



Risk Management Proposal

**Semen and Embryos from Sheep (*Ovis aries*) and
(*Capra hircus*) Goats**

March 2014

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1 Purpose

The purpose of this document is to:

- Show how options for the management of risk organisms have been assessed
- Provide recommendations for import requirements.

2 Background

Sheep and goat germplasm is considered a risk commodity, with the potential to harbour exotic viruses, bacteria, and prions. In October 2005, MPI completed an Import Risk Analysis (IRA) for sheep (*Ovis aries*) and goat (*Capra hircus*) genetic material (<http://www.biosecurity.govt.nz/files/regs/imports/risk/risk-analysis-sheep-goat-genetic-material.pdf>). This IRA, while relevant at the time, is now outdated since there have been technical advances as well as changes to the World Organisation for Animal Health (OIE) *Terrestrial Animal Health Code* (the *Code*) in the interim. Also, the IRA does not reflect the current New Zealand position relative to the appropriate level of protection (ALOP). Furthermore, it does not reflect MPI's interest in aligning with the *Code* where there are appropriate risk management measures. Measures that have been recommended within this risk management proposal (RMP) may therefore diverge from the 2005 IRA.

In January 2011 MPI issued the *Import Risk Analysis: Scrapie in sheep and goat germplasm* (<http://www.biosecurity.govt.nz/files/biosec/consult/import-risk-analysis-scrapie-sheep-goat.pdf>). This document is more directly reflected in the RMP recommendations.

For OIE listed diseases, the RMP will strive to align with the *Code*, provided this meets New Zealand's ALOP. Where there are variances, these will be justified within the RMP. In the case of non-OIE listed diseases the measures are those thought to best meet the ALOP.

In accordance with MPI processes, the IRAs are used to develop an IHS with generic import requirements. The generic IHS serves as the basis for country to country (bilateral) negotiations of country specific veterinary certificates. Additionally, the negotiations will take into account the verifiable health status of the exporting country, the national systems, legislation and import requirements of the exporting country for regulatory oversight of germplasm collection and processing, and the capabilities and preferences of the exporting country's Competent Authority. The assessments will be based on World Trade Organisation Terrestrial Animal Health Code (the *Code*) 3, Quality of Veterinary Services.

A guidance document will be issued by MPI and this will provide specific guidance information, a model veterinary certificate, and samples of bilaterally-agreed veterinary certification for trade in sheep and goat germplasm.

3 Objective

The objective is to effectively manage all biosecurity risks posed by the import of sheep and goat germplasm, consistent with New Zealand's domestic legislation and international obligations.

4 Options Assessment

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

The risks associated with semen and embryo collection, processing, storage, and transport were described in the IRA and methods to manage those risks are presented as general requirements in this document. The specific requirements for risk organisms, as described in the IRA, are described here and recommendations for requirements are provided.

5 General Requirements

The general requirements section of the IHS includes risk management measures for any semen or embryo donor, regardless of the country's disease freedom claims. These requirements align with the recommendations of the *Code* and the International Embryo Transfer Society (IETS).

The *Code* provides methods to prevent germplasm from being contaminated with risk organisms during collection, processing, and transport. Although the *Code*'s methods for embryos are not specific to sheep and goats, they have been adapted for these species in this document. The measures describe procedures for entry of a semen donor into a semen collection centre, which involves testing the donor prior to pre-entry isolation, testing during a 28 day isolation period, and annual testing on the centre. In the case of embryo collection, the *Code* describes three phases of risk: the health status of the flock/herd or country of origin, the processes followed during collection of embryos, and the testing of germplasm collected or surveillance of the donors.

It is recommended that the germplasm collection team should be approved by the Competent Authority. The team's practices, as well as the processing and storage of germplasm and any test samples, should be in accordance with the *Code* where applicable.

All germplasm donors should be resident in a collection flock/herd or held at an approved collection centre for at least the 28 days before collection. If testing before collection is permitted, the donor should be required to be isolated from other animals not of equivalent tested health status until the end of germplasm collection. On the day of collection, the health status of each donor should be confirmed to be free of clinical evidence of infectious diseases transmissible in germplasm by the approved veterinarian. Additionally, if risk is managed by ensuring absence of disease from the donor and establishment for a specific amount of time after collection, the germplasm should be stored for the amount of time specified under each disease before export. All germplasm should be stored in sealed, tamper-proof, labelled straws or containers.

For the production of embryos, consideration should be given to the health status of the semen donor, requiring that it be eligible for importation into New Zealand. Due to some measures existing for semen, but not for embryos (such as scrapie in sheep), semen donors should be required to satisfy the measures in the IHS applicable to semen donors.

The IETS manual provides guidance regarding trypsin washing and verification of the intact zona pellucida (intact and free of adherent material) after washing. These are important steps in processing to ensure that viruses will not be transmitted with the embryo. Trypsin is critical in removing infectious bovine rhinotracheitis virus and vesicular stomatitis virus. Micro-manipulation should only be permitted after washing and verification of the zona pellucida for maximum assurance that the embryo is free of virus.

6 Recommendations for Identified Risk Organisms

The biosecurity risks associated with the importation of semen and embryos from sheep and goat have been examined in the document *Import Risk Analysis: Sheep and Goat Genetic Material* (dated October 2005), the *Import Risk Analysis: Scrapie in sheep and goat germplasm* (dated January 2011), the *Rapid Risk Assessment: Schmallenberg virus in imported live animals and germplasm* (dated February 2013). Of the potential hazards, the IRAs concluded that risk management measures were justified for the hazards described in this RMP.

Diagnostic tests recommended by the *Code* and described in the *OIE Manual* (specifically those prescribed for international trade) should be used as the test of choice for all specified risk organisms in the IHS. Where there is no OIE prescribed test for a particular risk organism, or the exporting country proposes to use an alternative test, MPI Investigation and Diagnostic Centre (IDC) laboratory experts should assess the test as valid for diagnostic purposes in the importation of sheep and goat germplasm, and appropriate for screening for the risk organism and equivalent to the IHS requirement. MPI approved diagnostic tests will be listed in the MPI Document, *Approved diagnostic tests, vaccines, treatments and post-arrival testing laboratories testing for animal import health standards* (MPI-STD-TVTL).

The options which specify vaccination may require MPI approval of the vaccine. For a vaccine to gain approval, the Competent Authority should submit details of the vaccination protocol, including vaccine type, discussion of potential risks with the vaccine and how they can be managed (for example, reversion to virulence), and surveillance details, including how vaccinated animals are distinguished from infected animals. If satisfied with the information, MPI will list the approved vaccines in the MPI document, *Approved diagnostic tests, vaccines, treatments and post-arrival testing laboratories testing for animal import health standards* (MPI-STD-TVTL).

6.1 Akabane and Schmallenberg virus

6.1.1 Risk management measures presented in the 2005 risk analysis included:

Donors should:

- i. be resident for at least 21 days immediately before germplasm collection in a country or zone that is free from Simbu viruses; or*
- ii. be held in a disease free area or in insect free premises for at least the 21 days before collection of germplasm; or*
- iii. be tested, within the seven days prior to germplasm collection and again 3-6 weeks after the final germplasm collection using a Simbu-group reactive cELISA. Semen and embryos from animals that sero-convert or have rising titres between the two tests should be disqualified from entry into New Zealand. Animals that are serologically positive at the first test or negative at both tests are suitable for use as germplasm donors.*

6.1.2 Risk estimation presented in the 2013 Schmallenberg rapid risk assessment:

For live animals, the likelihood of exposure is assessed to be negligible. For germplasm imports, the consequences are assessed to be negligible. Therefore, SBV is not assessed to be a risk in imported live animals or their germplasm and risk management measures are not justified.

6.1.3 Discussion

Akabane and Schmallenberg (Simbu-group) viruses are arthropod-borne. No known competent vectors are present in New Zealand. Establishment or horizontal transmission between animals is not possible without the presence of *Culicoides spp.*, which have been demonstrated by active surveillance to be absent from New Zealand.

Akabane and Schmallenberg viruses are not OIE listed and the diseases they cause are not considered public health threats.

6.1.4 Recommendation

No measures are recommended because of the absence of a vector in New Zealand.

6.2 Bluetongue virus (BTV)

6.2.1 Risk management measures presented in the 2005 risk analysis included:

Donor animals should:

- i. be resident for the 100 days preceding germplasm collection in a country or zone that is free from bluetongue; or*
- ii. maintained free from contact with *Culicoides spp.* for the 100 days immediately before semen collection. This should be achieved by keeping them in a *Culicoides* free area, or in a seasonally free area in which *Culicoides* are inactive, or in an insect free isolation facility; or*
- iii. be tested serologically with negative results for bluetongue antibodies at least every 60 days during germplasm collection and between 28 and 60 days after collection with negative results. An OIE recommended test for the detection of sero-group antibodies should be used (Eaton, 2004); or*

- iv. *be tested by a virus isolation procedure or PCR on the day of commencement and conclusion of collection and at least every 7 days during collection of semen and on the day of collection of embryos.*

6.2.2 Discussion

Bluetongue is an OIE listed disease and the IETS classifies bluetongue in sheep embryos as category 2¹.

Whilst the 2005 sheep and goat germplasm IRA stated that risk management measures are justified, the more recent IRA for bovine germplasm (completed in February 2009) concluded that risk management measures are not justified. The reason for this is because New Zealand is free from *Culicoides* spp., the insect vector of bluetongue virus and hence the likelihood that the virus could establish here is negligible.

Nevertheless while reasonable from a risk and import cost perspective, abolition of measures against bluetongue virus for imported semen and embryos from sheep and goats could create disruption in trade because of a lack of alignment with the recommendations from the OIE and the requirements of other countries.

6.2.3 Recommendation

The IHS should align with the *Code* measures.

6.3 Borna disease virus

6.3.1 Risk management measures presented in the 2005 risk analysis included:

- i. *sheep and goat germplasm should be imported from countries in which the disease has never been reported or;*
- ii. *donors should be selected from flocks with a long history of freedom from the disease in countries in which the disease is notifiable or in which reliable histories are available and;*
- iii. *aliquots of semen and embryos from each collection batch of germplasm should be inoculated intracerebrally into rabbits or cultured on cell cultures derived from embryonic rabbit or rat brain with negative results.*

6.3.2 Discussion

Borna disease is not OIE listed. There is no evidence that it is venereally transmitted in any species of animal and the public health impact remains only speculative. Measures were excluded from the IHS for equine germplasm from the EU, where the disease is known to occur.

6.3.3 Recommendation

No measures are recommended.

6.4 Capripox virus (sheep and goat pox)

6.4.1 Risk management measures presented in the 2005 risk analysis included:

Donor animals (and sentinels) should:

- i. *be resident in a country that is free from the disease for at least the 21 days prior to germplasm collection; or*
- ii. *not have been vaccinated against capripox; and*
 - a. *be quarantined for the 21 days before collection of germplasm on a germplasm collection centre that is free from the disease. During this period they should be*

¹ For an explanation of the categories, please refer to the IETS *Manual* or the OIE *Code*.

regularly inspected and remain healthy. Inspection should include careful inspection and palpation of the skin and regular taking of temperature. If indigenous breeds of sheep that are of a breed that is highly resistant to sheep pox are to be donors they should be kept in close contact with sentinel sheep of a susceptible breed during the quarantine period; and

- b. remain disease free from the disease for 21 days after the collection of germplasm is complete; and*
- c. the germplasm collection centre should be situated in a sheep and goat pox-free zone.*

6.4.2 Discussion

Sheep and goat pox is an OIE listed disease and there are *Code* recommendations for import of semen. The *Code* prescribes premises and zone freedom that may or may not be combined with vaccination of the donor. The *Code* has no measures for embryos, but those prescribed for semen are also suitable for embryos.

The use of sentinel sheep is not prescribed by the *Code* and is not scientifically justifiable; there is no transmission early in the disease and animals with mild and inapparent infections rarely transmit disease. The detailed description of donor inspections is not recommended in the *Code* and hence will not be included.

6.4.3 Recommendation

The IHS should either require country freedom for germplasm donors or should be aligned with the *Code* measures.

6.5 Crimean Congo haemorrhagic fever virus (CCHF)

6.5.1 Risk management measures presented in the 2005 risk analysis included:

Donors should:

- i. have been resident for at least the 21 days before germplasm collection in a country that is free from the disease; or*
- ii. be scrupulously treated with a suitable acaricide and inspected to ensure that they are free from ticks and placed in isolation in tick-free germplasm collection premises. They should be kept in quarantine for a minimum of 3 weeks immediately before the start of and also during semen or embryo collection and regularly inspected and maintained in a tick-free state throughout the period of quarantine; or*
- iii. donors should be serologically tested within one week prior to the start of germplasm collection and 3-8 weeks after germplasm collection is completed. Germplasm collected from animals that were serologically positive at the first test and did not have a rising titre at the second test would be suitable for export. Germplasm from animals that are negative at both tests would be suitable for export. Germplasm from animals that sero-convert or have rising titres between the two tests should be disqualified from being exported to New Zealand. If any animal from a group of donors is disqualified due to the testing procedures, germplasm from all animals in the group should be disqualified.*

6.5.2 Discussion

Whilst it is an OIE listed disease, there is no *Code* chapter. It is only briefly mentioned in the bunyaviral disease chapter.

Although the known vector of CCHF is not present in New Zealand, bringing infected germplasm into New Zealand could have severe public health impact. Viraemic animals could appear healthy, increasing the chances of infected germplasm reaching New Zealand. An infected animal's blood or other tissue could lead to human infection with a mortality rate of 30% and human-to-human transmission.

There are no currently approved tests, but the risk would be considered managed by protecting donors from ticks for at least 21 days before collection.

6.5.3 Recommendation

Options could be country freedom or tick treatment, inspection and quarantine.

6.6 Foot and mouth disease virus (FMD)

6.6.1 Risk management measures presented in the 2005 risk analysis included:

Importations of semen and embryos should be restricted to importation from countries that are free from foot and mouth disease and in which vaccination is not practised.

6.6.2 Discussion

The IETS has categorised sheep and goat embryos as category 3. The 2011 bovine germplasm IHSs concluded that because of the extreme seriousness of FMD and the catastrophic consequences that would result from its introduction, importation should be limited to countries or zones that are either free from FMD virus without vaccination or be specifically approved by MPI if they are not free without vaccination (and therefore present a risk).

The new format of the IHS includes a section indicating that the Competent Authority is subject to an assessment (see 2.3 Exporting country systems and certification). MPI will maintain a published list of FMD free countries (rather than referring to the *Code* list). There is therefore no longer the need for a specific statement regarding approval of processing, collection, and storage facilities in the FMD section.

The measures in the *Code* for FMD free countries which vaccinate are considered to manage the risk.

6.6.3 Recommendation

The IHS should clarify that MPI must be satisfied that the countries are free from FMD and that the requirements to import will align with the *Code*.

6.7 Jaagsiekte sheep retrovirus (ovine pulmonary adenomatosis)

6.7.1 Risk management measures presented in the 2005 risk analysis included:

- i. *germplasm should be introduced from animals that have lived their whole lives in countries that are free from jaagsiekte; or*
- ii. *only embryos should be introduced: and*
 - a. *donor animals should be selected from flocks with a long history of freedom from jaagsiekte. Importation of embryos from countries where reliable records are not available should not be allowed; and*
 - b. *recipients of imported embryos and any offspring resulting from implanted embryos should be held in post arrival quarantine in New Zealand for at least three and a half years. At the end of three and a half years recipients of germplasm and the first generation progeny of the germplasm should be slaughtered and examined for the presence of lesions of jaagsiekte. Only second generation progeny should be released from quarantine when the first generation progeny have been shown to be free from the disease.*

6.7.2 Discussion

Lambs are persistently infected with jaagsiekte from an early age yet disease expression may take several years. Diagnosis of jaagsiekte is reliant on clinical evidence and post mortem findings, or viral DNA and RNA detection by PCR testing of peripheral blood mononuclear cells.

Whilst jaagsiekte is an OIE listed disease, there is no *Code* chapter. Despite the lack of international

standards for managing jaagsiekte in germplasm, some of the IRA measures are appropriate. The option of post-arrival quarantine is however highly restrictive and importers may attempt to avoid a prolonged quarantine by importing embryos via Australia.

Although the IETS classifies jaagsiekte as category 3 in embryos, semen may present greater risk because the virus can be found in peripheral blood leukocytes.

6.7.3 Recommendation

The IHS should specify country freedom or a period of premises freedom. This period should be long enough to allow clinical signs to manifest. If premises freedom cannot be certified, a PCR test may be an alternative.

The measures applied for embryos also offer an acceptable level of risk management for semen.

6.8 Louping ill and related viruses

6.8.1 Risk management measures presented in the 2005 risk analysis included:

Germplasm donors should:

- i. have been resident in a country that is free from the disease, for at least 21 days immediately before and during germplasm collection; or*
- ii. be scrupulously treated for ticks before being moved onto tick-free collection premises. They should be carefully inspected and maintained tick-free while on the germplasm collection centre. Germplasm collection should not begin until they have been on the tick-free premises for at least 21 days.*

6.8.2 Discussion

These tick-borne encephalitis viruses are not transmitted by the species of ticks present in New Zealand and no evidence has been found suggesting their transmission in germplasm. Although the disease can present a public health threat (rare and generally non-fatal), it is not OIE listed (with no Code chapter or recommendations).

6.8.3 Recommendation

Despite the recommendations made in the 2005 risk analysis, no measures are recommended because of the lack of vector in New Zealand and because germplasm is not considered to pose louping ill virus risk.

6.9 Maedi-visna virus

6.9.1 Risk management measures presented in the 2005 risk analysis included:

- i. donors of germplasm should have been born in and lived their entire lives in a country that is free from maedi-visna; or*
- ii. donors should be selected from disease free flocks, preferably from flocks in official accreditation schemes; and*
 - a. individual donors should be tested by an OIE recommended ELISA test 4-8 weeks after collection of germplasm. Germplasm from animals that are serologically positive should be disqualified from entry into New Zealand; or*
- iii. flocks that are not officially accredited should have been maintained as closed flocks and remained free from clinical disease for 3 years. A sample of sheep from the flock large enough to give a 99% confidence of detecting infection at a 1% prevalence rate in the flock should be tested by an OIE recommended serological test (Knowles and Herrmann, 2004). Donors should be selected only from flocks shown to be maedi-visna free; and*

- a. *individual donors should be tested by an OIE recommended ELISA 4-8 weeks after collection of germplasm. Germplasm from animals that are serologically positive should be disqualified from entry into New Zealand.*

6.9.2 Discussion

Infection of animals with maedi-visna occurs at a young age and seroconversion is prolonged and unpredictable. In addition, after seroconversion, the antibody response usually persists and seropositive sheep and goats are regarded as virus carriers.

Maedi-visna is an OIE listed disease and the IETS classifies it in sheep embryos as category 3.

6.9.3 Recommendation

The IHS should specify country freedom for germplasm donors. There are *Code* recommendations for semen donors. It is reasonable to apply the measures to embryo donors. Since it takes 21-28 days for antibodies to be detected, serological testing should align with the *Code* and be subsequent to entering isolation and then annually. If an embryo donor has not been isolated pre-collection, testing should be at least 21 days after entering the collection herd/flock.

6.10 Nairobi sheep disease virus

6.10.1 Risk management measures presented in the 2005 risk analysis included:

Donors of germplasm should:

- i. *be resident in countries that are free from the disease for at least the 21 days prior to germplasm collection; or*
- ii. *be scrupulously treated for ticks before being moved onto tick-free collection premises. They should be carefully inspected and maintained tick-free while on the germplasm collection centre. Germplasm collection should not begin until they have been on the tick-free premises for at least 21 days.*

6.10.2 Discussion

This virus is transmitted by the tick *Rhipicephalus appendiculatus* and is not contagious between sheep and goats. It presents minor public health concern (mild influenza-like disease) in the case of tick bite or needle stick. Because the New Zealand cattle tick is not a known vector, the disease would be unlikely to establish. Furthermore, it is unlikely that transmission would occur via germplasm collected according to *Code* recommendations. There is no scientific evidence supporting the imposition of measures for germplasm.

Nairobi sheep disease is an OIE listed disease. Although there is no *Code* chapter, it is described with other Bunyaviruses in the *Terrestrial Manual*.

6.10.3 Recommendation

Despite the recommendations made in the 2005 risk analysis, no measures are recommended because of the lack of vector in New Zealand and because germplasm is not considered to pose Nairobi sheep disease virus risk.

6.11 Peste des petits ruminants virus (PPR) and rinderpest virus

6.11.1 Risk management measures presented in the 2005 risk analysis included:

The recommendations in the Terrestrial Animal Health Code for PPR should be the basis for ensuring that PPR and rinderpest viruses are not imported in germplasm. It is recommended that donors of germplasm should:

- i. *be kept in a country that is free from rinderpest and PPR, for at least 3 months prior to collection of germplasm; or*
- ii. *be kept for the 21 days prior to collection, in an establishment or germplasm collection centre where there have been no animals introduced in the 21 days prior to collection and no animal in the establishment showed signs of PPR or rinderpest at the time of collection or for the following 21 days. The germplasm collection centre should not be situated in a PPR infected zone; and*
 - a. *the donors have not been vaccinated against rinderpest or PPR and were tested with an OIE recommended serological test for PPR, with negative results, not less than 21 days after collection of germplasm; or*
 - b. *the donors have been vaccinated against PPR or rinderpest at least 21 days before and not more than 4 months prior to germplasm collection.*

6.11.2 Discussion

The 2009 IRA for cattle germplasm does not include any measures for rinderpest. In May 2011 the OIE and the Food and Agriculture Organization of the United Nations (FAO) announced that global eradication of rinderpest had been achieved.

PPR is an OIE listed disease and recommendations are provided for both semen and embryo imports. The recommendations for semen are that donors are to be clinically free of the disease at the time of collection and for 21 days after, resident in a disease free establishment (semen) or flock/herd (embryos) and may or may not be vaccinated. Unvaccinated animals are also to be serologically tested.

6.11.3 Recommendation

No measures should be required for rinderpest.

For PPR the IHS should specify either country freedom or align with the *Code* measures for importing semen and embryos from PPR-infected countries. The *Code*'s requirement for serological testing of unvaccinated embryo donors should be extended to apply to unvaccinated semen donors.

6.12 Rift Valley fever virus (RVF)

6.12.1 Risk management measures presented in the 2005 risk analysis included:

To prevent the importation of infected germplasm the OIE recommendations for trade in live animals (Anonymous, 2004) should be applied to germplasm donors. Immediately prior to collection of germplasm, donors of should have:

- i. *resided for the 30 days prior to the collection of germplasm and during germplasm collection in a Rift Valley fever-free country or zone; or*
- ii. *resided for the 6 months prior to and during the collection of germplasm in a Rift Valley fever infected country in which climatic changes predisposing to outbreaks of Rift Valley fever have not occurred in the previous 6 months; or*
- iii. *been held in mosquito-free premises for at least the 30 days prior to the collection of germplasm and during germplasm collection.*

6.12.2 Discussion

RVF is a zoonotic disease and it is unknown whether mosquitoes indigenous to New Zealand can transmit the virus. The *Code* recommends measures for *in vivo* embryos but not for semen. The recommendations are that embryo donors are to be clinically free of the disease from 28 days prior to 28 days after collection, and either tested twice by serology (with no rise) or vaccinated. It is reasonable to apply the embryo measures to semen donors.

6.12.3 Recommendation

Both IHSs should either require country freedom or align with the *Code* measures for embryos or donors should be in vector-proof premises for the 30 days before and during collection.

6.13 Vesicular stomatitis virus

6.13.1 Risk management measures presented in the 2005 risk analysis included:

Donors should:

- i. be resident for the 21 days prior to germplasm collection and during germplasm collection, in a country or zone that is free from vesicular stomatitis; or*
- ii. be kept in an insect free quarantine station for at least the 30 days prior to and during germplasm collection; and be subjected to an OIE recommended serological test with a negative result, 3-6 weeks after germplasm collection.*

6.13.2 Discussion

Measures for vesicular stomatitis are included in the 2011 bovine germplasm IHS. Although rare in small ruminants, vesicular stomatitis is a serious concern because it is clinically indistinguishable from FMD.

Vesicular stomatitis is *Code* listed and recommendations are provided for embryo imports. The *Code* recommends embryo donors to be resident in an establishment free of the disease and serological testing prior to collection. The recommended testing does not ensure the exclusion of animals infected while in the establishment or incubating the disease at the time of collection. Also, since viraemia is not an issue in this disease, testing would be unnecessarily trade restrictive. The risk should be managed through a storage requirement of at least 30 days after collection, prior to shipment to New Zealand, during which time no case of VS was reported. The *Code* requirement for serological testing is therefore not required.

It is reasonable to apply the embryo measures to semen donors.

6.13.3 Recommendation

For consistency, measures similar to those recommended in the 2011 bovine germplasm IHS should be applied. These measures either provide for country or zone freedom or establishment freedom at the time of collection and for the 30 days after.

6.14 Wesselsbron disease virus

6.14.1 Risk management measures presented in the 2005 risk analysis included:

Prior to germplasm collection donors should have:

- i. resided for the 21 days prior to the collection of germplasm and during the collection of germplasm in a country or zone in which Wesselsbron disease virus does not circulate (as shown by serological surveys); or*
- ii. been held in mosquito-free premises or area (e.g. frost prone areas during the winter) for at least the 21 days prior to, and during the collection of germplasm; or*
- iii. been subjected to a serological test within a week prior to germplasm collection and again 3-6 weeks after germplasm collection. Germplasm would be suitable for importation if there was a positive test prior to germplasm collection or two negative tests. Germplasm should be disqualified from importation if there is a rising titre or seroconversion between the two tests.*

6.14.2 Discussion

Wesselsbron disease is not OIE listed. The virus is known to be present in semen and infected animals are believed to excrete the virus into germplasm during the viraemic period of 1-4 days length. There are also human health concerns with this virus, but the principal known vectors are not present in New

Zealand. The risk analysts have determined that a testing requirement would be disproportionate to the risk posed by this virus.

6.14.3 Recommendation

Sanitary measures are warranted due to the zoonotic potential of this disease. The IHS should either require country freedom or premise freedom.

6.15 *Brucella melitensis* (caprine and ovine brucellosis)

6.15.1 Risk management measures presented in the 2005 risk analysis included:

It is recommended that:

- i. *germplasm should be collected from animals that are resident in countries that are officially free from caprine and ovine brucellosis according to the OIE standards for country freedom; or*
- ii. *germplasm should be collected from donors resident in flocks that are officially free from brucellosis according to the OIE definition for officially free flocks; or*
- iii. *germplasm should be collected from donors resident in flocks that are free from brucellosis according to the OIE definition of freedom from Brucellosis; and*
 - a. *for semen - an aliquot of semen from each batch, before addition of antibiotics, should be cultured for isolation of Brucella spp (Nielsen and Ewart, 2004), with negative results.*
 - b. *for embryos - an aliquot of embryos made up from substandard embryos or an aliquot of available embryos, and wash fluid from the first wash without the addition of antibiotics should be cultured with negative results.*
 - c. *After removal of the aliquots for testing, embryos and semen should be further processed according to standard methods with the addition of antibiotics.*

6.15.2 Discussion

Caprine and ovine brucellosis are OIE listed. There is a Code chapter with descriptions for officially free countries or zones, officially free flocks/herds, and free flocks/herds. It also recommends measures for embryos and semen (either official flock/herd freedom or flock/herd freedom combined with donor testing) and the OIE provides a testing protocol to ensure semen collection centre disease freedom.

6.15.3 Recommendation

The IHS should either require official country, zone or flock/herd freedom or donors should align with the Code recommendations.

6.16 *Mycoplasma* and related mollicutes

6.16.1 Risk management measures presented in the 2005 risk analysis included:

Either:

- i. *donors should be selected from countries that are free from (contagious bovine pleuropneumonia) CCPP and contagious agalactia; and*
 - a. *aliquots of semen and embryos from each collection batch should be cultured for Mycoplasma and Ureaplasma spp. and all isolates identified. Once isolates have been identified a decision should be made about whether to allow importation of the germplasm; or:*
- ii. *flocks from which donors are selected should be subjected to serological testing using OIE recommended tests (Nicholas, 2004; Rurangirwa and Kinyili, 2004). The numbers of animals sampled for testing should be sufficient to detect infection in a flock with 99% confidence at a flock prevalence of 1%. The serological tests should be conducted with Mycoplasma agalactiae, Mycoplasma capricolum subsp. capricolum, Mycoplasma mycoides subsp. mycoides and Mycoplasma capricolum subsp. capripneumoniae antigens.*

- a. donors should be selected only from flocks that are shown to be free from *Mycoplasma spp. antibodies*; and
- b. individual donors should be isolated in a collection facility situated in a CCPP-free zone, for the 45 days immediately before germplasm collection; and
- c. donors should be tested with negative results, by OIE recommended serological tests with *Mycoplasma agalactiae*, *Mycoplasma capricolum subsp. capricolum*, *Mycoplasma mycoides subsp. mycoides* and *Mycoplasma capricolum antigens*, between 14-28 days after completion of germplasm collection; and
- d. aliquots of semen and embryos from each collection batch should be cultured for *Mycoplasma* and *Ureaplasma spp.* and all isolates should be identified. Once isolates have been identified a decision should be made about whether to allow importation of the germplasm.

6.16.2 Discussion

Whilst the IRA refers to various mycoplasmas, only pathogens that are OIE listed or those that have been classified in a risk analysis as a significant risk should be included in the IHS.

In the case of contagious bovine pleuropneumonia (CBPP), this has been isolated from sheep and goats, but the infection is mild and since it is unlikely a bacteraemia develops, germplasm will not be infected. With regard to *M. bovis*, natural infection is not considered to cause disease in sheep and goats, and no evidence could be found that sheep and goats may transmit this to cattle.

The only mycoplasmas of concern in sheep and goats are the causative organisms of contagious agalactia and contagious caprine pleuropneumonia (CCPP), both of which are OIE listed. The IETS classifies *Mycoplasmas* in goat embryos as category 4.

For contagious agalactia the *Code* makes recommendations for the import of live sheep and goats and it is reasonable to apply these measures to embryo donors. Although there is no OIE prescribed test, there are *Code* recommended protocols to ensure semen collection centre disease freedom from contagious agalactia.

There are *Code* recommendations for CCPP for import of caprine embryos. They include flock/herd and zone freedom, isolation, and donor and germplasm testing. There are also *Code* recommended testing protocols to ensure semen collection centre disease freedom from CCPP.

6.16.3 Recommendation

In the case of contagious agalactia the semen IHS should either require country freedom or align with the *Code*. The *Code* has semen collection centre testing protocols, which follow the recommendations for live animal importation, except that 21 days in PEI is not required. Testing should also be required since there is a subclinical carrier state which persists for longer than 6 months. Embryos should be subject to the same requirements as semen.

CCPP requirements should only apply to goats. The IHS should either require country freedom or in the case of semen align with the *Code* recommended semen collection centre testing protocols and in the case of embryos with the *Code* recommendations applicable to embryos. Although the *Code* measure for embryos does not describe a serological testing regime, the *Code* semen testing protocol does and it should also be an option for embryo donors. Although the *Code* does not include a PCR option for semen, it does for embryo collection fluids and this option should be included for semen. There will not be a requirement which prevents vaccinated donors, however at this time tests are unable to distinguish between natural and vaccine induced antibodies and a donor which tests positive would not be permitted.

6.17 *Salmonella* spp

6.17.1 Risk management measures presented in the 2005 risk analysis included:

It is recommended that:

Aliquots of semen and embryos and wash fluid from embryo processing should be cultured according to OIE recommended culture methods. All isolated strains of Salmonella spp. should be fully identified before final clearance is given to import germplasm. Aliquots of semen for culturing should be collected in pre-enrichment media before the addition of extender containing antibiotics to the semen. Embryos that are substandard for use as embryos for transplantation should be used for culturing. If no substandard embryos are available then an aliquot of embryos should be used for culturing. In addition the first washing of embryos should be carried out in medium that does not contain antibiotics and this medium should be centrifuged and the deposit cultured. Entry of germplasm that is contaminated with any Salmonella of a species that is exotic to or unwanted in New Zealand should be prohibited.

6.17.2 Discussion

The most likely way that sheep and goat germplasm would be contaminated with *Salmonella* is from septicaemic/bacteraemic donors or from the environment. However, since the Code specifies hygiene standards during germplasm collection and donors are certified as being clinically healthy at the time of collection, such contamination is unlikely.

Also, no evidence was found suggesting that salmonellosis is likely to be transmitted via germplasm that has been collected according to Code recommendations. Furthermore the risk of exotic *Salmonella* being introduced into New Zealand is insignificant when compared to the risk from human travellers entering the country.

6.17.3 Recommendation

No specific measure for *Salmonella* is recommended other than the general Code requirement that bactericidal antibiotics are added to imported germplasm.

6.18 *Mycobacterium caprae* and *bovis*

6.18.1 Risk management measures presented in the 2005 risk analysis included:

It is recommended that:

- i. germplasm donors should originate from countries in which tuberculosis does not occur in goats; or*
- ii. if imported from countries where tuberculosis is endemic in goats donors should be sourced from accredited flocks; and*
 - a. donors should be tested, with negative results, by the tuberculin test and the gamma interferon test within 30 days after the collection of germplasm.*

6.18.2 Discussion

Tuberculosis is rare in sheep, but less rare in goats. *M. caprae* has not been reported in New Zealand and there is a National Pest Management Strategy aimed at the eradication of tuberculosis (*M. bovis*).

There are no Code recommendations for tuberculosis in sheep and goats but the Code does make recommendations for semen collection centre testing protocols for goats.

6.18.3 Recommendation

No measures should be required for sheep germplasm.

In the case of goats, the IHS should either require country freedom or align with the Code recommended semen collection centre testing protocols. These measures should be adapted and applied to embryo donors.

6.19 *Leptospira* serovars

6.19.1 Risk management measures presented in the 2005 risk analysis included:

Germplasm should be prepared according to the recommendations of OIE Terrestrial Animal Health (Anonymous, 2003, 2004b) and IETS (IETS, 2002) including the use of penicillin and streptomycin in semen diluents and embryo washing media as recommended in the OIE Terrestrial Animal Disease [sic] Code (2004) for bovine semen (Article 3.2.1.9) and embryos (Code Section 3.3.2.4).

6.19.2 Discussion

Leptospira are sensitive to several antibiotics and germplasm can be treated by using suitable antibiotics in germplasm.

6.19.3 Recommendation

No specific measure for *Leptospira* is recommended other than the general Code requirement that bactericidal antibiotics are added to imported germplasm.

6.20 *Chlamydia abortus* (enzootic abortion of ewes, EAE)

6.20.1 Risk management measures presented in the 2005 risk analysis included:

It is recommended that:

- i. donors should be selected from animals that have been resident since birth or for the previous 2 years in a country that is free from the infection; or*
- ii. donors should be selected from flocks or from animals kept on germplasm collection centres that are infection-free as defined in the OIE Terrestrial Animal Health Code; and*
 - a. individual donors should be tested serologically using an OIE recommended test, 2-3 weeks after germplasm collection; and*
 - b. aliquots of semen and embryos should be tested for Chlamydia by culture, PCR or antigen detection ELISA. In the case of embryos, wash fluid and embryos that are substandard and not suitable for export, could be used for testing; or*
- iii. a sample of the flock should be tested with negative results by an OIE recommended serological test, the sample being large enough to give a 99% confidence of detecting infection at a prevalence of 1%. Donors should only be selected from flocks that are shown to be free from the infection; and*
 - a. individual donors should be tested serologically using an OIE recommended test, 2-3 weeks after germplasm collection; and*
 - b. aliquots of semen and embryos should be tested for Chlamydia by culture, PCR or antigen detection ELISA. In the case of embryos, wash fluid and embryos that are substandard and not suitable for export, could be used for testing.*

6.20.2 Discussion

EAE is an economically significant disease, which poses a public health threat, and infected animals can be subclinically infected.

The IETS classifies EAE as category 4 and there is a Code chapter with recommendations for semen; these measures require donors originate from a free establishment and testing of donor and semen. The Code describes measures for an EAE free flock and this includes a testing regime required to demonstrate flock freedom. Since the estimated prevalence would vary for each country, the Competent Authority should determine a statistically valid testing regime with an appropriate confidence level. It is reasonable to adapt the semen measures for embryo donors.

6.20.3 Recommendation

The IHS should either require country freedom or align with the Code measures for semen. These measures should also apply to embryo donors.

6.21 *Coxiella burnetii* (Q Fever)

6.21.1 Risk management measures presented in the 2005 risk analysis included:

- i. donors should be scrupulously treated with a suitable acaricide and inspected to ensure that they are free from ticks and placed in isolation in tick-free germplasm collection premises. They should be kept in quarantine for a minimum of 4 weeks days immediately before the start of semen or embryo collection and regularly inspected and maintained in a tick-free state throughout the period of quarantine and germplasm collection; and
 - a. donors should be tested by a complement fixation test or ELISA, with negative results 14-30 days after the final collection of the germplasm. A positive test should result in prohibition of importation of the germplasm.

6.21.2 Discussion

Q fever is not an economically significant disease of livestock but can cause serious disease in humans. It is OIE listed but there is no Code chapter with recommendations for germplasm.

Venereal transmission in cattle has been reported and the presence of *Coxiella burnetii* in sheep and goat semen is possible. If it were to be introduced, the New Zealand cattle tick could become infected and could transmit the disease.

6.21.3 Recommendation

For consistency, measures similar to those required in the 2011 bovine germplasm IHS should be applied. The option of flock/herd isolation and testing should, however, not be included because infection can spread over large distances by aerosol.

Options provided should be either serological testing of the donor or PCR testing of the germplasm. Owing to the intermittent shedding of the organism it is recommended that animals that have previously been confirmed positive be disqualified from importation.

6.22 Scrapie

6.22.1 Risk management measures presented in the 2005 risk analysis included:

For embryos:

- The international standard
- Importation of embryos from scrapie-free countries
- Importation of embryos from scrapie-free flocks
- Restrict donors to particular genotypes
- Restrict donors to animals over a certain age
- Restrict donors to animals negative on RAMALT biopsy
- Restrict donors to animals negative on bioassay
- Quarantine of offspring

For semen:

- The international standard
- Importation of semen from scrapie-free countries
- Importation of semen from scrapie-free flocks
- Restrict rams to particular genotypes
- Restrict rams to animals over a certain age
- Restrict donors to rams negative on RAMALT biopsy
- Restrict donors to rams negative on bioassay
- Quarantine of offspring

6.22.2 Discussion

Scrapie is OIE listed. The *Code* has Articles for both semen (sheep and goats) and embryos (*in vivo*-derived goat embryos) and also provides requirements for a scrapie-free establishment. The *Code* also has general recommendations for disease prevention and control (Section 4) which should be applied as stated in the *Code*.

The IETS classifies scrapie in sheep embryos as category 1 and the *Code* states no measures (beyond Chapter 4.7) are required for importation, irrespective of the origin of the donor.

However, there is less experimental data available on the risk of transmission of scrapie in goat embryos, and therefore the IETS classification of scrapie in goat embryos is category 4.

There is strong scientific evidence that scrapie is not transmitted via semen. However, too few experiments have been done to demonstrate that the risk of transmission by this route is negligible. Therefore, measures are justified for sheep and goat semen.

There is good evidence in sheep that certain genotypes are resistant to scrapie, but this is not the case for goats.

Therefore there are two options for sheep semen from countries or zones not free from scrapie: establishment freedom as per the *Code*, or restriction of imports to semen from rams of resistant genotypes.

For goat semen, there is only one option apart from country or zone freedom: establishment freedom as per the *Code*.

6.22.3 Recommendation

For goat embryos the measures in the IHS should require country or zone freedom or establishment freedom or the OIE recommended measures for countries or zones not free from scrapie.

In accordance with the recommendations of the *Code*, for in-vivo derived sheep embryos the IHS should require no measures beyond the *Code* recommendations (collection and processing of in vivo derived embryos from livestock and equids), which will be stated in the general requirements section.

For goat semen, the IHS should require country or zone freedom or establishment freedom.

For sheep semen the IHS should require country or zone freedom or establishment freedom or scrapie-resistant genotypes.