Overseas Market Access Requirements Notification - Animal Products Act 1999 - Standards Branch, Animal and Animal Products Directorate, Ministry for Primary Industries

Ref: AE-US-05L
Date: 31 August 2012

OMAR B BOVEMBEC.USA 31.08.12 – BOVINE EMBRYOS to THE UNITED STATES OF AMERICA

A. Statutory authority

Pursuant to section 60 of the Animal Products Act 1999:

(i) I notify the following overseas market access requirements, entitled bovine embryos to The United States of America

(ii) Revoke OMAR B BOVEMBEC.USA 24.09.10.

This notice takes effect from date of signing.

Dated at Wellington this 25th day of September 2012.

Signed: Howard Pharo BVSc, MScTAD, MPP, MANZCVSc
Manager Import and Export Animals
Animal and Animal Products Directorate
Standards Branch
(pursuant to delegated authority)

B. The United States of America requirements

Bovine embryos exported from New Zealand to The United States of America must comply with the import regulations of The United States of America listed in this notice as follows:

(i) An Import Permit is required for the exportation of bovine embryos from New Zealand to The United States of America.

(ii) An Official Veterinarian of New Zealand Ministry of Agriculture and Forestry must certify, after due enquiry, the following:

1. Country freedom

1.1 New Zealand is officially free of Akabane virus, Aino virus, bluetongue, epizootic hemorrhagic disease, brucellosis (*Brucella abortus* & *B. melitensis*), contagious bovine pleuropneumonia, ephemeral fever, foot-and-mouth disease and rinderpest.

Vaccination against these diseases is prohibited in New Zealand.

2. Herd of origin

2.1 During the twelve (12) months prior to the collection of embryos for export to the United States, there has been no evidence of bovine tuberculosis (Tb) found in the donor dams or on any premises on which the donor dams were located during that time.

3. Donor animals

3.1 The donor dams have been part of the national herd of New Zealand for at least sixty (60) days prior to the collection of the embryos for export to the United States, and they are free from any movement or quarantine restrictions.

3.2 During the sixty (60) days prior to the collection of embryos for export to the United States, the donor dams were not corralled, pastured or held with animals of a lesser health status or under any restrictions that would have made them ineligible as embryo donors for export to the United States.

3.3 During the sixty (60) days prior to the collection of embryos for export to the United States, the donor dams were inspected by the team veterinarian and appeared healthy, and were found clinically free of diseases transmissible by embryos. The donor sires were also inspected if natural breeding or fresh semen was used for fertilisation.

3.4 Each of the donor dams was examined on the day of embryo collection and appeared healthy, and was clinically free of diseases transmissible by embryos.

3.5 Each embryo donor (and semen sire in case of natural breeding) originated from a Tb free herd and was tested, with a negative result, to either an intradermal Tb caudal fold test or cervical test performed within twelve (12) months after the last collection of embryos.

[The caudal fold test involved the intradermal injection of 0.1 mL *M. bovis* purified protein derivative (PPD) tuberculin (2000 – 5000 IU) into either side of the caudal fold, with reading by visual observation and palpation

seventy-two (72) hours (plus or minus six (6) hours) following injection. A negative test result means no detectable response using both visual examination and palpation.]

The cervical test was administered and read as described in the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, i.e. the version current at the time of testing.

Date test read to be recorded on the export certificate.

4. Embryo collection team and fertilisation of the embryos

4.1 The embryo collection team:

4.1.1 is approved by the New Zealand Ministry of Agriculture and Forestry as having facilities suitable for the collection of embryos for export;

4.1.2 is under the direct supervision and sanitary control of a team veterinarian who is approved by the New Zealand Ministry of Agriculture and Forestry, and who is responsible for the hygiene of the facilities and the health of the animals.

4.2 The embryos were fertilised:

either 4.2.1 by artificial insemination (AI), using semen from a semen collection centre approved by the New Zealand Ministry of Agriculture and Forestry for the export of semen;

or 4.2.2 by natural breeding or the use of fresh semen from a donor sire(s) certified as having met the same residency, health and tested health status as the female donor animals;

or 4.2.3 with semen imported into New Zealand from a country considered by the USDA as free of foot-and-mouth disease and rinderpest.

(Delete as appropriate)

5. Embryo collection, processing and storage

5.1 The team veterinarian supervised the flushing of embryos from the donor dams and verified that the processing, storage and shipping of those embryos was in accordance with the requirements described in this protocol.

5.2 Embryos were collected using a closed flushing system and any instrument or equipment that contacted the tissues of the female reproductive tract or flushing fluids was either new or pre-sterilised equipment.

5.3 Each embryo was washed at least ten (10) times and treated with trypsin, in accordance with the latest published edition of the *Manual of the International Embryo Transfer Society* (IETS).

5.4 Embryos from different donors were not washed together.

5.5 After the last wash, each embryo was microscopically examined over its entire surface at not less than 50x magnification and the zona pellucida was found to be intact and free from any adherent material.

5.6 The embryos were packaged in straws that were identified in accordance with the latest published edition of the IETS *Manual*.

5.7 All equipment used to process the embryos was either new or sterilised between each use, with standard sterilisation procedures being observed.

5.8 All media and additives of ruminant origin, such as fetal bovine serum and bovine serum albumin, were sourced from countries free of foot-and-mouth disease and rinderpest. Trypsin of porcine origin was sourced from countries free of foot-and-mouth disease, rinderpest, classical swine fever and African swine fever.

5.9 Prior to its use for exporting embryos to the United States, the shipping container was examined by the team veterinarian and found to be clean and empty of embryos and other biological materials.

5.10 The embryos were stored under lock and key, or in the custody of the team veterinarian, and segregated from embryos of a lesser health status until they were placed in the shipping container.

6. Transportation

6.1 The shipping container contained only new liquid nitrogen and was:

either 6.1.1 new;

or 6.1.2 disinfected, using:

Name of active ingredient used.

Date of disinfection to be recorded.

(Delete as applicable)

6.2 Prior to export, the shipping container was sealed by a Ministry of Agriculture and Forestry veterinarian, using a MAF seal bearing the marks to be recorded. Serial number of the shipping container to be recorded.

C. Definitions

For the purposes of this document:

Any term or expression that is defined in the Animal Products Act 1999 and used, but not defined in this document, has the same meaning as in this Act.

Explanatory note

These overseas market access requirements are based on the export certificate for bovine embryos to the United States of America, dated 31 August 2012.

Additional Information on OMAR Notification: BOVEMBEC.USA 31.08.12

1. This OMAR replaces the one of 24 September 2010. The only changes made were to amend the TB concentration and clarify the requirements for method of TB testing. The changes were agreed with APHIS.

2. An Import Permit is required. This can be obtained from:

   U.S. Department of Agriculture (USDA)
   Animal and Plant Health Inspection Service (APHIS)
   Veterinary Services (VS)
   National Center for Import and Export, (NCIE) Unit 39
   4700 River Road
   Unit 39
   Riverdale, MD 20737-1231

   Telephone: (301) 734-8364
   Facsimile: (301) 734-4704

3. The shipment of the embryo consignment must be routed directly to the United States from New Zealand with no stops en route other than those provided for on the USDA Import Permit.

4. The embryos must be collected by an embryo collection team that is approved by MAF and under the supervision of an embryo team veterinarian approved by MAF.

5. Clause 3.5: the USDA have clarified that they do not accept a comparative or gamma interferon TB test.

6. Clause 5.1: the collection and processing of embryos should be done by or under the direct supervision of the embryo team veterinarian.

7. Where there are multiple donors per health certificate, the embryos must originate from the same embryo facility/team.

Section 61.A of the Animal Products Amendments Act 2005 states that 'The Crown is not liable, and nor is the Director-General or any employee of the Ministry liable, for any loss arising through the refusal or failure of the relevant authority of an overseas market to admit export animal material or animal product to that market'

Schedule of Donor and Embryo Details for the Official Assurance for Bovine Embryos to the United States of America

Schedule of Donor and Embryo Details for the Official Assurance for Bovine Embryos to the United States of America

I: DONOR DAM					
Breed					
Herd book number / Identification					
Date of birth					
Date Tb test					
II: DONOR SIRE					
Breed					
Herd book number / Identification					
Date of birth					
Date(s) of semen collection					
Straw identification					
III: IDENTIFICATION OF THE EMBRYOS					
Date(s) of collection					
Number of embryos					
Straw identification					
Number of straws					