Bovine Germplasm

BOVIGERM.GEN

[Document Date]

Consultation

TITLE

Import Health Standard: Draft for consultation Bovine Germplasm ihs

COMMENCEMENT

This Import Health Standard comes into force on [Effective Date]

REVOCATION

This Import Health Standard revokes and replaces the following:

- a) Import Health Standard for Bovine Semen, BOVSEMID.GEN, 27 June 2011
- b) Import Health Standard for Bovine Embryos, BOVEMID.GEN, 27 June, 2011

ISSUING AUTHORITY

This Import Health Standard is issued under section 24A of the Biosecurity Act 1993.

Dated at Wellington, [Document Date]

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Introduction

This introduction is not part of the Import Health Standard (IHS), but is intended to indicate its general effect.

Purpose

This IHS specifies the minimum requirements that must be met when importing bovine semen and bovine embryos into New Zealand.

The identified risk organisms associated with bovine semen and bovine embryos that are managed by this IHS are:

- Bovine herpes virus 1.1, 1.2a, and 5, IBR/IPV (semen only)
- Bovine leukaemia virus, BLV (semen only)
- Bovine viral diarrhoea virus type 2, BVDV2
- Foot and mouth disease virus. FMDV
- Lumpy skin disease virus, LSDV
- · Rift Valley fever virus, RVF
- Bovine brucellosis, Brucella abortus, B. melitensis, B. suis (semen only)
- Campylobacter fetus subspecies venerealis (semen only)
- Coxiella burnetii, Q fever
- Mycobacterium bovis, bovine tuberculosis
- Mycoplasma mycoides subsp. mycoides, contagious bovine pleuropneumonia, CBPP
- Mycoplasma bovis

Background

The Biosecurity Act 1993 (the Act) provides the legal basis for excluding, eradicating and effectively managing pests and unwanted organisms.

Import health standards issued under the Act set out requirements to be met to effectively manage biosecurity risks associated with importing goods. They include requirements that must be met in the exporting country, during transit, and before biosecurity clearance can be given.

Guidance boxes are included within this IHS for explanatory purposes. The guidance included in these boxes is for information only and has no legal effect.

A guidance document also accompanies this IHS providing information on how requirements may be met.

Who should read this Import Health Standard?

This IHS should be read by importers of bovine semen and bovine embryos.

Why is this important?

It is the importer's responsibility to ensure the requirements of this IHS are met. Consignments that do not comply with the requirements of this IHS may not be cleared for entry into New Zealand and/or further information may be sought from importers. Consignments that do not comply with the requirements of this IHS may be re-shipped or destroyed under the Act or tested/treated in accordance with this IHS prior to release or equivalence determined. Importers are liable for all associated expenses.

The costs to MPI in performing functions relating to the importation of bovine semen and bovine embryos will be recovered in accordance with the Act and any regulations made under the Act. All costs involved with

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documentation, transport, storage and obtaining a biosecurity clearance must be covered by the importer or agent.

Equivalence

The Chief Technical Officer (CTO) may issue a direction under section 27(1)(d) of the Act that measures different from those set out in this IHS may be applied to effectively manage risks associated with the importation of these goods.

If an equivalent measure is approved, an import permit may be issued under section 24D(2) of the Act if the Director-General considers it appropriate to do so. The details of the CTO direction on equivalence will be included as notes in the special conditions section of the permit to inform the inspector's assessment of the commodity.

MPI's preference is that the exporting country's Competent Authority makes equivalence requests. Equivalence requests can be lodged with animal.imports@mpi.govt.nz.

Inspection

On arrival, all documentation accompanying the consignment will be verified by an inspector. The consignment may also be subject to inspection.

Document History

Refer to Schedule 1.

Other information

This is not an exhaustive list of compliance requirements and it is the importer's responsibility to be familiar with and comply with all New Zealand laws.

Environmental Protection Authority (EPA) and new organisms

Importers of new organisms must meet all requirements of the Hazardous Substances and New Organisms (HSNO) Act 1996.

Before an inspector can authorise a new organism to go to a containment facility, the EPA must have given approval for importation of that organism into containment in accordance with the HSNO Act.

See guidance document for inspection and verification requirements and for more information about HSNO Act requirements.

Harmonised System (HS) Codes

The harmonised system is an international product numbering classification developed by the World Customs Organisation (WCO). The New Zealand harmonised system is found here: http://aria.stats.govt.nz/aria/

Bovine semen and bovine embryos imported using this IHS will be under one of the following HS Codes:

HS Code	Commodity Description
05111010	Bovine semen
05119991	Bovine embryos

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Trade Single Window (TSW)

All goods imported into New Zealand need to be cleared by the New Zealand Customs Service (Customs) and the Ministry for Primary Industries (MPI). This is achieved by lodging required documentation in through the Trade Single Window (TSW) portal.

For more information about TSW please visit https://www.customs.govt.nz/business/trade-single-window/

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Part 1: Requirements

1.1 Application

(1) This IHS applies to all imports of frozen semen and *in vivo* derived embryos from the Bovinae subfamily from all countries into New Zealand.

1.2 Incorporation by reference

- (1) The following international standards are incorporated by reference in this IHS under section 142M of the Act:
 - a) The World Organisation for Animal Health (OIE) *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (the *Manual*), available at the OIE website: http://www.oie.int/international-standard-setting/terrestrial-manual/access-online/.
 - b) The OIE *Terrestrial Animal Health Code* (the *Code*), available at the OIE Website: http://www.oie.int/international-standard-setting/terrestrial-code/access-online/.
 - c) The International Embryo Transfer Society Manual (the IETS Manual), available at the IETS website: http://www.iets.org/.
 - d) The International Committee for Animal Recording, available at the ICAR website: www.icar.org.
- (2) The following material is incorporated by reference in this IHS under section 142M of the Act:
 - a) MPI Approved Diagnostic Tests, Vaccines, Treatments and Post-arrival Testing Laboratories for Animal Import Health Standards (MPI-STD-TVTL).
- (3) Under section 142O(3) of the Act it is declared that section 142O(1) does not apply. That is, a notice under section 142O(2) of the Act is not required to be published before material that amends or replaces the standards, guideline or lists incorporated under clauses 1.2(1) and (2) above has legal effect as part of this IHS.

Guidance

 Incorporation by reference means that standards, guidelines or lists are incorporated into the IHS and they form part of the requirements

1.3 Definitions

- (1) For the purposes of this IHS and the associated guidance, terms used that are defined in the Act have the meanings set out there. The Act is available at http://www.legislation.govt.nz/.
- (2) See Schedule 2 for additional definitions that apply.

1.4 Requirements for clearance

- (1) In order to obtain biosecurity clearance, bovine semen must:
 - a) Meet the requirements of clauses 1.5-1.9 and 1.11-1.13 of *Part 1: Requirements*, and *Part 2: Specified Requirements*; and
 - b) Be imported from a country that the CTO is satisfied meets the export country systems and certification requirements of clause 1.5; and
 - c) Be accompanied by a veterinary certificate that meets the requirements of clause 1.13, has been agreed by the CTO, and details the measures in Part 2 that the importing country will meet; and
 - d) Be accompanied by an import permit where required by clause 1.12.

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- (2) In order to obtain biosecurity clearance, bovine embryos must:
 - a) Meet the requirements of clauses 1.5 1.6, 1.8, and 1.10 -1.13 of *Part 1: Requirements*, and *Part 2: Specified Requirements*; and
 - b) Be imported from a country that the CTO is satisfied meets the export country systems and certification requirements of clause 1.5; and
 - c) Be accompanied by a veterinary certificate that meets the requirements of clause 1.13, has been agreed by the CTO, and details the measures in Part 2 that the importing country will meet; and
 - d) Be accompanied by an import permit where required by clause 1.12.

1.5 Exporting country systems and certification

- (1) Importers may import bovine semen and bovine embryos only if a CTO is satisfied, on the basis of evidence, that the veterinary services of the exporting country are capable of ensuring that bovine semen and bovine embryos imported from that country can meet the requirements of this IHS.
- (2) The evidence must include details about all of the following, that the CTO considers applicable to the bovine semen and bovine embryos from that exporting country:
 - a) The ability of the exporting country's Competent Authority to verify the animal health status of bovine semen and bovine embryos in the exporting country, zone or compartment, with respect to the risk organisms identified in *Part 2: Specified Requirements*.
 - b) The adequacy of the national systems and/or programmes and standards in the exporting country for regulatory oversight of the germplasm collection.
 - c) The capability of the exporting country's Competent Authority to support the issue of veterinary certificates as required by this IHS.
- (3) Importers may not import from a country where a CTO has determined that the Veterinary Services of the exporting country are no longer capable of ensuring that bovine semen and bovine embryos imported from that country can meet the requirements of this IHS.

Guidance

- The evidence will be obtained during evaluation of the Veterinary Services of the Competent Authority of the exporting country in accordance with section 3 of the *Code*.
- Once the CTO is satisfied with the exporting country's evidence for exporting systems and certification, MPI and the Competent Authority may commence negotiation of the country-specific veterinary certificate.
- In order to be satisfied with the evidence provided an in-country or desk-top audit may be carried
 out at any time, including prior to the first shipment of commodity.
- See *Guidance Document* for more information about exporting country systems and certification, and for a list of currently approved countries and country-specific veterinary certificates.

1.6 Diagnostic tests, vaccines and treatment

- (1) All pre-export and/or surveillance testing required by this IHS must be:
 - a) conducted by a laboratory approved by the Competent Authority of the exporting country; or
 - b) conducted by a laboratory approved by the Competent Authority of any other country approved to export the specified type of germplasm to New Zealand.
- (2) All laboratory samples required by this IHS must be collected, processed, and stored in accordance with the recommendations in the *Code* and/or the *Manual* or as described in *MPI-STD-TVTL*.
- (3) All diagnostic test(s) and vaccines that are required to be used or undertaken by this IHS must be those that have been approved by MPI for that purpose and documented in <u>MPI-STD-TVTL</u>.

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- (4) All products and vaccinations required by this IHS to be administered to meet the specific disease requirements in *Part 2: Specified Requirements* must have been administered according to the manufacturer's instruction in a country that the CTO has agreed meets the requirements of clause 1.5.
- (5) All requirements in this IHS for the administration of a vaccine require that either the final dose of a primary vaccination course has been administered or the recommended booster to complement the primary course has been administered.
- (6) Where products required by this IHS have been administered, the product name, manufacturer, active ingredients (where applicable), and the dose and date of the treatment must be recorded on the veterinary certificate.
- (7) Where vaccines required by this IHS have been administered, all vaccine names, whether they are inactivated or modified live virus, and the virus types and strains included in the vaccine must be recorded on the veterinary certificate.

Guidance

See Guidance Document for more information about tests and vaccination.

1.7 Semen collection centre requirements

- (1) Semen collection must be carried out in a semen collection centre that complies with the recommendations for centres in the *Code* chapter *General Hygiene in Semen Collection and Processing Centres*.
- (2) The semen collection centre must be:
 - a) approved for export by the Competent Authority;
 - b) subjected to regular inspection, at least every 12 months, by an Official Veterinarian;
 - c) under the supervision of a semen collection centre veterinarian approved by the Competent Authority.
- (3) The name and approval number of the semen collection centre must be recorded on the veterinary certificate.
- (4) Semen donors may be transferred from one approved semen collection centre to another approved centre of equal health status without isolation or testing if the Competent Authority ensures that all of the following requirements are met:
 - Donors have been examined by the approved semen collection centre veterinarian on the day of entry into the centre and show no evidence of infectious disease transmissible in semen.
 - b) Transfer is direct.
 - c) Donors are protected from insect attack during transit.
 - d) Donors do not come into direct or indirect contact with animals of lower health status.
 - e) The means of transport is disinfected before use.

1.8 Donor requirements

- (1) Semen donors must meet the requirements in the Code chapter *Collection and Processing of Bovine, Small Ruminant, and Porcine Semen*, and any additional requirements in Part 2: *Specified Requirements* of this IHS.
- (2) During the 28 days in which semen donors are held in pre-entry isolation prior to entering the semen collection centre (as prescribed in the *Code*), they must not be used for natural mating and must be isolated from animals not of equivalent health status.

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- (3) Embryo donors must meet the recommendations in the Code chapter *Collection and Processing of In Vivo Derived Embryos from Livestock and Equids* and any additional requirements in Part 2: *Specified Requirements* of this IHS.
- (4) Embryo donors must be resident in the embryo collection herd for at least 28 days prior to embryo collection for export to New Zealand. While resident with the collection herd, the herd must not be subject to veterinary restrictions for the identified risk organisms managed in Part 2 of this IHS.
- (5) During the 28 days in which embryo donors are resident with the embryo collection herd, they must be isolated from animals not of equivalent health status.
- (6) Germplasm donors that were imported to the exporting country must have lived continuously in an approved countries for at least the 60 days before germplasm collection.
- (7) On the day of germplasm collection, the embryo collection team veterinarian or semen collection centre veterinarian must determine that the donor is free from clinical evidence of infectious diseases transmissible in germplasm.
- (8) Where a specific requirement of this IHS for a risk organism is met by pre-collection testing, the germplasm donors must be isolated from other animals not of equivalent tested health status, from the time of the test sample collection until completion of germplasm collection for export.
- (9) Where a specific requirement of this IHS for a risk organism is met by monitoring the germplasm donors for clinical signs for a specified time after collection, the germplasm must be stored for that amount of time prior to export.

Guidance

• See Guidance Document for the model veterinary certification.

1.9 Semen collection, processing and storage

- (1) Semen collection, processing and storage must comply with the sections relevant for bovine semen in the Code chapter Collection and Processing of Bovine, Small Ruminant, and Porcine Semen.
- (2) Where Part 2 requires testing within a certain time period before or after semen collection:
 - a) Semen collection may be a time period of up to 60 consecutive days.
 - b) Samples for testing before collection must be obtained within the specified period before the first day of the semen collection period.
 - c) Tests required after semen collection must have samples collected within the specified period after the last day of the semen collection period.
- (3) A cryogenic or cooling agent used in the freezing process, storage and transport must not have been used previously in association with any other product of animal origin.
- (4) All straws must be sealed, and clearly and permanently marked to identify the donor and the date(s) of freezing. The markings must conform to international standards of the *International Committee for Animal Recording (ICAR)*. If a code is used for this information, its decipher instructions must accompany the consignment.
- (5) Semen may only be stored with germplasm that has been collected and processed in accordance with the *Code*.
- (6) Semen must be held in a storage place approved by the Competent Authority of the exporting country until the time of export.
- (7) Subject to (8), semen may only be imported into New Zealand if the semen is imported directly from the country in which it was collected.

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- (8) If semen is collected in a country that meets the requirements of 1.5 and stored in another country (exporting country) that meets the requirements of 1.5, that semen may be imported into New Zealand if the consignment is accompanied by:
 - A declaration from the Competent Authority of the exporting country identifying the semen from the origin country as the semen being exported to New Zealand;
 - b) A veterinary certificate from the Competent Authority of the exporting country that certifies that the semen has been stored and transported in the exporting country in accordance with the requirements of this IHS;
 - c) Evidence that the semen was collected, processed, and stored in the origin country in accordance with the requirements of this IHS in the form of either:
 - i) A veterinary certificate issued by the Competent Authority of the origin country certifying that the semen meets the requirements of this IHS; or
 - ii) A letter from the Competent Authority of the origin country confirming the semen meets the requirements of this IHS and indicating which requirements therein have been fulfilled.

1.10 Embryo collection, processing and storage

- (1) Embryos must be collected, washed, processed, stored and traceability maintained under the supervision of an embryo collection team veterinarian and in accordance with the recommendations in the OIE Code chapter on Collection and Processing of In Vivo Derived Embryos from Livestock and Equids.
- (2) The embryo collection team must operate in accordance with the conditions listed in the OIE Code chapter on Collection and Processing of In Vivo Derived Embryos from Livestock and Equids.
- (3) Embryos must be collected, washed, processed, stored and traceability maintained under conditions that comply with the recommendations in the IETS *Manual*.
- (4) At the time of embryo collection each embryo must be examined over its entire surface at not less than 50X magnification and found to have an intact zona pellucida and be free of adherent material.
- (5) Any micro-manipulation that causes a breach of the zona pellucida must be done as per the procedures described in the OIE *Code* chapter *Collection and Processing of Micromanipulated Oocytes or Embryos from Livestock and Horses and the IETS Manual.*
- (6) All biological products of animal origin used in the media and solutions for collection, processing, washing or storage of embryos must be free of pathogenic organisms including pestiviruses and prions. Media and solutions must be sterilised by approved methods according to the IETS *Manual* and handled in a manner that ensure that sterility is maintained.
- (7) All straws must be sealed, and clearly and permanently marked to identify the donor and the date(s) of freezing. The markings must conform to international standards of the *International Committee for Animal Recording (ICAR)* and the IETS *Manual*. If a code is used for this information, its decipher instructions must accompany the consignment.
- (8) Embryos may only be stored with germplasm that has been collected and processed in accordance with the OIE *Code*.
- (9) Embryos must only be held in a storage place approved by the Competent Authority of the exporting country until the time of export.
- (10) Subject to (11), embryos can only be imported into New Zealand if the embryos are imported directly from the country in which they were collected.
- (11) If embryos are collected in a country that meets the requirements of clause 1.5 and stored in another approved country (exporting country), those embryos may be imported into New Zealand if the consignment is accompanied by:

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- a) A declaration from the Competent Authority of the exporting country identifying the embryos from the origin country as the embryos being exported to New Zealand;
- A veterinary certificate from the Competent Authority of the exporting country that certifies that the embryos have been stored and transported in the exporting country in accordance with the requirements of this IHS;
- c) Evidence that the embryos were collected, processed, and stored in the origin country in accordance with the requirements of this IHS in the form of either:
 - i) A veterinary certificate issued by the Competent Authority of the origin country certifying that the embryos meet the requirements of this IHS; or
 - ii) A letter from the Competent Authority of the origin country confirming the embryos meet the requirements of this IHS and indicating which requirements therein have been fulfilled.

1.11 Transport

- (1) All transport containers in which germplasm is transported to New Zealand must be new or disinfected and must be free of contamination. When a transport container is disinfected, the disinfectant, its active chemical and the date of disinfection must be recorded on the veterinary certificate.
- (2) The container must only be filled with fresh (previously unused) liquid nitrogen.
- (3) All transport containers in which semen is transported to New Zealand must be sealed, by either the semen collection centre veterinarian or an Official Veterinarian, using tamper-evident seals that are positioned to ensure that no germplasm can be added after the transport container has been sealed. The seal number must be recorded on the veterinary certificate.
- (4) Where semen is transferred from one transport container to another, the date of transfer, approved collection centre, reason for transfer, and the name of veterinarian involved in the transfer must be recorded on the veterinary certificate.

1.12 Import permit information

(1) An import permit under section 24D of the Act is required prior to the importation of consignments of bovine semen and bovine embryos from all countries.

Guidance

Completed applications can be submitted to Animal Imports <u>animal.imports@mpi.govt.nz</u>
 Application forms can be found on the MPI website at: <u>Permit Application for Importing Semen</u> and Embryos

1.13 The documentation that must accompany goods

- (1) The consignment must arrive in New Zealand with the documentation that is specified in, and meets the requirements of, clauses 1.13.1 to 1.13.3 below.
- (2) All documentation that is required by this clause 1.13 to accompany bovine semen and bovine embryos must, unless otherwise stated:
 - a) be original;
 - b) accompany the imported goods;
 - c) be in English or have an English translation that is clear and legible;
 - d) be endorsed on every page by the Official Veterinarian with their original stamp, signature and date or be endorsed in the space allocated and all pages have paper based alternative security features.

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Guidance

- Copies of all documents that are required to accompany the goods should be submitted to the Biosecurity Inspector at the airport/port of arrival as early as possible to avoid delays in border clearance. The recommended timeframe is at least 3 working days in advance of arrival.
- A Trade Single Window (TSW) lodgement is required to meet both MPI and Customs requirements. For more information about TSW please visit: https://www.customs.govt.nz/business/trade-single-window/

1.13.1 Import permit

(1) An import permit (copy acceptable) as required by clause 1.12.

1.13.2 Veterinary certificate

- (1) A veterinary certificate from the exporting country's Competent Authority. The veterinary certificate must include the following:
 - a) A unique consignment identifier;
 - b) Species, donor identification, quantity (of semen/embryos);
 - c) Dates of collection;
 - d) For semen, the name and address of the approved semen collection centre, and date of donor entry;
 - e) For embryos, confirmation of the Competent Authority's approval of the embryo collection team, and date of entry into and address of the embryo collection herd/centre;
 - f) Name of the approved veterinarian;
 - g) Name and address of the importer (consignee) and exporter (consignor);
 - h) Transport container number seal number and disinfection information;
 - A list of all vaccines administered to meet specific disease import requirements, including vaccine name, the virus types and strains included in the vaccine (where applicable), and vaccination date(s).
 - j) Name, signature and contact details of the Official Veterinarian;
 - Where semen and embryos are transferred from one transport container to another, the date of transfer, approved collection centre or storage facility the germplasm was transferred at, reason for transfer and name of the veterinarian involved in the transfer;
 - l) Certification and endorsement by the Official Veterinarian that the relevant general requirements outlined in Part 1 of this IHS have been met; and
 - m) Certification and endorsement by the Official Veterinarian that the relevant specified requirements outlined in Part 2 of this IHS have been met.

Guidance

- Where equivalent measures have been negotiated and agreed with MPI, and a CTO has, prior to
 import, issued a direction under section 27(1)(d) of the Act that is different from those in this
 standard in the form of a negotiated veterinary certificate, a country-specific veterinary certificate
 must accompany the consignment.
- See Guidance Document for more information about equivalence and country-specific veterinary certificates.

1.13.3 Laboratory reports

- (1) Original laboratory reports; copies of laboratory reports endorsed by the Official Veterinarian; or a tabulated summary of laboratory results endorsed by the Official Veterinarian of all tests required by *Part 2: Specified Requirements* of this IHS must include:
 - a) Unique identification for each animal, consistent with the veterinary certificate
 - b) Dates of sample collection or vaccination

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- c) Test/vaccination type
- d) Test result.
- (2) Notwithstanding (1), if upon reviewing an exporting country's certification process (clause 1.5) an MPI CTO determines that reports are verified by the Official Veterinarian prior to certification, laboratory results may not be required.

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Part 2: Specified Requirements

- (1) Subject to clause (2), bovine semen and bovine embryos must comply with every OIE *Code* recommendation relating to the risk organisms specified in this Part.
- (2) Bovine semen and bovine embryos must comply with the following measures for the risk organisms specified in this Part.

2.1 Bovine herpes virus 1.1, 1.2a, and 5 (Infectious Bovine Rhinotracheitis/Infectious Pustular Vulvovaginitis, IBR/IPV)

- (1) At the time of collection of semen for export to New Zealand, the exporting country must be free from BHV 1.1, BHV 1.2a and BHV5 in accordance with the OIE *Code*; or
- (2) The semen collection centre must be maintained free from BHV 1.1, 1.2a, and 5 from commencement until conclusion of semen collection for export to New Zealand, through compliance with the recommendations in the OIE *Code* in relation to BHV, including:
 - a) The centre must:
 - Test all cattle prior to pre-entry isolation for antibodies using a test listed in <u>MPI-STD-TVTL</u>, with negative results;
 - ii) Test 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
 - iii) Thereafter, annually re-test all donors for antibodies, with negative results; or
- (3) The semen donor must be:
 - a) held in isolation for the 30 days following collection;
 - b) tested for BHV 1.1, 1.2a, and 5 using a test listed in <u>MPI-STD-TVTL</u> at least 21 days after semen collection for export to New Zealand, with negative results; or
- (4) An aliquot of semen from each semen collection for export to New Zealand must be tested for BHV1.1, 1.2a, and 5 with a test listed in MPI-STD-TVTL, with negative results.

Note: there are no import requirements for embryos.

2.2 Bovine leukaemia virus (Enzootic Bovine Leukosis, EBL)

- (1) The semen donor must be resident at the time of semen collection in an EBL-free herd in accordance with the OIE *Code*; and
 - a) if less than two years of age, the semen donor must come from a serologically negative 'uterine' dam; or
 - b) the semen donor must be subjected to a test listed in <u>MPI-STD-TVTL</u> for EBL on blood samples on two occasions with negative results, the first test being carried out at least 30 days before and the second test at least 90 days after collection of the semen; or
- (2) An aliquot of semen from each collection for export to New Zealand must be tested for BLV with a test listed in <u>MPI-STD-TVTL</u>, with negative results.

Note: there are no import requirements for embryos.

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2.3 Bovine viral diarrhoea virus genotype 2 (BVDV2)

- At the time of germplasm collection for export to New Zealand, the exporting country must be recognised by the CTO as free from BVDV2; or
- (2) Semen:
 - a) The semen collection centre must be maintained free from BVDV2 from commencement until conclusion of semen collection for export to New Zealand, through compliance with the recommendations in the OIE Code in relation to BVDV2, including:
 - i) The collection centre must:
 - 1) Test all cattle within 30 days prior to pre-entry isolation with a test listed in <u>MPI-STD-</u>
 TVTL:
 - 2) Test all cattle after 21 days isolation with a test listed in MPI-STD-TVTL;
 - 3) If any animal seroconverts, keep all animals in pre-entry isolation until there is no more seroconversion for 3 weeks;
 - 4) Only approve entry for groups where pre-entry isolation results indicate the absence of antigen-positive cattle;
 - 5) Thereafter, annually re-test seronegative cattle;
 - 6) For seropositive donors, test semen for BVDV with a test listed in <u>MPI-STD-TVTL</u> with negative results, prior to use of that animal as a semen donor; or
 - b) An aliquot of semen from each semen collection for export to New Zealand must be tested for BVDV2 with a test listed in <u>MPI-STD-TVTL</u>, with negative results.
- (3) Embryos:
 - a) The embryo donor must be tested for BVDV2:
 - i) between 28-14 days prior to collection with a test listed in MPI-STD-TVTL;
 - ii) isolated from untested cattle between the test date and embryo collection; or
 - b) A pooled sample of embryos/oocytes, collection fluids and/or washing fluids from each embryo collection for export to New Zealand must be tested for BVDV2 with a test listed in MPI-STD-TVTL, with negative results.

2.4 Foot and mouth disease (FMD)

- (1) Semen:
 - a) The donor must be resident for at least the 3 months before semen collection in a country or zone that is free from FMD without vaccination in accordance with the OIE *Code*; or
 - The herd of origin, semen collection centre, donor animal and semen for export must comply with OIE Code recommendations for export of bovine semen from countries or zones presenting a risk of FMD; and
 - i) Each semen collection, processing and storage facility in the exporting country intended to be used during the preparation of an export consignment to New Zealand must be approved by an MPI Chief Technical Officer (CTO).
- (2) Embryos:
 - a) The donor must be resident for at least the 3 months before embryo collection in a country or zone that is free from FMD without vaccination in accordance with the OIE *Code*; or
 - b) The herd of origin, embryo collection herd where the donors were resident during embryo collection, donor animal and embryos for export must comply with the OIE *Code* FMD Article *Recommendations for the Importation of In Vivo Derived Embryos of Cattle*; and

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i) Each embryo collection, processing and storage facility in the exporting country, intended to be used during the preparation of an export consignment to New Zealand, must be approved by an MPI CTO.

Guidance

The approval will be dependent on the establishment, 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 MPI approval may include site inspection. MPI reserves
the right to supervise collection or require any other measures deemed necessary to ensure
compliance with facility and operating standards upon which the approval is based.

2.5 Lumpy skin disease (LSD)

- (1) The germplasm donor must be resident for 6 months prior to germplasm collection in a country or zone that is free of LSD as defined by the OIE *Code*; or
- (2) The germplasm donor must be resident in an establishment that was free of clinical evidence of LSD during a period from at least 6 months prior to commencement, until 28 days after conclusion of germplasm collection for export to New Zealand; or
- (3) An aliquot of semen or a sample of embryos/oocytes, collection fluids and/or washing fluids from each germplasm collection for export to New Zealand must be tested for LSD with a test listed in <u>MPI-STD-TVTL</u> with negative results.

2.6 Rift Valley fever virus (RVF)

- (1) The donor must be resident, for at least the 30 days prior to, and during germplasm collection for export to New Zealand in a country or zone that is free from RVF in accordance with the OIE *Code*; or
- (2) The donor showed no sign of RVF within the period from 14 days prior to and 14 days following germplasm collection; and either
 - a) the donor must be vaccinated against RVF at least 14 days prior to collection; or
 - b) the donor must be demonstrated to be seropositive on the day of collection with a test listed in MPI-STD-TVTL; or
 - c) testing of paired samples with a test listed in <u>MPI-STD-TVTL</u> must demonstrate that seroconversion did not occur between germplasm collection and 14 days after.

2.7 Brucella suis, Brucella melitensis, and Brucella abortus (bovine brucellosis)

- (1) The semen donor must be kept since birth in a country or zone that is free from *Brucella* in accordance with the OIE *Code*; or
- (2) The semen collection centre must be maintained free from *Brucella* from commencement until conclusion of semen collection for export to New Zealand, through compliance with the recommendations in the OIE *Code* in relation to *Brucella*.
 - a) The centre must require that:
 - Prior to pre-entry isolation the donors must be either from a country or zone that is free from Brucella in accordance with the OIE Code or must be from a herd officially free from Brucella;
 - ii) During the 30 days prior to pre-entry isolation, donors must be tested with a test listed in MPI-STD-TVTL for Brucella, with negative results;

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- iii) All cattle in pre-entry isolation must be tested with a test listed in <u>MPI-STD-TVTL</u> for Brucella, with negative results;
- iv) At least annually all cattle resident in the semen collection centre must be tested with a test listed in <u>MPI-STD-TVTL</u> for <u>Brucella</u>, with negative results.

Note: there are no import requirements for embryos.

2.8 Campylobacter fetus subspecies venerealis (bovine genital campylobacteriosis, BGC)

- (1) The semen donor must never have been used for natural service; or
 - a) must have only been mated virgin heifers.
- (2) After a minimum of 7 days in pre-entry isolation, the semen donor must undergo testing for *Campylobacter fetus* subspecies *venerealis* as follows:
 - a) Animals less than six months old or kept since that age only in a single sex group prior to preentry isolation must be tested with test listed in <u>MPI-STD-TVTL</u>, once on a preputial specimen, with a negative result.
 - b) Animals aged six months or older that could have had contact with females prior to pre-entry isolation must be tested with an approved test three times at weekly intervals on preputial specimens, with a negative result in each case.
 - c) Annual testing:
 - i) A preputial specimen/s from donor bulls and any in-contact animals on semen production must be tested with an approved test or culture.
 - ii) Bulls returning to collection after a lay-off of more than six months must be tested not more than 30 days prior to resuming production.

Note: there are no import requirements for embryos.

2.9 Coxiella burnetii (Q-fever)

- (1) The germplasm donor must never have been confirmed positive for Q fever; and either
 - The donor must be subjected to a serological test listed in <u>MPI-STD-TVTL</u> for Q fever, on a sample collected between 21 and 120 days after each germplasm collection for export to New Zealand, with negative results; or
 - b) An aliquot of semen or a sample of embryos/oocytes, collection fluids and/or washing fluids from each germplasm collection for export to New Zealand must be tested for Q fever with a test listed in MPI-STD-TVTL, with negative results; or
 - Within the 6 month period before or after germplasm collection for New Zealand, but before export, the embryo collection herd or semen collection centre herd must be tested for Q fever, with negative results. This testing must be with a test listed in MPI-STD-TVTL and must be performed on either the whole herd or a random sample of at least 60 animals (whichever is the lesser number); and
 - i) The herd must be isolated for the period between semen collection and diagnostic sampling.

2.10 Mycobacterium tuberculosis (bovine tuberculosis)

- (1) Semen:
 - a) The semen collection centre must be:

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- i) free from bovine tuberculosis in accordance with the OIE Code;
- ii) located in a country or zone that has been recognised by the CTO as free from bovine tuberculosis; or
- b) The semen collection centre must be maintained free from bovine tuberculosis from commencement until conclusion of semen collection for export to New Zealand, through compliance with the recommendations in the OIE *Code* in relation to bovine tuberculosis; and
 - Prior to pre-entry isolation, donors must be from a herd free from bovine tuberculosis, either in accordance with the OIE *Code* or the competent authority of the exporting country;
 - ii) During the 30 days prior to entry to the semen collection centre, donors must be tested with a test listed in *MPI-STD-TVTL* for bovine tuberculosis, with negative results:
 - iii) At least annually all resident cattle were tested with a test listed in <u>MPI-STD-TVTL</u> for bovine tuberculosis, with negative results.

(2) Embryos:

- a) No clinical signs of bovine tuberculosis were observed in the embryo collection herd during the 24 hours prior to embryo collection for export to New Zealand; and either
 - i) The donors must be:
 - from an embryo collection herd that is free from bovine tuberculosis in accordance with the OIE Code or the competent authority of the exporting country;
 - 2) from a country or zone that has been recognised by the CTO as free from bovine tuberculosis; or
 - ii) The donor must be:
 - 1) from an embryo collection herd that is free from bovine tuberculosis, either in accordance with the OIE *Code* or the competent authority of the exporting country;
 - subjected to a test listed in <u>MPI-STD-TVTL</u> for bovine tuberculosis during the period between 30 days prior to and 12 months after embryo collection for export to New Zealand, with negative results.

2.11 *Mycoplasma mycoides* subspecies *mycoides SC* (contagious bovine pleuropneumonia, CBPP)

- (1) The germplasm donor must be born in and have been continuously resident in a country that is recognised by the CTO as free from CBPP; or
- (2) The germplasm donor must:
 - a) never have been vaccinated for CBPP;
 - b) be kept since birth, or for at least the 6 months prior to commencement 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*;
 - c) be serologically tested for CBPP, using a test listed in <u>MPI-STD-TVTL</u> on two occasions 21 to 30 days apart, with the last test within 14 days prior to germplasm collection for export to New Zealand, with negative results.

2.12 Mycoplasma bovis

- (1) Semen:
 - Collection and processing of semen must be in accordance with the recommendations of the OIE Code, except for:

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- The following antibiotic combination must be used at the specified final dose per mL of extended semen:
 - 1) Gentamicin (500 μ g), tylosin (100 μ g), lincomycin–spectinomycin (300/600 μ g) (GTLS); or
 - 2) Another MPI approved antibiotic combination, listed in MPI-STD-TVTL;
- ii) Antibiotics must be prepared and stored as separate stock solutions as described by the manufacturer to maintain potency;
- iii) Antibiotics must be added to media/extender on the day of processing;
- iv) The semen must remain in the antibiotic solution at the recommended concentration for a minimum of 2 hours at no less than 5°C before being frozen in the antibiotic solution; or
- b) The semen must be subjected to another MPI approved antibiotic combination and protocol, listed in MPI-STD-TVTL; or
- c) Each semen collection for export to New Zealand must be tested with a validated PCR test for *M. bovis* listed in *MPI-STD-TVTL*, with negative results.

(2) Embryos:

- Collection and processing of embryos must be in accordance with the recommendations of the OIE Code, except for:
 - i) The embryos must be subjected to the protocol described in the IETS *Manual*: tylosin (200 µg/mL) incubation at 37°C in the antibiotic treatment for a minimum of 4 hours after being washed 10 times; or
- b) The embryos must be subjected to another MPI approved antibiotic combination and protocol, listed in MPI-STD-TVTL; or
- c) Each embryo collection for export to New Zealand must be tested with a validated PCR test for *M. bovis* listed in *MPI-STD-TVTL*, with negative results.



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Schedule 1 – Document History

Date First Issued	Title	Shortcode
TBA	Import Health Standard: Bovine Germplasm	BOVIGERM.GEN
Date of Issued Amendments	Title	Shortcode

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Schedule 2 – Definitions

Approved Veterinarian

A veterinarian approved by the relevant Competent Authority to collect semen or embryos for export to New Zealand.

Competent Authority

The Veterinary or other Governmental Authority of an OIE Member, that has the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations in the *Code* in the whole territory.

Donor

Female animal from which embryos were collected, or male animal from which semen was collected.

Director-General

The chief executive of the Ministry for Primary Industries.

Germplasm

Semen or embryos collected from animals that are eligible for importation under this import health standard.

IETS

International Embryo Transfer Society.

IETS Manual

Manual for embryo collection, processing and transfer as written by the IETS. Any references to this Manual are to the most current version.

In Vivo Derived Embryos

Embryos recovered after fertilisation in the reproductive tract of the female donor.

MPI

Ministry for Primary Industries, New Zealand.

Official Veterinarian

A veterinarian authorised by the Competent Authority of the country to perform certain designated official tasks associated with animal health and/or public health and inspections of commodities and, when appropriate, to certify in conformity with the provisions of the OIE *Code* Chapter for certification procedures.

OIE

The World Organisation for Animal Health.

The Code

The OIE Terrestrial Animal Health Code as found on the OIE website.

The Manual

The World Organisation for Animal Health (OIE) Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.

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Veterinary Certificate

A certificate, issued in conformity with the provisions of the *Code* Chapter for certification procedures, describing the animal health and/or public health requirements which are fulfilled by the exported commodities.

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