Import Health Standard

For

Bovine Embryos

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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 27th day of June 2011.

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

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

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Import Health Standard for Bovine Embryos

Date: 18 November 2013

Chief Technical Officer (CTO) Direction 2013 035:

Where the IHS for bovine embryos from all countries (bovemid.gen, 2011), and European Union, Canada, and Australia veterinary certificates state:

"Donors have never recorded a positive test for Q fever"

MPI will accept as equivalent, the following wording:

"Donors have never been confirmed positive for Q fever"

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 an amendment to the standard is minor, the amendment or revocation may be carried out without consultation.

3. A guidance document issued by the Director-General accompanies this import health standard. The guidance document provides information relevant to how requirements may be met and includes definitions of terms used in this standard.

Scope

4. This standard specifies the requirements that must be met to import, non-cloned, *in vivo* derived bovine embryos into 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 of bovine embryos must be subject to risk management measures for specified risk organisms 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 bovine embryos 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; Notifiable)
   - 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; Reportable under the Bovine Tb Pest Management Strategy)
   - Contagious bovine pleuropneumonia, CBPP, *Mycoplasma mycoides subsp. mycoides SC* (Unwanted; Exotic; Notifiable)
   - *Mycoplasma bovis* (Unwanted; Exotic; Notifiable)
   - Q fever*, Coxiella burnetii* (Unwanted; Exotic; Notifiable)

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

9. MAF will, in conjunction with the veterinary authority of the exporting country, determine how the relevant identified risks are to be managed, taking into account:
   - the verifiable health status of the exporting country/zone/compartment; AND
   - the national systems and standards in the exporting country for regulatory oversight of the germplasm industry; AND
   - the capabilities and preferences of the exporting country's Competent Authority.

   Once this determination has been concluded, country-specific Zoosanitary Certificate templates will be included in the guidance document.

Definitions

10. The definitions below relate to requirements for importing the consignment, for all other definitions see the guidance document.

Approved Embryo Collection Team
An embryo collection team demonstrated by the Veterinary Authority as having met the recommendations as described in the OIE Code.

Donor(s)
Female animal(s) from which embryos are collected, or male animal(s) from which semen was collected.

Embryo Collection Herd
The herd the embryo donor is resident in at the time of embryo collection.

Germplasm
Animal genetic material, i.e. frozen semen and frozen *in vivo* derived embryos.

Herd of origin
The herd in which the donor animal resided prior to entering the germplasm collection centre or embryo collection herd. If the donor animal has been on the germplasm collection centre or embryo collection herd for more than 90 days in the case of bulls or 60 days in the case of females the germplasm collection centre or embryo collection herd can be deemed to be the herd of origin.

IETS
The International Embryo Transfer Society. http://www.iets.org/

IETS Manual
The manual of the International Embryo Transfer Society. Any reference to the IETS Manual is to the most current version.

PART B. GENERAL REQUIREMENTS

Approved countries

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

Donor eligibility

12. Donors that were imported to the exporting country must have lived continuously in the exporting country for at least 60 days and in the herd of origin for at least 30 days prior to embryo collection for export to New Zealand.

13. Donors must be resident in the embryo collection herd for at least 30 days prior to embryo collection for export to New Zealand.

Embryo collection team and herd approval requirements

14. At the time of embryo collection for export to New Zealand, the embryo collection team must be 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 or legislation of the exporting country (where MAF deems this to be equivalent) and the current IETS manual.

15. The veterinary authority must have knowledge of and authority over the embryo collection herd until completion of testing specified in this standard.

Donor and herd health status

16. The donors must not be resident in any establishment that is subject to quarantine restrictions, for at least the 60 days before the first embryo collection

for the consignment to New Zealand until completion of the testing of the donors as required by this standard.

17. Where a specific requirement for a risk organism is met by pre-collection testing, donors must be isolated from other cattle not of an equivalent tested health status, from the time of the pre-collection test until completion of embryo collection for export to New Zealand.

18. On the day(s) of collection of the embryos, the approved embryo collection team veterinarian, or veterinarian responsible to the team veterinarian, is responsible for monitoring the health status of each donor and recording that the donor was free from clinical evidence of infectious diseases transmissible in embryos.

19. The semen used to produce the embryos in the consignment either:
    - was imported directly from New Zealand or is eligible for export to New Zealand; OR
    - must be 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
    - where natural service or fresh semen was used, donor males must be inspected, and found free from clinical evidence of infectious diseases transmissible in semen, and are of an equivalent isolation and tested health status to the donor females.

Embryo collection, processing, storage and transport

20. Embryos must be collected, washed, processed, traceability maintained, and stored under the supervision of an approved embryo collection team veterinarian and in accordance with the recommendations in the OIE Code chapters on collection and processing of *in vivo* derived and micro-manipulated bovine embryos.

21. All the embryos in the consignment must be fertilised *in vivo*, collected, processed, traceability maintained, stored, and transported in accordance with OIE Code recommendations.

22. Embryos must be collected, washed, processed, traceability maintained, and stored under conditions that comply with the recommendations in the IETS Manual. The embryos must be treated with trypsin during the washing process as described in the IETS Manual. Each embryo must have an intact zona pellucida and be examined over its entire surface at not less than 50X magnification and found to be free of adherent material.

23. Any micro-manipulation that causes a breach of the zona pellucida must be done as per the procedures described in the OIE Code and IETS Manual. These include specifications on the facilities used and require that micro-manipulation only be carried out on an embryo having an intact zona pellucida and that it be done subsequent to the last wash and examination of the embryo.

24. 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. Media and solutions must be 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 OIE Code and IETS Manual, or a combination of antibiotics with equivalent activity, must be added to collection, processing, washing and storage media. The names of antibiotics added and their concentration must be stated on the zoosanitary certificate.

25. All straws must be sealed, and clearly and permanently marked to identify the donor and the date(s) of freezing. If a code is used for this information, its decipher must accompany the consignment. The marking should, in accordance with the OIE Code, conform to the international standards of the International Committee for Animal Recording (ICAR; www.icar.org) and the IETS.

26. The embryos for export must be stored in the frozen state for at least 30 days before shipment to New Zealand, and during this time the donors and all animals in contact with them must remain healthy and free from any diseases transmissible in embryos.

27. The embryos must only be stored with germplasm that has been collected and processed in compliance with the OIE Code. Containers must be held until export in a storage place approved by the veterinary authority of the exporting country.

28. The embryos must be placed in transport containers filled with fresh (previously unused) liquid nitrogen. Transport containers may be either new or empty and disinfected. For the transport container used to transport the embryos to New Zealand, the disinfectant used, its active chemical and date of disinfection must be recorded on the zoosanitary certificate.

29. The transport container, in which the embryos are to be transported to New Zealand, must be sealed, by either the embryo collection team veterinarian or an official veterinarian, using tamper evident seals. The seal number must be recorded on the zoosanitary certificate.

Laboratory testing

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

31. Samples of embryos/oocytes, collection fluids, and washing fluids for laboratory testing must be 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.

32. Laboratory or other diagnostic 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

33. Documentation must be in English, but may be bilingual (language of exporting country/English).

34. The documentation that accompanies the consignment to New Zealand must consist of:
    - an original zoosanitary certificate, signed and stamped on every page by an official of the competent veterinary authority of the exporting country;

    AND

    - an import permit issued under section 22(2) of the Act;

    AND EITHER

        - a tabulated summary of laboratory tests for each donor completed in accordance with the specific requirements in the zoosanitary certificate (indicating donor identification consistent with the zoosanitary certificate, dates of germplasm collection, and for each relevant disease the date/s samples were drawn, the test undertaken and the reported result);

        OR

        - copies of laboratory reports for all tests.

Clearance

35. Upon arrival in New Zealand the documentation accompanying the consignment must be inspected by an Inspector at the port of arrival. The Inspector may also inspect the consignment.

36. Providing that the documentation meets all requirements noted in the zoosanitary certificate, the consignment may be given a biosecurity clearance under section 26 of the Biosecurity Act 1993 and the consignment released to the importer.

PART C. SPECIFIC REQUIREMENTS FOR IDENTIFIED RISK ORGANISMS

Borna disease

EITHER

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

OR

38. Borna disease is officially notifiable in the exporting country, and the donors have been resident for the previous 3 months in herds, where there have been no

reported cases in the 12 months prior to embryo collection for export to New Zealand;

OR

39. Donors or aliquots of embryos/oocytes, collection fluids, and/or washing fluids from each embryo collection for export to New Zealand have been tested for Borna disease, using a MAF-approved test and process, with negative results.

Bovine viral diarrhoea type 2 (BVDV2)

EITHER

40. At the time of embryo collection for export to New Zealand, the exporting country was free of BVDV2, i.e. there have been no cases of BVDV2 for at least 3 years;

OR

41. Donors have been tested for BVDV including:
    - prior to, or at the time of embryo collection for export to New Zealand, all donors were tested serologically for BVDV antibodies and antigen; AND
    - seronegative donors were again tested serologically, 21 to 40 days subsequent to embryo collection for export to New Zealand, for BVDV antibodies and antigens.

Cattle that are not eligible as embryo donors for export to New Zealand are either:
- donors that are antigen-positive in initial testing; OR
- donors that seroconvert or are antigen-positive in the post-collection test.

OR

42. A pooled sample of embryos/oocytes, collection fluids and/or washing fluids from each embryo collection for export to New Zealand has been tested for BVDV2, by virus isolation (VI) or a MAF approved reverse transcriptase polymerase chain reaction (RT-PCR) test, with negative results.

Crimean Congo haemorrhagic fever (CCHF)

EITHER

43. The exporting country has been recognised by MAF as being free of CCHF or CCHF is officially notifiable in the exporting country, and there has not been a reported case of CCHF in the exporting country for the 21 days before and during embryo collection for export to New Zealand;

OR

44. Donors were serologically tested for CCHF using MAF approved methods such as an enzyme linked immunosorbent assay (ELISA) to detect IgG and IgM antibodies. Blood samples must be collected within 7 days prior to commencement of embryo collection and every 21 to 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

45. Donors were 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

46. The herds of origin, embryo collection herd where the donors were resident during embryo collection, donor animals and embryos for export must comply with OIE Code recommendations for export of bovine embryos from countries or zones presenting a risk of FMD; AND
    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 MAF. The approval will be dependant 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 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

47. 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

48. Donors must have been 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 embryo collection for export to New Zealand;

OR

49. 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 polymerase chain reaction (PCR) test for LSD, with negative results.

Rift Valley fever (RVF)

EITHER

50. Donors were resident, for at least the 30 days prior to, and during embryo collection for export to New Zealand, in a country or zone that is free from RVF in accordance with the OIE Code;

OR

51. Donors were serologically tested for RVF, using an OIE prescribed test, on the day of embryo collection for export to New Zealand, and at least 14 days later, and showed no significant rise in titre;

OR

52. Donors showed no evidence of RVF in the period from 28 days prior, to 28 days following embryo collection for export to New Zealand, and were vaccinated with a MAF approved vaccine against RVF at least 21 days prior to embryo collection.

Vesicular stomatitis (VS)

EITHER

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

OR

54. VS is officially notifiable in the exporting country, and no known cases have occurred within 100km of the embryo collection herd, where the donors were resident during embryo collection, during the period from 30 days prior to commencement, until 30 days after conclusion of embryo collection for export to New Zealand;

OR

55. Donors were:
    - resident for the 30 days prior to and during embryo collection in a herd where no case of VS was reported in that period; AND

- subjected to a serological test for VS, between 21 to 42 days after embryo collection for export to New Zealand, with negative results.

Bovine tuberculosis

56. Donors and other susceptible animals in the embryo collection herd showed no clinical signs of bovine tuberculosis during the 24 hours prior to embryo collection for export to New Zealand;

AND EITHER

57. Donors were:
    - from a embryo collection herd that is free from bovine tuberculosis in accordance with the OIE Code or the veterinary authority of the exporting country; AND
    - from a country or zone that has been recognised by MAF as being free of bovine tuberculosis;

OR

58. Donors were:
    - from an embryo collection herd that is free from bovine tuberculosis, either in accordance with the OIE Code or the veterinary authority of the exporting country; AND
    - subjected to an OIE prescribed test for bovine tuberculosis during the period between 30 days prior to 12 months after embryo collection for export to New Zealand, with negative results.

Contagious bovine pleuropneumonia (CBPP)

EITHER

59. Donors were born in, and have been continuously resident in, a country that is free from CBPP i.e. there have been no cases of CBPP for at least 3 years;

OR

60. Donors have:
    - never been vaccinated for CBPP; AND
    - been kept since birth, or for at least the 6 months prior to commencement 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

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

Mycoplasma bovis

61. Donors have never recorded a positive test for *Mycoplasma bovis*.

Q fever

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

AND EITHER

63. Donors were subjected to a MAF approved serological test for Q fever, on a sample collected between 21 and 120 days after each embryo collection for export to New Zealand, with negative results;

OR

64. A sample of embryos/oocytes, collection fluids and/or washing fluids from each embryo collection for export to New Zealand was tested for Q fever by a MAF approved PCR test, with negative results;

OR

65. Within the 6 month period before or after embryo collection for export to New Zealand, the embryo collection herd has been tested for Q fever, with negative results. This testing can be a MAF approved serological test done on either the whole herd or a random sample of at least 60 animals (whichever is the lesser number); AND
    The embryo collection herd has been isolated for the period between embryo collection and diagnostic sampling.

PART D. EQUIVALENCE

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).