

*Risk management proposal:
Bovine semen and embryos*

FOR PUBLIC CONSULTATION

21 June 2010

DRAFT

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Purpose

The purpose of this document is to show how the options put forward in the import risk analysis for risks associated with importation of bovine germplasm (semen and embryos) have been assessed. In addition it provides recommendations on import requirements to be included in the import health standard (IHS).

Stakeholder feedback is sought on the proposed management options.

The IHS is developed under Section 22 of the Biosecurity Act.

Background

Bovine embryos and semen are high risk commodities because they are living biological materials known to be capable of transmitting some important exotic viral, bacterial, and protozoan diseases, and would be transplanted or inseminated into susceptible recipients. These commodities nevertheless present a lower risk and safer alternative to importation of live animals.

New Zealand has a history of importation of bovine semen and embryos from a limited number of countries, and continues to import under existing import health standards. In February 2009, MAFBNZ issued a new import risk analysis for bovine germplasm. In July 2009 work began on the new import health standard for bovine semen and bovine embryos. Completion of the new standard is a priority on the work program for 2009/2010 within the ruminant portfolio of the Animal Imports Team.

In accordance with new MAF processes, the import health standards for bovine semen and embryos are presented in a single standard addressing all requirements to manage biosecurity risks. Upon completion of bilateral negotiations and subsequent to the import health standards being issued, a guidance document outlining which risk management measures apply to specific countries and the bilaterally-agreed format for zoo-sanitary certification for the trade will be issued. At this point, the existing standards will be revoked.

Objective

The objective is to effectively manage all biosecurity risks associated with the importation of bovine embryos and semen, in a way that is consistent with New Zealand's domestic legislation and international obligations.

Options Assessment

The 2009 import risk analysis for bovine germplasm identified the disease causing organisms likely to be associated with imported bovine germplasm. Risk assessment processes then identified whether the organism was to be classified as a hazard in the commodity requiring risk management measures.

The following organisms were deemed to hazards requiring risk management measures:

- Borna disease virus
- Bovine viral diarrhoea virus type 2
- Crimean Congo haemorrhagic fever virus

- Foot and mouth disease virus
- Exotic bovine herpes viruses (semen only)
- Lumpy skin disease virus
- Rift Valley fever virus
- Vesicular stomatitis virus
- Exotic *Brucella* spp. (semen only)
- *Mycobacterium bovis*
- *Mycoplasma mycoides* subsp. *mycoides* SC
- Other exotic *Mycoplasma* spp.
- Exotic *Salmonella* spp.
- Exotic *Leptospira* spp.
- *Chlamydomphila abortus*
- *Coxiella burnetii*

The risk management process identified the options available for effectively managing the risk. These included OIE Code listed recommendations as well as options of similar, lesser, or greater stringency, where available, as well as options of unrestricted entry or prohibition.

For a detailed analysis of potential hazards and their risks refer to the supporting import risk analysis, which contains the relevant risk assessments and an analysis of potential management options against the identified biosecurity risks:

<http://www.biosecurity.govt.nz/files/regs/imports/risk/cattle-germplasm-ra.pdf>

Work on a new import health standard for cattle germplasm, to be based on the 2009 import risk analysis, was begun in July 2009.

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

The recommended options for risk management in the new IHS were developed through a process of internal and external consultation. Considerations in this process included alignment with international standards, i.e. the OIE, alignment with existing practices in the bovine germplasm industry, acceptable levels of risk, expected effects on trade and practical applications.

Internal consultation among MAFBNZ staff from the directorates of International Coordination, Policy and Risk and Border Standards resulted in the formulation of a set of preliminary options for mitigation of risks. The decisions of the group were presented on March 3, 2010 at a stakeholder forum to gain input on, and assist stakeholders in understanding the basis for, risk management decisions in the import health standard.

Subsequent internal discussions among members of the Policy and Risk Group, the Animal Imports and Exports Group, and the International Coordination Group as a result of stakeholder input resulted in further modifications.

I. Bluetongue (BT) – embryos and semen

Options for management of risk presented in the 2009 import risk analysis for bovine germplasm:

Because New Zealand is free of *Culicoides* spp., the insect vector of bluetongue virus, the likelihood that the virus could establish in New Zealand was determined in the risk analysis to be negligible. The risk analysis concludes that risk management measures are not justified.

Other risk management considerations:

While reasonable from a risk and import cost perspective, abolishment of measures against bluetongue virus for imported bovine semen would be contrary to OIE Code recommendations. This could create disruption in trade because of a lack of alignment with the requirements of other countries.

IHS Recommended options:

It is recommended that no risk management measures against bluetongue be placed on imports of bovine embryos.

For imports of bovine semen:

EITHER

At the time of collection the exporting country was free from BT in accordance with the requirements of the OIE Code; OR

Semen donors were kept in a BT virus free zone, as defined by the OIE Code, for at least the 100 days immediately prior to, and during, collection of the semen for consignment to New Zealand; OR

Semen donors were kept during the seasonally free period in a BT virus seasonally free zone, as defined by the OIE Code, or otherwise protected from *Culicoides* for at least the 100 days immediately prior to commencement of, and during, semen collection for the consignment to New Zealand; OR

Semen donors were subjected to MAF-approved antibody detection tests for BT, such as the competitive enzyme linked immunosorbent assay (ELISA) or the agar gel immunodiffusion test (AGID), between 28 and 60 days after the last collection for this consignment, with negative results; OR

Semen donors were subjected to MAF-approved agent detection tests for BT, such as a virus isolation (VI) test or a polymerase chain reaction (PCR) test, on blood samples collected at commencement and conclusion of, and at least every 7 days (for VI test) or at least every 28 days (for PCR test) during, semen collection for this consignment, with negative results

II. Borna disease – embryos and semen

Options for management of risk presented in the 2009 import risk analysis for bovine germplasm:

- Require germplasm donors to have been resident since birth in countries where the disease has never been reported.

- Require donors to originate from herds with a greater than 5 year history of freedom from the disease in countries in which the disease is notifiable or in which reliable histories are available.
- Test aliquots of semen and embryos from each collection by inoculation intracerebrally into rabbits or by culture on cell cultures from embryonic rabbit or rat brain with negative results.
- PCR test of peripheral cells from donors with negative results. (Accuracy and reliability of this testing methodology have been questioned.)

It is proposed that all of the options suggested in the risk analysis be used, in modified form, in the import health standard.

IHS Recommended options:

EITHER

Donors have been resident since birth in a country or countries that has never had a reported case of Borna disease; OR

Borna disease is officially notifiable in the exporting country, and the donors have been resident since birth in herds where there has been no reported case in the period from 5 years prior to commencement of collection until conclusion of collection of germplasm for export; OR

Donors or aliquots of germplasm (embryos or semen) have been tested using a MAF approved test and process, and are negative for Borna disease.

III. Bovine viral diarrhoea virus (BVDV2) – embryos and semen

Options for management of risk presented in the 2009 import risk analysis for bovine germplasm:

- Require donor bulls to have been resident on a semen collection centre where bulls are maintained and tested as specified in the OIE Code chapter on collection and processing of bovine semen.
- Require each batch of semen be tested by VI or reverse transcriptase polymerase chain reaction (RT-PCR). (This measure is in the proposed measures for bulls that have been on semen collection centre for less than 6 months at the time of collection of germplasm for the consignment to New Zealand.)
- Require that embryo donors be tested and maintained similarly to bulls on semen collection centre per OIE Code chapter on collection and processing of bovine semen.
- Require non-fertilized, degenerated, and zona pellucida compromised embryos, collection fluid and washing fluid from each donor collected and be tested by VI or RT-PCR, with negative result. (Note that this measure is in the proposed measures for donors that have been on the embryo collection centre for less than 6 months at the time of collection for the consignment to New Zealand.)

In accordance with suggestions for risk management in the import risk analysis it is recommended that risk management measures against BVDV serotype 2 include a requirement for maintenance of germplasm collection premise freedom from BVDV in accordance with the OIE Code.

Other risk management considerations:

Industry put forth a request to extend the period after entry to collection premises that donor germplasm be required to be subject to testing for BVDV from 6 months to 3 years based on recent reports of persistent testicular infections that resulted in shedding of BVDV for over 5 years.

It is recognised that at present there is no validated VI or RT-PCR test that could be used for germplasm that is currently on the shelf; this option nevertheless provides opportunity for the future.

IHS Recommended options:

EITHER

At the time of collection, the exporting country was free of BVDV2, i.e. there have been no cases of BVDV2 for at least 3 years; OR

The germplasm collection centre must have been maintained as free from BVDV from the commencement until after conclusion of collection of semen/embryos for export to New Zealand through compliance with the recommendations in the OIE Code in relation to BVDV, including:

- testing all cattle for antibodies and antigen using prescribed tests prior to entry into pre-entry isolation and during pre-entry isolation, and only approving entry for groups where pre-entry isolation results indicate the absence of sero-conversion and absence of antigen-positive cattle; AND
- thereafter annual retesting of sero-negative cattle; AND
- for seropositive donors, testing of semen/embryos or oocytes, collection fluids and/or washing fluids for BVDV2, with negative results, prior to initial dispatch; AND
- for seronegative donors, an antibody test using prescribed methods, with negative result, from samples collected after the conclusion of germplasm collection for export

Germplasm donors that have been on the germplasm collection centre for less than 3 years have had an aliquot of semen/embryos or oocytes, collection fluids and/or washing fluids from each collection in the consignment tested for BVDV2 using prescribed methodology, such as VI or validated RT-PCR, with negative results.

IV. Crimean Congo Haemorrhagic Fever (CCHF) – embryos and semen

Options for management of risk presented in the 2009 import risk analysis for bovine germplasm:

- Require germplasm donors to have been resident for at least the 21 days before germplasm collection in a country or zone that is free from the disease.
- Require scrupulous treatment of germplasm donors with acaricide, and inspection and placement in tick free germplasm collection premises. Donors would be required to be quarantined for at least 3 weeks prior to start of and during germplasm collection with regular inspection and maintenance of tick free status.
- Require serological testing of germplasm donors within 7 days prior to start of germplasm collection and 3-8 weeks after germplasm collection.

All of the risk management options suggested in the import risk analysis were included as proposed options for the import health standard.

IHS Recommended options:

EITHER

CCHF is officially notifiable in the exporting country, and there has never been a reported case of CCHF in the country or countries in which the donors have been resident for the 21 days before, and during, germplasm collection for export; OR

Germplasm donors were treated for ticks with an efficacious acaricide in accordance with the manufacturer's directions, inspected after ten days and found to be free of ticks, and then were resident in a tick free germplasm collection premises for at least 3 weeks prior to the commencement of collection until conclusion of collection of germplasm for export. Verification of tick freedom in the germplasm collection facilities is performed by inspections performed at least monthly where no ticks were found; OR

Germplasm donors were serologically tested for CCHF using prescribed methods such as a validated ELISA to detect IgG and IgM antibodies on blood samples collected within 7 days prior to commencement, every 60 days thereafter, until 21 to 60 days after conclusion of collection of germplasm for export. The results must indicate:

- That any donor seronegative at the start of testing has maintained a seronegative status; AND
- That any donor seropositive at the start of testing did not have a rise in titre over consecutive tests.

V. Foot and mouth disease (FMD) – embryos and semen

Options for management of risk presented in the 2009 import risk analysis for bovine germplasm:

- Institute measures in accordance with the OIE Code.
- Prohibit importation of germplasm from countries that are infected with foot and mouth disease.

Other risk management considerations:

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

IHS Recommended options:

EITHER

Donors were resident for at least the 3 months before, and during, germplasm collection in a country or zone that was free from FMD without vaccination in accordance with the OIE Code; OR

In the case of semen from countries or zones presenting a risk of FMD, the herds of origin, germplasm collection facilities, donors, and germplasm for export must comply with OIE Code recommendations for export from countries or zones presenting a risk of FMD. In this case, MAF will individually approve each semen collection and processing and storage facility/ies in the exporting country intended to be used during the preparation of an export consignment to New Zealand. The approval will be dependant on the facility, its location and operating standards and that the verification systems of the veterinary authority achieve a very high level of risk management for FMD. The process for MAF approval may include site inspection. MAF also reserves the right to supervise collection, require the use of New Zealand approved semen collection personnel, or require any other measures deemed necessary to ensure compliance with facility and operating standards upon which the approval is based; OR

In the case of embryos, MAF will individually approve each embryo collection and processing and storage facility/ies in the exporting country intended to be used during the preparation of an export consignment to New Zealand. The approval will be dependant on the facility, its location and operating standards and that the verification systems of the veterinary authority achieve a very high level of risk management for FMD. The process for MAF approval may include site inspection. MAF reserves the right to supervise collection, require the use of New Zealand approved embryo collection personnel, or require any other measures deemed necessary to ensure compliance with facility and operating standards upon which the approval is based.

VI. Bovine Herpes Virus (IBR/IPV) - semen only

Options for mitigating risk presented in the 2009 import risk analysis for bovine germplasm:

- Test each batch of semen by a VI test (or a suitable PCR test when available).
- Require that donors be from herds or breeding centres that are maintained free from IBR in accordance with the OIE Code.
- Require isolation of donor animals for at least 30 days after semen collection and testing by a validated serological test with negative result, at least 21 days after semen collection.

Each of the options presented in the import risk analysis were included, in modified form, in the recommended options for the IHS.

IHS Recommended options:

EITHER

The semen collection centre must have been maintained as free from IBR/IPV from the commencement until after conclusion of collection of semen for export to New Zealand through compliance with the recommendations in the OIE Code, including:

- testing all cattle, prior to entering pre-entry isolation, for antibodies using a prescribed test, with negative results; AND
- testing all cattle, in pre-entry isolation, for antibodies, with negative results, or where an animal in a group has tested positive, re-testing the remaining animals with negative results not less than 21 days after removal of the positive animal; AND

- thereafter, annual re-testing of all donor bulls for antibodies, with negative results; AND
- a negative antibody test result from sampling after the time of collection of semen for export to New Zealand must be supplied; OR

An aliquot equivalent to at least 0.05ml of raw semen from each semen collection for the export consignment to New Zealand must have been subjected to a VI test or validated PCR test, for both BHV1 and BHV5, with negative results.

VII. Lumpy skin disease (LSD) - embryos and semen

Options for management of risk from the 2009 import risk analysis for bovine germplasm:

- Donors have been resident for 6 months prior to germplasm collection in a country or zone that is free of LSD as defined by the OIE Code.
- Donors could be required to be resident in an establishment or germplasm collection centre that has been free from LSD for at least 6 months. All animals on the centre could be required to be free from any sign of LSD for at least 28 days after completion of germplasm collection.
- Aliquots of semen and embryo wash fluid and substandard embryos, or an aliquot of embryos, from each batch of imported germplasm could be tested by a PCR method for LSD.

Each of the options presented in the import risk analysis were included, in modified form, in the recommended options for the IHS.

IHS Recommended options:

EITHER

Donors must have been resident for 6 months prior to germplasm collection in a country that is free of LSD in accordance with the OIE Code; OR

Donors must have been resident in an establishment or germplasm collection centre that was free of clinical evidence of LSD from at least 6 months prior to commencement until 28 days after conclusion of collection of germplasm for export to New Zealand; OR

An aliquot of germplasm from each germplasm collection for the export consignment must be subject to a validated PCR test for LSD, with negative result.

VIII. Rift Valley Fever (RVF) – embryos and semen

Options for management of risk presented in the 2009 import risk analysis for bovine germplasm:

- Donors have been resident for 30 days prior to collection of germplasm, and during germplasm collection, in a RVF free country or zone.
- Donors have been resident for 6 months prior to and during collection of germplasm in a RVF infected country in which climatic changes predisposing to RVF outbreaks have not occurred in the previous 6 months.
- Donors were held in mosquito-free premises at least 30 days prior to, and during collection.

Each of the options presented in the import risk analysis were included, in modified form, in the recommended options for the IHS.

IHS Recommended options:

During the 3 months prior to, and during, germplasm collection for consignment to New Zealand, the exporting country was free of RVF in accordance with the current OIE Code; OR

Donors were resident for the 6 months prior to and during collection of germplasm for export to New Zealand in a RVF infected country, during which climatic changes predisposing to RVF outbreaks have not occurred; OR

Donors were kept in mosquito-free premises from at least 30 days prior to commencement until conclusion of collection of germplasm for consignment to New Zealand.

IX. Vesicular stomatitis (VS) – embryos and semen

Options for management of risk presented in the 2009 import risk analysis for bovine germplasm:

- Donors have been resident for at least the 30 days prior to and during germplasm collection, in a country or zone that is free of VS.
- Donors have been resident on a property where no cases of VS were known to have occurred within 100 kilometres of the collecting centre, during the period from 30 days before the first collection of germplasm until 30 days after the last collection of germplasm, for the consignment to New Zealand.
- Donors have been kept in an insect free quarantine station for at least 30 days prior to and during germplasm collection and have been subjected to an OIE recommended serological test, with negative result, between 3-6 weeks after germplasm collection.

Each of the options presented in the import risk analysis were included, in modified form, in the recommended options for the IHS.

IHS Recommended options:

Donors were resident in a country that is free from VS in accordance with the OIE Code; OR

VS is officially notifiable in the exporting country, and no cases have occurred within 100km of the germplasm collection premises during the period from 30 days prior to commencement until 30 days after conclusion of germplasm collection for export; OR

Donors were kept in insect free premises from at least the 30 days prior to commencement until conclusion of germplasm collection for export to New Zealand, and were subject to a validated serological test for VS, with negative results, between 3-6 weeks after germplasm collection for export to New Zealand.

VIII. Brucellosis - semen only

Options for management of risk presented in the 2009 import risk analysis for bovine germplasm:

- Donor bulls could be required to be kept since birth in a country or zone that is officially free from brucellosis.
- Donor bulls could be housed at an artificial breeding centre where the testing programme for bulls includes testing with both the complement fixation test and the buffered antigen agglutination test.
- Donor bulls could be required to be kept in a herd officially free from bovine brucellosis, showed no clinical sign of bovine brucellosis on the day of collection of the semen and were subjected to a buffered *Brucella* antigen test with negative results during the 30 days prior to collection. (Note: This option is for bulls not maintained on an approved semen collection centre - the standard will require that bulls are housed on a semen collection centre.)
- Donor bulls were kept in a herd free from bovine brucellosis, showed no clinical sign of bovine brucellosis on the day of collection and were subjected to the buffered *Brucella* antigen and complement fixation tests with negative results during the 30 days prior to collection. (Note: This option is for bulls not maintained on an approved semen collection centre.)

Each of the options suggested in the import risk analysis were included as recommended options in the import health standard in modified form.

Other risk management considerations:

In the interest of alignment with the recommendations of the OIE Code, the second option was modified to require maintenance of semen collection centre freedom from brucellosis in accordance with the recommendations of the OIE Code chapter on collection and processing of bovine semen.

IHS Recommended options:

Donors have been kept since birth in a country or zone that is free of bovine brucellosis in accordance with the OIE Code; OR

The semen collection centre must have been maintained as free from bovine brucellosis from the commencement until after conclusion of collection of semen for export to New Zealand through compliance with the recommendations in the OIE Code in relation to bovine brucellosis, including:

- Prior to entry into pre-entry isolation the donor bulls were either from a country or zone that is free from bovine brucellosis in accordance with the OIE Code; OR were from a herd officially free from bovine brucellosis in accordance with the OIE Code and were subjected to a prescribed serological test for bovine brucellosis with negative results during the 30 days prior to departure for the semen collection centre; AND
- Donor animals, in pre-entry isolation prior to entering the semen collection facilities, were subjected to a serological test for *Brucella abortus*, with negative results; AND
- All bulls and teasers resident in the semen collection facilities have been tested, at least annually for bovine brucellosis, with negative results.

IX. Bovine tuberculosis – embryos and semen

Options for management of risk presented in the 2009 import risk analysis for bovine germplasm:

- Semen donors could be required to show no clinical sign of bovine tuberculosis on the day of collection of the semen.
- Semen donors could be required to be kept in an artificial insemination centre free from bovine tuberculosis in a country, zone or compartment free from bovine tuberculosis and which only accepts animals from free herds in a free country, zone or compartment as defined by the OIE.
- Semen donors could be required to show negative results to tuberculin tests carried out annually and be kept in a herd free from bovine tuberculosis as defined by the OIE.
- Embryo donors and all other susceptible animals in the herd of origin could be required to show no clinical sign of bovine tuberculosis during the 24 hours prior to embryo collection.
- Embryo donors could be required to have originated from a herd free from bovine tuberculosis in a country, zone or compartment free from bovine tuberculosis.
- Embryo donors could be required to be kept in a herd free from bovine tuberculosis, be isolated in the establishment of origin for the 30 days prior to departure to the collection centre, and be subjected to a tuberculin test for bovine tuberculosis with negative results.

Other risk management considerations:

In accordance with suggested options in the import risk analysis, alignment with the OIE Code and the New Zealand bovine tuberculosis pest management strategy was chosen for management of the risk associated with bovine tuberculosis for bovine germplasm imported to New Zealand.

IHS Recommended options:

For bovine semen:
EITHER

Donors have been kept since birth in a country that is free from bovine tuberculosis in accordance with the OIE Code; OR

The semen collection centre must have been maintained as free from bovine tuberculosis from the commencement until conclusion of collection of semen for export to New Zealand through compliance with the recommendations in the OIE Code in relation to bovine tuberculosis, including:

- Prior to entry into pre-entry isolation the donor bulls were either from a country that is free from bovine tuberculosis in accordance with the OIE Code; OR were from a herd officially free from bovine tuberculosis in accordance with the OIE Code and were subjected to a OIE prescribed test for bovine tuberculosis with negative results during the 30 days prior to departure for the semen collection centre; AND
- All bulls and teasers resident in the semen collection facilities have been tested at least annually, using an OIE prescribed test for bovine tuberculosis, with negative results.

For bovine embryos:
EITHER

Donors have been kept since birth in a country that is free from bovine tuberculosis in accordance with the OIE Code; OR

Donors and other susceptible animals in the herd of origin showed no clinical signs of bovine tuberculosis during the 24 hours prior to collection of embryos for consignment to New Zealand; AND

Donors originate from a herd free of bovine tuberculosis as defined by the current OIE Code or by the veterinary authority of the MAF approved exported country and were subjected to an OIE prescribed test for bovine tuberculosis during the 30 day period of isolation prior to embryo collection.

X. Contagious bovine pleuropneumonia (CBPP) - semen and embryos

Options for management of risk presented in the 2009 import risk analysis for bovine germplasm:

- Donors of germplasm could be required to originate from a country or zone that is free from CBPP.
- Donors could be required to not be vaccinated against CBPP and be kept since birth or for at least 6 months in an establishment where no case of CBPP has been reported and the establishment is not situated in a CBPP infected zone.
- Donors could be subjected to an OIE recommended serological test with negative results on two occasions 21-30 days apart with the last test done within 14 days prior to germplasm collection.

Each of the options presented in the import risk analysis were included, in modified form, in the recommended options for the IHS. The second and third options were included as a combination of requirements for countries infected with CBPP.

IHS Recommended options:

Donors were born in and have been continuously resident in a country that is free of CBPP in accordance with the OIE Code; OR

Donors have never been vaccinated for CBPP; AND

Donors have been kept since birth or for at least the 6 months prior to commencement and until conclusion of germplasm collection for export to New Zealand in establishments where no case of CBPP has been reported, and which are not situated in a CBPP infected zone as defined by the OIE Code; AND

Donors must be serologically tested, with negative results, using OIE prescribed methods on two occasions 21-30 days apart, with the last test within 14 days prior to each germplasm collection for export to New Zealand.

XI. Other mollicutes (*Mycoplasma* or *Ureaplasma* spp.)

Options for management of risk presented in the 2009 import risk analysis for bovine germplasm:

- Monitor literature to see whether resistance to various antibiotics is reported, and revise the requirements for the antibiotics to be used in semen extender and embryo wash solutions as necessary.
- Culture of germplasm prior to addition of antibiotics. This option would preclude import of product not specifically prepared for New Zealand, i.e. 'on shelf' product.

- Culture of germplasm after addition of antibiotics. This option would be less rigorous than the last but would allow the importation of frozen germplasm that has already been processed and is available “on shelf”.

Other risk management considerations:

Historical risk for other mollicutes has been accepted because most species included under this heading are minor pathogens and probably present in New Zealand. However New Zealand is demonstrably free of *Mycoplasma bovis* which is now a well recognised pathogen of economic importance. For this reason more stringent measures against this organism are now proposed for the IHS.

Comment [AU1]:

An additional option for whole herd testing for *Mycoplasma bovis* is proposed to provide an opportunity to access on-shelf semen when the donor bull may not be available for testing (e.g. dead). Annual testing for other organisms, in accordance with OIE requirements, will facilitate the availability of samples for testing in these circumstances. We expect that only rarely will the value of the genetic material outweigh the additional cost of testing.

We recognise that New Zealand requirements for this organism are unique. The presentation of this range of options seeks to provide a wide range of mechanisms to deliver assurance that the donor animal/s is not infected, while limiting the restrictions impact on New Zealand access to on-shelf germplasm internationally.

IHS Recommended options:

EITHER

Donors were subject to a MAF approved serological test for *Mycoplasma bovis*, with negative result, on a sample collected between 21 and 120 days after each collection of embryos or last collection of semen for export to New Zealand; OR

A sample of germplasm from each germplasm collection for the export consignment must be subject to a validated PCR test for *Mycoplasma bovis*, with negative result; OR

A MAF approved validated ELISA serological test for *Mycoplasma bovis* was performed, with negative result, on the whole resident herd on the semen collection centre (in the case of semen)/ the whole herd of origin (in the case of embryos) or on a random sample of 60 animals from those herds (whichever is the lesser number) no more than six months before/after germplasm collection for consignment to New Zealand; AND

In the case of bovine embryos the donors have never recorded a positive test for *Mycoplasma bovis*.

XII. Salmonella

Options for management of risk presented in the 2009 import risk analysis for bovine germplasm:

- Require official certification that donors originate from farms on which outbreaks of salmonellosis have not occurred in the previous 3 years.

- Require culture of semen or embryos or wash fluid sediment. Where pathogenic *Salmonella* spp. exotic to New Zealand are isolated, importation of germplasm could be prohibited.

Other risk management considerations:

Property freedom would be difficult to certify.

Culture of germplasm after addition of antibiotics is the only option that would be practically feasible since culture prior to addition of antibiotics would require preparation of germplasm specifically for New Zealand. This would however significantly reduce access to genetics while increasing costs.

Culture of germplasm after addition of antibiotics would have questionable sensitivity because organisms would be present at low levels. In addition, culture of germplasm for *Salmonella* would add significantly to importation costs.

Historical risk from contamination of imported bovine germplasm with *Salmonella* spp. has been accepted, and *Salmonella* species generally require higher levels of contamination than would be likely to be present in germplasm, and an oral route of entry, to be infective.

For these reasons, it was concluded that measures specifically against *Salmonella* should not be placed in the new import health standard for bovine germplasm.

IHS Recommended options:

It is proposed that no measures be placed in the standard specifically against *Salmonella* species.

XIII. Leptospirosis

Options for management of risk presented in the 2009 import risk analysis for bovine germplasm:

- Serological testing of donors to demonstrate freedom from exotic *Leptospira* spp.
- PCR or culture of germplasm for exotic *Leptospira* spp.
- Preparation of germplasm in accordance with the recommendations of the OIE Code, including the use of suitable antibiotics in semen diluents and embryo washing media.

Other risk management considerations:

Serological testing of donors for leptospirosis is complex and difficult to interpret. Culture of *Leptospira* spp. is also difficult, and selection of primers for PCR has not yet been achieved for all serovars. Therefore the third option, preparation of germplasm in accordance with the recommendations of the OIE Code, including the use of suitable antibiotics in semen diluents and embryo washing media, was chosen.

IHS Recommended options:

Require preparation of germplasm in accordance with the recommendations of the OIE Code chapter on collection and processing of bovine semen, and the OIE Code

chapter on collection of embryos of livestock, including the use of suitable antibiotics in semen diluents and embryo washing media.

XIV. *Chlamydophila abortus*

Options for management of risk presented in the 2009 import risk analysis for bovine germplasm:

- Donors resident since birth or for the previous 2 years in a country or zone free from *Chlamydophila abortus* based on no laboratory confirmation of infection in any species for at least 2 years.
- Individual donors could be tested serologically using an OIE recommended test for *Chlamydophila abortus*, 2-3 weeks after germplasm collection.
- Aliquots of germplasm could be tested for *Chlamydophila abortus* by PCR or antigen detection ELISA, with negative results.
- Tetracycline or macrolide antibiotics could be added to imported germplasm.

Other risk management considerations:

C. abortus infection in cattle is only recognised where there is a close association between cattle and infected sheep, or where bedding (indoor lambing typically) used for sheep flocks infected with *C. abortus* is recycled in dairy herd housing. This would be highly unlikely in a bovine germplasm collection facility.

For this reason, it was concluded that measures specifically against *Chlamydophila* should not be placed in the new import health standard for bovine germplasm.

IHS Recommended options:

It is recommended that no measures be placed specifically against *Chlamydophila abortus*.

XV. Q fever – embryos and semen

Options for mitigating risk presented in the 2009 import risk analysis for bovine germplasm:

- Require acaricide treatment and subsequent inspections to demonstrate tick freedom during the 30 day quarantine of germplasm donors.
- Donors could be tested by an ELISA test, with negative results, 21-60 days after the final collection of germplasm for export to New Zealand. Consider prohibiting germplasm from any animals that have ever been known to test positive.
- MAF approved test on each collection of germplasm.

Other risk management considerations:

Acaricide treatment and 30 day quarantine in tick free premises would add considerable cost to the import of bovine germplasm. It would also significantly limit access to bovine genetics by precluding import of “on-shelf” germplasm.

Serological testing of donors has been used historically to mitigate risk from Q fever in bovine germplasm. The Investigation and Diagnostic Laboratory is working to

develop a PCR test for semen which, when validated, could be an option to serological testing of bulls.

An additional option for whole herd testing for Q fever is proposed to provide an opportunity to access on-shelf semen when the donor bull may not be available for testing (e.g. dead). Annual testing for other organisms, in accordance with OIE requirements, will facilitate the availability of samples for testing in these circumstances. We expect that only rarely will the value of the genetic material outweigh the additional cost of testing.

We recognise that New Zealand requirements for this organism are unique. The presentation of this range of options seeks to provide a wide range of mechanisms to deliver assurance that the donor animal/s is not infected, while limiting the restrictions impact on New Zealand access to on-shelf germplasm internationally.

IHS Recommended options:

EITHER

Donors were subject to a prescribed serological test for Q fever, with negative result, on a sample collected between 21 and 120 days after each collection of embryos or last collection of semen for export to New Zealand; OR

A sample of semen or embryos/oocytes, collection fluid, and/or washing fluid from each germplasm collection for the export consignment must be subjected to a validated and MAF approved PCR test for Q fever, with negative result; OR

Serological testing for Q fever was performed, with negative result, on the whole resident herd of cattle on the semen collection premises(semen)/herd of origin(embryo) or on a random sample of 60 animals from those herds (whichever is the lesser number) no more than six months before/after germplasm collection for consignment to New Zealand; AND

In the case of embryos the donor/s have never recorded a positive test for Q fever.