Attachment D
August 2000

QUARANTINE REQUIREMENTS FOR THE IMPORTATION OF OVINE EMBRYOS FROM CANADA, THE UNITED STATES OF AMERICA AND MEMBER STATES OF THE EUROPEAN UNION

1 GENERAL

1.1 These conditions apply to frozen embryos fertilised by rams, and collected from ewes, which, immediately prior to the pre-collection periods[1], were living in Canada, the United States of America (USA) or a Member State of the European Union (EU).

1.2 Each consignment of embryos must be accompanied by a copy of a valid *Permit to Import Quarantine Material into Australia* obtained, prior to the export of the embryos, from the Australian Quarantine and Inspection Service (AQIS) office in the State of Australia to which the importation is to be made.

1.3 Each consignment must be accompanied by an Animal Health Certificate which conforms to, or includes equivalent information to, the template shown at Attachment 1. The Certificate must be in English and signed by the embryo collection team veterinarian[2] and an *Official Veterinarian*.[3] The Certificate must be stamped on each page with an Official stamp.

The Animal Health Certificate must include an attached table showing details of the donor(s), embryo identification, embryo collection dates, dates of sampling for tests, type of tests used, the dates of the pre-collection and collection periods and details of the autopsy performed on the donor female.

The embryos must be fertilised *in vivo*, collected and processed by an approved *embryo collection team* and meet the requirements specified in Section 2 of this document. This must be certified under *V Sanitary information* in the Animal Health Certificate.

1.4 All collections of embryos and all servicing of storage containers prior to export must be performed under the supervision of either the team veterinarian or the *Official Veterinarian*. Blood and fleece samples must be collected for diagnostic tests or DNA testing by the team veterinarian, the *Official Veterinarian* or a registered veterinarian appointed by the team veterinarian and acting under written instruction. The program may be subject to direct audit by AQIS at any time during the collection period.

1.5 The final identification and placement of the embryos into new, unused liquid nitrogen in a new, or properly disinfected, container prior to export of the embryos to Australia must be performed under the supervision of an *Official Veterinarian*.

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[1] The pre-collection period is the 30 day period immediately prior to the first collection of embryos/semen from donors

[2] The team veterinarian supervises the embryo collection team, is responsible for all team procedures and should be specifically approved for this purpose by the *Official Veterinarian*. The embryo collection team veterinarian must be registered with the Animal and Plant Health Inspection Service (APHIS) in the USA, the Canadian Food Inspection Agency (CFIA) in Canada, or the *Veterinary Administration* in the appropriate EU Member State as approved to collect embryos for export and issued with an identification number (code) by the International Embryo Transfer Society (IETS).

[3] An *Official Veterinarian* is a veterinarian authorised by APHIS, CFIA or the *Veterinary Administration* of the exporting Member State of the EU to perform animal health and/or public health inspections of commodities and, when appropriate, perform certification in conformity with the provisions of Chapter 1.3.2. of the Office International des Epizooties (OIE) International Animal Health Code (*Code*).

1.6 The embryos must be shipped to the Australian importer care of AQIS.

1.7 AQIS may vary or review the conditions at any time.

2 ANIMAL HEALTH CERTIFICATION

[Note: Unless otherwise specified, "donor" *refers to both the female donor of the ova and the male donor of the semen used to fertilise the ova to produce the embryos.]*

Each consignment must be accompanied by a valid *Permit to Import Quarantine Material into Australia* and an Animal Health Certificate which conforms to, or includes equivalent information to that in, the template shown at Attachment 1.

The Animal Health Certificate must attest, under **V Sanitary Information,** that:-

2.1 Immediately prior to the pre-collection period each donor was living in Canada, the United States of America or Member States of the European Union in a country or zone recognised by the OIE as being free from foot and mouth disease.

2.2 The exporting county meets the *Code* Article definitions for country freedom from sheep and goat pox (capripoxvirus).

2.3 The embryos came from donors (both male and female), 5 years of age or older prior to export of the embryos, and

- which had lived only in a country or zone where:
  - scrapie has been compulsorily notifiable during the previous 6 years;
  - an effective and continuous national surveillance system is practiced;
  - brains from clinically suspect animals which are slaughtered or die are examined in a laboratory in accordance with the diagnostic techniques set out in the OIE Manual of Standards for Diagnostic Tests and Vaccines or the USDA Voluntary Scrapie Flock Certification Program Standards, Appendix 1;
  - the feeding of ruminant derived meat-and-bone meal to sheep and goats is banned;
  - scrapie-affected sheep and goats are slaughtered and their carcasses disposed of in a manner that would reliably preclude the spread of scrapie infective agent (such as complete incineration), and
  - procedures are followed which allow tracing of each scrapie affected animal back to its flock of birth.

- which are of a homozygous PrP genotype known to be susceptible to scrapie, in relation to the particular breed of sheep (approved by AQIS), as verified in the attached certificate/s from a laboratory/laboratories officially approved by the *Veterinary Administration* to do PrP genotype testing.

  [Note: Breeds and genotypes permitted without consultation with AQIS:
  - *Suffolk – QQ at Codon 171, and*
  - *Cheviot, Texel, Charollais – VRQ/VRQ (at Codons 136/154/171).*

  Requests for the importation of embryos from other breeds will be considered by AQIS after receiving details of breed specific PrP genotype and scrapie susceptibility through the veterinary administration of the exporting country.
  Suffolk semen donors may be of genotype QH but must undergo the same autopsy procedure as required of female donors]

. which originated from flocks:
EITHER
certified as Complete Monitored status in the USDA Voluntary Scrapie Flock Certification Program
OR
- in which no case of scrapie has been confirmed or suspected during the 5 years immediately prior to collection;
- in which all animals are identified and can be traced back to their flock of birth;
- for which records of parentage, and movements of animals in and out of the flock, are maintained for a minimum period of 5 years;
- into which, during the previous 5 years, introductions were only permitted from flocks with equivalent scrapie status, and
- in which no animals have commingled with flocks of lower scrapie status during the previous 5 years

OR
for which confirmed information is available which would provide equivalent security to the above.*
*[*Note: Applications for this option must be made to AQIS through the Veterinary Administration of the exporting country*.]

2.4 Each donor was isolated from all ruminants, except other donors of equivalent health status, during the pre-collection and the collection periods. Prior to entry into quarantine each donor was individually identified by microchip[4] implanted midline between the shoulder blades.

2.5 Donors were:
. not vaccinated against any diseases during the pre-collection period nor during collection
. clinically inspected at least each week during the pre-collection period and on each day blood samples were collected and, at each inspection, were found to be free from signs of contagious and infectious diseases (by the team veterinarian, *Official Veterinarian* or a registered veterinarian appointed by the team veterinarian and acting under written instruction).

2.6 All animal health testing, to meet these conditions, was performed at laboratories, and using tests, approved by the *Veterinary Administration* of the exporting country.

2.7 Bluetongue (BT)

Each donor was
EITHER
kept in a BT virus free, or seasonally free, country or zone for at least the 60 days before commencement of, and during, collection of the embryos
OR
subjected to a serological test to detect antibody to the BT virus group, such as the BT competition enzyme-linked immunosorbent assay (ELISA) or the BT agar gel immunodiffusion (AGID) test, between 28 and 60 days after collection, with negative results
OR
subjected to a BT virus isolation test or polymerase chain reaction (PCR) test on a blood sample taken on the day of collection, with negative results.

[4] The microchip, or electronic implant is any radio frequency identification device approved for use by the exporting country *Veterinary Administration* which is tamper resistant and readable by equipment available to the *Veterinary Administration.*

2.8 *Brucella melitensis* infection

Each donor:
EITHER
has lived only in a country or zones which meet *Code* requirements for country freedom (Article 3.3.2.1.)
OR
immediately prior to the pre-collection period, was part of a flock officially free from *B melitensis* infection (Article 3.3.2.2.)
and
gave a negative result to a complement fixation test (CFT) and a Rose Bengal plate agglutination test for *B melitensis* infection on the same blood sample taken during the pre-collection period or at autopsy.

2.9 Contagious agalactia (CA)

Each donor has lived on premises in which contagious agalactia has not been diagnosed during the 6 months immediately prior to the pre-collection period.

2.10 Maedi-visna (MV)

Each donor :
EITHER
immediately prior to embryo collection was part of an accredited MV free flock recognised by the *Veterinary Administration*
OR
immediately prior to embryo collection was part of a flock in which MV had not been diagnosed during the previous 3 years and during this 3 year period no commingling[5] with goats occurred and no animals were introduced from flocks with a lesser disease status
AND
gave a negative result to
either
an approved ELISA for MV antibodies on two blood samples collected 30 days apart during the pre-collection period, at the time of collection or at autopsy
or
an approved virus isolation technique using white blood cells (mononuclear cells) or embryo collection fluid collected at embryo collection or at autopsy
or
an approved nucleic acid recognition test, eg. a polymerase chain reaction (PCR) test on white blood cells (mononuclear cells) or embryo collection fluid collected at the time of collection or autopsy.

2.11 Enzootic abortion of ewes

Each donor has lived on premises in which enzootic abortion of ewes (EAE) had not been diagnosed during the 2 years immediately prior to the pre-collection period
AND
gave a negative result to a CFT test for EAE during the pre-collection period.

[5] Animals grouped together having physical contact. This does not include incidental contact between animals off the flock's premises, such as occurs at shows and sales.

2.12 Jaagsiekte

Each donor:
EITHER
has only lived in flocks which include animals older than 5 years, and
in which, as far as can be determined, after due enquiry and examination of official records, all animals remained free from jaagsiekte, based on the absence of clinical signs, for at least 5 years immediately prior to collection of embryos. During this period no animals were introduced from flocks with a lesser jaagsiekte status
OR
gave a negative result to a pathological examination or immune or nucleic acid test for jaagsiekte virus/viral components in lung and associated lymphoid tissues in accordance with procedures approved by the *Veterinary Administration* for the detection of jaagsiekte.
*[*Note: This testing must be carried out at a laboratory approved by the Veterinary Administration to carry out histopathological diagnosis and/or immune or nucleic acid detection testing.*]

2.13 The semen donors were of equivalent tested health assurance standards to those prescribed for the female donors and the embryos were produced:
EITHER
by insemination with fresh semen collected from identified males
OR
by insemination with semen collected, processed and stored at centres registered under the competent authority of the exporting country.

2.14 Samples for DNA testing
Before the export of embryos, blood and fleece samples were collected from each male and female donor and labelled in accordance with Chapter 9 of the Manual of the International Embryo Transfer Society (IETS) 3rd edition, 1998.
*[*Note: Information on the collection and submission of samples for DNA testing is provided in Attachment 2.*]

2.15 Before the export of embryos each female donor was autopsied under the supervision of an *Official Veterinarian* or a registered veterinary pathologist employed at a Veterinary laboratory approved by the *Veterinary Administration* and acting under written instruction from the *Official Veterinarian*
AND
gave a negative result to tests for scrapie prion protein (PrPsc)* on specimens of brain, brain stem, spinal cord, palatine tonsils, spleen, mesenteric lymph nodes and distal ileum using immunohistochemical methods or techniques of equivalent sensitivity in accordance with procedures laid down by the *Veterinary Administration* for the detection of scrapie infective agent.
*[*Note: This testing must be carried out at a laboratory approved by the veterinary administration to carry out testing for scrapie prion protein (PrPsc).*]

2.16 The embryos were collected, handled and stored in accordance with *Code* (Appendix 4.2.3.3.). Materials of animal origin used during the collection, handling or storage of the embryos contained no living micro-organisms, were sourced from Australia or New Zealand and were subjected to quality control methods in accordance with Chapter 10 of the Manual of the International Embryo Transfer Society (IETS) 3rd edition, 1998. Equipment which came in contact with the embryos, or the reproductive organs of the donors, was either new or

treated by a process recommended for the destruction of TSE infective agents in accordance with the recommendations of the veterinary administration of the exporting country*.
*[*Note: Processes include autoclaving at 136 degrees C for 1 hour or soaking in a 2 percent available chlorine solution (equivalent to 20,000 ppm) for 1 hour. (from Appendix 2 USDA Voluntary Scrapie Flock Certification Program Standards)*]

2.17 The embryos in this consignment have been stored:
- only with other embryos, collected for export to Australia, or of equivalent health status;
- in sealed containers or in unsealed containers kept in a secure area locked under the supervision of the team veterinarian, and
- since the end of the collection period until export in a secure place.

2.18 The embryos were identified and placed into new, unused liquid nitrogen in a new or properly disinfected container under the supervision of an *Official Veterinarian*. The contents of the container were verified by the *Official Veterinarian* prior to sealing of the liquid nitrogen container and the number or mark on the seal recorded on the certificate prior to export.

3 IMPORTERS/AGENTS RESPONSIBILITIES

3.1 It is the responsibility of the importer to arrange for any other health certification or testing of donors (eg for inherited diseases or genetic defects or for movement of animals or genetic material into certain zones in Australia).

3.2 The importer must nominate a person who will be accessible to AQIS and who will accept responsibility for ensuring that all import requirements are met and for Customs clearance and Quarantine inspection and clearance in Australia.

4 POST ARRIVAL

4.1 The consignment will be held by AQIS until a Quarantine Officer has checked the certification, conducted an audit of the contents of the shipping container and received DNA test results from an AQIS recognised laboratory.

4.2 In the event of a consignment arriving in Australia without the correct certification, with the seals on the transport containers broken or in any other way not having met these requirements, the consignment may be retained in quarantine, returned to the country of origin or destroyed without recompense.

4.3 Under the supervision of a Quarantine Officer the fleece and blood samples should be submitted to an AQIS recognised laboratory for DNA testing. A laboratory report of the DNA profiles of the donors must be provided to the regional AQIS office before the embryos will be released by AQIS. All testing will be carried out at the importer's expense.

4.4 If required by AQIS, samples of tissues will be collected from the progeny resulting from imported embryos and tested at an AQIS recognised laboratory at the importer's expense.

SARAH KAHN
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ANIMAL HEALTH CERTIFICATE

Import Permit Number: Importing Country: AUSTRALIA.
Species and Category: OVINE EMBRYOS Exporting Country:

I Information concerning each donor

Ewe: *Ram:*
Breed: Breed:
Herd book number: Herd book number:
Identification- Microchip number Identification- Microchip number:
Date of insertion: Date of insertion:
Flock of origin: Flock of origin:

II Information concerning embryos and semen from each donor

Embryos *Semen*
Date of collection: Date of collection/Breeding date:
Number of embryos: Freeze date/Batch number:
Number of straws: Straw identification:
Straw identification:

III Origin of the embryos

Exporter name: Owner name:
Exporter address: Owner address:

Name and address of premises at which embryos were collected:

IV Destination of the embryos

Name of consignee:
Address of consignee:

V Sanitary information

The undersigned embryo collection *team veterinarian* and the undersigned *Official Veterinarian* certify in respect of the donor animals described in part 1 of this certificate, and in respect of the ovine embryos described in part II of this certificate, that:

(Certification as detailed in Section 2 of this document)

The attached table shows details of the donor(s), embryo identification, embryo collection dates, dates of sampling for tests, type of tests used, the dates of the pre-collection and collection periods and details of the autopsy performed on the donor ewe.

Name of the veterinarian performing the autopsy: Autopsy date:

Name:……Signature:.....Date:.....IETS No./Code…….
(Embryo Collection *team veterinarian*)

Name:……Signature:.....Date:.....
(*Official Veterinarian*)

Note: Official Stamp must be endorsed on all pages.

Collection, preparation and submission of samples for DNA testing

The DNA profile of donor blood and fleece will be determined at a laboratory recognised by AQIS for the purposes of conducting DNA testing.

Blood samples

Approximately 0.1 ml of blood should be collected from donors and carefully applied to the filter paper supplied by the laboratory. The blood is allowed to absorb into the filter paper, dry and is then sealed in the sample collector supplied. The card should then be labelled with the donor's identification number and attached to the health certificate accompanying the consignment of embryos.

Fleece samples

Collect enough fleece to cover approximately one quarter of the surface of the collection card supplied by the laboratory. Stick the fleece onto the card making sure that the amount of fleece does not prevent sealing. The card with fleece attached should be labelled with the donor's identification number and attached to the health certificate accompanying the consignment of embryos.

Submission of samples on arrival

Under the supervision of an AQIS inspector a the cards containing blood and fleece from each donor should be sent together to an AQIS recognised laboratory for DNA testing.