covers may be used.
3) The hand of the person collecting the semen should not come into contact with the animal's penis. Disposable gloves should be worn by the collector and changed for each collection.
4) The artificial vagina should be cleaned completely after each collection where relevant. It should be dismantled, its various parts washed, rinsed and dried, and kept protected from dust. The inside of the body of the device and the cone should be disinfected before re-assembly using approved disinfection techniques such as those involving the use of alcohol, ethylene oxide or steam. Once re-assembled, it should be kept in a cupboard which is regularly cleaned and disinfected.
5) The lubricant used should be clean. The rod used to spread the lubricant should be clean and should not be exposed to dust between successive collections.
6) The artificial vagina should not be shaken after ejaculation, otherwise lubricant and debris may pass down the cone to join the contents of the collecting tube.
7) When successive ejaculates are being collected, a new artificial vagina should be used for each mounting. The vagina should also be changed when the animal has inserted its penis without ejaculating.
8) The collecting tubes should be sterile, and either disposable or sterilised by autoclaving or heating in an oven at 180°C for at least 30 minutes. They should be kept sealed to prevent exposure to the environment while awaiting use.
9) After semen collection, the tube should be left attached to the cone and within its sleeve until it has been removed from the collection room for transfer to the laboratory.

Article 4.6.7. Conditions applicable to the handling of semen and preparation of semen samples in the laboratory

1) Diluents
   a) All receptacles used should have been sterilised.
   b) Buffer solutions employed in diluents prepared on the premises should be sterilized by filtration (0.22 µm) or by autoclaving (121°C for 30 minutes) or be prepared using sterile water before adding egg yolk (if applicable) or equivalent additive and antibiotics.
   c) If the constituents of a diluent are supplied in commercially available powder form, the water used should have been distilled or demineralised, sterilized (121°C for 30 minutes or equivalent), stored correctly and allowed to cool before use.
   d) Whenever milk, egg yolk or any other animal protein is used in preparing the semen diluent, the product should be free of pathogens or sterilised; milk heat-treated at 92°C for 3–5 minutes, eggs from SPF flocks when available. When egg yolk is used, it should be separated from eggs using aseptic techniques. Alternatively, commercial egg yolk prepared for human consumption or egg yolk treated by, for example, pasteurisation or irradiation to reduce bacterial contamination, may be used. Other additives should also be sterilized before use.
   e) Diluent should not be stored for more than 72 hours at +5°C before use. A longer storage period is permissible for storage at -20°C. Storage vessels should be stoppered.

f) A mixture of antibiotics should be included with a bactericidal activity at least equivalent to that of the following mixtures in each ml of frozen semen: gentamicin (250 µg), tylosin (50 µg), lincomycin–spectinomycin (150/300 µg); penicillin (500 IU), streptomycin (500 µg), lincomycin-spectinomycin (150/300 µg); or amikacin (75 µg), divekacin (25 µg).
The names of the antibiotics added and their concentration should be stated in the international veterinary certificate.

2) Procedure for dilution and packing
   a) The tube containing freshly collected semen should be sealed as soon as possible after collection, and kept sealed until processed.
   b) After dilution and during refrigeration, the semen should also be kept in a stoppered container.
   c) During the course of filling receptacles for dispatch (such as insemination straws), the receptacles and other disposable items should be used immediately after being unpacked. Materials for repeated use should be disinfected with alcohol, ethylene oxide, steam or other approved disinfection techniques.
   d) If sealing powder is used, care should be taken to avoid its being contaminated.
3) Conditions applicable to the storage and identification of frozen semen
   Semen for export should be stored in straws separately from other genetic material not meeting the requirements of this chapter with fresh liquid nitrogen in sterilised/sanitised flasks before being exported.
   Semen straws should be sealed and code marked in line with the international standards of the International Committee for Animal Recording (ICAR).
   Prior to export, semen straws should clearly and permanently be identified and placed into new liquid nitrogen in a new or sterilised flask or container under the supervision of an Official Veterinarian. The contents of the container or flask should be verified by the Official Veterinarian prior to sealing with an official numbered seal before export and accompanied by an international veterinary certificate listing the contents and the number of the official seal.
2) Sperm sorting
   Equipment used for sex-sorting sperm should be clean and disinfected between animals in accordance with the recommendations of the licencer of the system. Where seminal plasma, or components thereof, is added to sorted semen prior to cryopreservation and storage, it should be derived from animals of same or better health status.
   Semen straws containing sex-sorted sperm should be permanently identified as such.

Page 7: [1] Commented [A5] **Author**

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

While we support the before and after testing regime, it is not clear why the post-collection testing period has been extended to include -10d from collection; we would like clarification on this matter and encourage that semen be held in the country of origin until negative test results are returned.

OIE specifies 'establishment' here which is different than either 'AI centre' or compartment; please explain and justify this distinction.