Import Health Standard
For
Bovine Embryos

Short Name: bovemid.gen

Ministry of Agriculture and Forestry
P.O Box 2526
Wellington 6011
New Zealand
Issuing Authority

This standard is issued under section 22 of the Biosecurity Act 1993 (the Act).

Dated at Wellington this day of 2010

Manager Animal Imports and Exports
Ministry of Agriculture and Forestry (MAF)

For Director General
Ministry of Agriculture and Forestry
(Pursuant to delegated authority)

Version number: 0.1
Import Health Standard for Bovine Embryos

PART A. BACKGROUND, SCOPE AND OUTCOMES

Background

1. Under section 22 of the Biosecurity Act, this document is the import health standard for bovine embryos.

2. If this standard needs to be amended or revoked urgently, or the Director General considers that an amendment is minor, the amendment or revocation may be carried out without prior consultation.

3. A guidance document will be issued by MAF to accompany this import health standard. The document will provide guidance information relevant to how requirements may be met including definitions of terms (shown in italics) used in this standard.

Scope

4. This standard specifies the requirements that must be met to import bovine embryos to New Zealand, bovine embryos being embryos derived from any member of the sub-family Bovinae.

5. The bovine embryos must meet the general requirements and documentation requirements contained in PART B of this standard and to the extent that PART C of this standard applies, the specific requirements contained in PART C of this standard.

Outcomes

6. All imports must be subject to risk management measures for specified risk organisms associated with the commodity appropriate to the status of the risk organism, their likelihood of entry and/or establishment in New Zealand and consequent impacts.

7. The risk organisms associated with the commodity that are subject to specific risk management requirements are (with category and legal status under the Biosecurity Act as well as presence in New Zealand):
   - Borna disease virus (Unwanted; Exotic)
   - Bovine viral diarrhoea virus type 2, BVDV2 (Unwanted; Exotic)
   - Crimean Congo haemorrhagic fever virus, CCHFV (Unwanted; Exotic)
   - Foot and mouth disease virus, FMDV (Unwanted; Exotic; Notifiable)
   - Lumpy skin disease virus, LSDV (Unwanted; Exotic; Notifiable)
   - Rift Valley Fever virus, RVFV (Unwanted; Exotic; Notifiable)
   - Vesicular stomatitis virus (Unwanted; Exotic; Notifiable)
   - Bovine tuberculosis, Mycobacterium bovis (Unwanted; Notifiable under the Bovine Tb Pest Management Strategy)
   - Contagious bovine pleuropneumonia, CBPP, Mycoplasma mycoides subsp. mycoides SC (Unwanted; Exotic; Notifiable)
   - Mycoplasma bovis
   - Q fever, Coxiella burnetii (Unwanted; Exotic; Notifiable)

8. For each risk organism, specific risk management requirements are specified in PART C using the general form:
   - Country, zone or compartment freedom; OR
o Specified measures to verify premises and/or donor freedom.

9. MAF and the veterinary authority of the exporting country will negotiate the content of the zoosanitary certificate to achieve an equivalent level of risk management as specified by this standard, taking into account:
   o the verifiable health status of the exporting country/zone/compartment; AND
   o the national systems and standards in the exporting country for regulatory oversight of the germplasm industry; AND
   o the capabilities and preferences of the exporting country’s veterinary authority.

Upon conclusion of negotiations, country-specific zoosanitary certificate templates will be included in the guidance document for this standard.

PART B. GENERAL REQUIREMENTS

Approved countries

10. Countries must be approved by MAF to export bovine embryos to New Zealand. A list of approved countries is included in the guidance document for this standard.

Donor eligibility

11. Donors that were imported to the exporting country must have lived continuously in the exporting country for at least 90 days and in the herd of origin for at least 30 days prior to embryo collection for export.

Embryo collection team and facility requirements

12. At the time of embryo collection for consignment to New Zealand, the embryo collection team was approved by and registered with the veterinary authority of the exporting country to collect, process, and store bovine embryos for export in accordance with the current recommendations of the OIE Code.

13. During the collection of embryos for consignment to New Zealand, and until the testing specified in this standard was completed, donors were held in a veterinary authority approved and registered embryo collection facility. During this time they were isolated from animals not of an equivalent health status.

14. Prior to collection of embryos for this consignment the donors must be subject to a period of isolation of at least 30 days in accommodation specifically approved for this purpose by the veterinary authority of the exporting country. During this time they were isolated from animals not of an equivalent health status.

Donor and facility health status

15. The herd(s) of origin of the donors and the embryo collection facilities must remain free from any quarantine restrictions from 90 days before the first embryo collection for the consignment until completion of the testing of the donors as required by this certificate.

16. Each donor was inspected by the veterinary authority approved embryo collection team veterinarian or an Official Veterinarian on each day that embryos were collected for consignment to New Zealand, and was found to be free from clinical signs of infectious diseases transmissible in embryos.
17. The semen used to produce the embryos in the consignment either:
   o met the minimum health standards for semen imported into the exporting country; OR
   o was collected and processed at a semen collection centre that fully complies with the current OIE Code chapter on collection and processing of bovine semen; OR
   o where natural service or fresh semen was used, donor males were of an equivalent isolation and tested health status to the donor females.

**Embryo collection, processing, storage and transport**

18. Embryos must have been collected, handled, processed, and stored under the supervision and authority of a veterinary authority approved embryo collection team veterinarian in accordance with the recommendations in the OIE Code chapter on collection and processing of in vivo derived bovine embryos.

19. All the embryos in the consignment were fertilised in vivo, collected, processed, identified, stored, and transported in accordance with OIE Code recommendations.

20. Embryos were collected, washed, processed, identified, and stored under conditions which comply with the recommendations in the Manual of the International Embryo Transfer Society (IETS). The embryos were treated with trypsin during the washing process as described in the **IETS Manual**. Each embryo had an intact zona pellucida and was examined over its entire surface at not less than 50X magnification and found to be free of adherent material.

21. All biological products of animal origin used in the media and solutions for collection, processing, washing or storage of embryos were free of pathogenic organisms including pestiviruses. Media and solutions were sterilised by approved methods according to the **IETS Manual** and handled in such a manner as to ensure that sterility was maintained. Antibiotics as recommended in the **IETS Manual**, or a combination of antibiotics with equivalent activity, were added to collection, processing, washing and storage media.

22. All straws must have been sealed and clearly marked with the identification of the donor animals and the date of freezing. If a code is used for this information, its cipher must accompany the consignment. The code marking should, in accordance with the OIE Code, conform to the international standards of the International Committee for Animal Recording (ICAR; [www.icar.org](http://www.icar.org)) and the IETS ([http://www.iets.org](http://www.iets.org)).

23. The embryos for export were stored in the frozen state for at least 28 days before shipment to New Zealand and during this time the donors and all animals in contact with them must have remained healthy and free from any diseases transmissible in embryos.

24. The embryos must have been stored only with semen or embryos that were eligible for export. Containers must have been held until export in a storage place approved by the veterinary authority of the exporting country.

25. The embryos must have been placed in transport containers filled with fresh (previously unused) liquid nitrogen. Transport containers may be either new or disinfected. If disinfected, the date of disinfection, the disinfectant used, and its active chemical must be recorded on the zoosanitary certificate.

26. Prior to export, the container in which the embryos are to be transported must be sealed by either the veterinary authority approved embryo collection team veterinarian or by an
**Official Veterinarian** AND the seal number must be recorded on the zoosanitary certificate.

**Laboratory testing**

27. All required laboratory testing must have been conducted at a laboratory approved by the veterinary authority of the exporting country to conduct export testing.

28. Samples of embryos/oocytes, collection fluids, and washing fluids for laboratory testing must have been collected, processed, and stored in accordance with the recommendations in the OIE Code chapter on collection and processing of in vivo derived embryos of livestock.

29. Laboratory or other diagnostics tests must be those prescribed for that disease by the OIE for use during international trade, or specifically approved by MAF.

**Documentation accompanying the consignment**

30. The documentation that accompanies the consignment to New Zealand must consist of:
   o An original zoosanitary certificate signed and stamped on every page by an official of the veterinary authority of the exporting country; AND
   o a tabulated summary of laboratory test results for each donor completed in accordance with the specific requirements in the zoosanitary certificate (indicating donor identification consistent with the zoosanitary certificate, the dates of embryo collection, and for each relevant disease the date/s samples were drawn, the test undertaken, the laboratory, the reported result, and the accession number reference); AND
   o copies of laboratory reports for all tests (N.B. where the requirement is a regimen of multiple tests, for instance during qualification to enter and annually while resident on a collection facility, tested health status can be verified by providing laboratory reports of the most recent test/s); AND
   o an import permit.

**PART C. SPECIFIC REQUIREMENTS FOR IDENTIFIED RISK ORGANISMS**

**Borna disease**

EITHER

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

32. Borna disease is officially notifiable in the exporting country, and 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 for export; OR

33. Donors or samples of embryos/oocytes, collection fluids, and/or washing fluids have been tested using a MAF-approved test and process, and are negative for Borna disease.

**Bovine viral diarrhoea type 2 (BVDV2)**

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

35. The embryo collection facility must have been maintained as free from BVDV from the commencement until after conclusion of collection of embryos for export to New Zealand through compliance with the recommendations of the OIE Code applicable to animals entering and residing on an artificial insemination centre 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 test results indicate the absence of sero-conversion and absence of antigen-positive cattle; AND
   - thereafter, annual re-testing of sero-negative cattle; AND
   - for every seropositive donor, testing of embryos/oocytes, collection fluids, and/or washing fluids for BVDV using a prescribed test, with negative result, prior to initial dispatch; AND
   - for seronegative donors, an antibody test using prescribed methods, with negative result, from samples collected after the conclusion of embryo collection for export; AND

36. Embryo donors that have been on the embryo collection facility for less than 3 years have had a sample of embryos/oocytes, collection fluids, and/or washing fluids from each collection in the consignment tested for BVDV2 using prescribed methodology, such as virus isolation (VI) or validated reverse transcriptase polymerase chain reaction (RT-PCR), with negative results.

Crimean Congo haemorrhagic fever (CCHF)

EITHER

37. 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, embryo collection for export to New Zealand; OR

38. 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 embryo collection facility for at least 3 weeks prior to the commencement of collection until conclusion of collection of embryos for export to New Zealand. Verification of tick freedom in the embryo collection facility is performed by inspections done at least monthly where no ticks were found; OR

39. Donors were serologically tested for CCHF using prescribed methods such as a validated enzyme linked immunosorbent assay (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 embryo collection for export to New Zealand. 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.

Foot and mouth disease (FMD)

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

41. **MAF** will individually approve each embryo collection, 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.

**Lumpy skin disease (LSD)**

**EITHER**

42. **Donors** must have been resident for 6 months prior to embryo collection in a country or zone that is free of LSD as defined by the *OIE Code*; **OR**

43. **Donors** must have been resident in an establishment or embryo collection facility 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 collection of embryos for export to New Zealand; **OR**

44. A sample of embryos/oocytes, collection fluids, and/or washing fluids from each embryo collection for the export consignment to New Zealand must have been subjected to a validated polymerase chain reaction (PCR) test for LSD, with negative result.

**Rift Valley fever (RVF)**

**EITHER**

45. **Donors** were resident, for at least the 3 months prior to and during embryo collection, for consignment to New Zealand, in a country or zone that is free from RVF in accordance with the *OIE Code*; **OR**

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

47. **Donors** have been held in mosquito-free premises for at least the 30 days prior to commencement until conclusion of collection of embryos for consignment to New Zealand.

**Vesicular stomatitis (VS)**

**EITHER**

48. **Donors** were resident in a country that is free from VS in accordance with the *OIE Code*; **OR**
49. VS is officially notifiable in the exporting country, and no cases have occurred within 100km of the embryo collection facility during the period from 30 days prior to commencement until 30 days after conclusion of collection of embryos for export to New Zealand; OR

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

**Bovine tuberculosis**

**EITHER**

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

52. 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

53. 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 exporting country, and were subjected to an OIE prescribed test for bovine tuberculosis during the 30 day period of isolation prior to collection of embryos for the consignment to New Zealand.

**Contagious bovine pleuropneumonia (CBPP)**

**EITHER**

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

55. Donors have never been vaccinated for CBPP; AND

56. Donors have been kept since birth or for at least the 6 months prior to commencement and until conclusion of embryo 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

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

**Mycoplasma bovis**

58. Donors have never recorded a positive test for Mycoplasma bovis; AND

**EITHER**

59. 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 for export to New Zealand; OR
60. A sample of embryos/oocytes, collection fluids and/or washing fluids from each embryo collection for each donor in the consignment for export to New Zealand, was subjected to a validated and MAF approved PCR test for *Mycoplasma bovis*, with negative result; OR

61. The herd of origin has been subject to a MAF approved whole herd serological test or a serological test on a random sample of at least 60 animals (whichever is the lesser number) for *Mycoplasma bovis* no more than 6 months before/after embryo collection for consignment to New Zealand, with negative results.

**Q fever**

62. Donors have never recorded a positive test for Q fever; AND

EITHER

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

64. A sample of embryos/oocytes, collection fluids, and/or washing fluids from each embryo collection for each donor in the consignment for export to New Zealand, must have been subjected to a validated and MAF approved PCR test for Q fever, with negative result; OR

65. The herd of origin has been subjected to a MAF approved whole herd serological test or a serological test on a random sample of at least 60 animals (whichever is the lesser number) for Q fever no more than 6 months before/after embryo collection for consignment to New Zealand, with negative results.

**PART D. EQUIVALENCE**

66. The requirements for importation of bovine embryos are met if, in the opinion of the Director-General, the measures taken for managing the risks associated with the importation of those goods, are equally effective at managing those risks as the requirements specified in (1) to (65) above. If an equivalence measure(s) is approved, MAF will issue an import permit (under Section 22 of the Biosecurity Act).