14 August 2013

BIOSECURITY MEASURES FOR THE IMPORTATION OF LABORATORY MOUSE EMBRYOS

1. Scope

1.1. These biosecurity measures apply to the importation of embryos derived from *Mus musculus* (house mouse).

1.2. Embryos can be imported from countries approved by the Department of Agriculture, Fisheries and Forestry (DAFF). DAFF will consider applications to import from a country, subject to an evaluation and acceptance of the Veterinary Authority's ability to provide health certification for mouse embryos according to the principles of the World Organisation for Animal Health (OIE) Terrestrial Animal Health Code.

1.3. These requirements apply only to embryos collected from laboratory mice bred and housed for their lifetime in premises recognised as bona fide scientific facility, usually as evidenced by the existence of an Animal Ethics Committee or equivalent arrangement within the organisation.

2. General Requirements

2.1. A valid import permit is required and must be issued prior to importation. Permit applications should be sent to Animal Import Operations, DAFF Canberra, for assessment.

Animal Import Operations
GPO Box 858
Canberra ACT 2601
Email animalimports@daff.gov.au
Phone +61 6272 4454
Fax +61 6272 4454

2.2. It is the importer's responsibility to ensure they have complied with the requirements of any regulatory and advisory bodies prior to and after importation. It is the importer's responsibility to arrange for any additional testing for genetic and endemic infectious diseases, or for the movement of animals or genetic material into certain animal health zones within Australia.

2.3. The importer or agent must nominate a person who will be accessible to DAFF officers and who will accept responsibility for ensuring that all biosecurity requirements are met including the inspection.

2.4. Consignments must be addressed and sent to DAFF at the port of arrival. Each consignment must be accompanied by a valid Import Permit or by means to identify the Import Permit and the International Veterinary Certificate.

2.5. Consignments must not be sent through international mail.

2.6. In the event of a consignment arriving in Australia without the correct certification or in any other way not meeting these requirements, the consignment may be detained in quarantine, returned to the country of origin or destroyed without recompense.

2.7. Fees may be applied by DAFF to cover costs such as those associated with inspection, collection, testing, processing, or quarantine and any Australian Government veterinary supervision of the consignment.

2.8. Nothing in these requirements prevents importers from specifying their own disease-freedom or testing requirements, as part of a commercial contract.

3. Documentation

3.1. An International Veterinary Certificate must accompany each consignment. The International Veterinary Certificate must be signed by the Official Veterinarian* and the veterinarian in charge of the donor colony. The International Veterinary Certificate must:

- be written in English and, if required, the official language of the country of export
- meet the requirements of the '**certification before export'** section and confirm that **all pre-export requirements** have been met
- provide details of the certifying authority, identification of the embryos, place of origin of the embryos and donor animals, consignor and consignee, destination and means of transport
- reference the DAFF import permit number.

The International Veterinary Certificate must display the following information against each embryo donor:

- species
- institution of donor residence
- colony identification
- dates on which embryos were collected.

The International Veterinary Certificate must display the following information against each semen donor (if applicable):

- institution of donor residence
- colony identification
- date of semen collection.

The International Veterinary Certificate must display the following information against each ova donor (if applicable):

- institution of donor residence
- colony identification
- date of ova collection.

The International Veterinary Certificate must also include the following details:

- number of embryos in this consignment

- number of ampoules, straws or vials in this consignment
- ampoule, straw or vial identification.

*An Official Veterinarian means a veterinarian authorised by the Veterinary Authority of the exporting country to perform certain official tasks associated with animal health and/or public health, inspections of commodities and, when appropriate, to certify to conformity with the Certification Procedures of the *Trade measures, import/export procedures and veterinary certification* chapter in the OIE Terrestrial Animal Health Code.

3.2. The official veterinarian must:

- provide a separate veterinary certificate for each consignment
- sign, date and stamp (with the stamp of the Veterinary Authority) each page of the veterinary certificate and any attached documents (e.g. laboratory reports) with date, signature and Official Veterinarian stamp
- record his/her name, signature and contact details on the veterinary certificate.

4. Certification before export

The following certification statements must be provided on the veterinary certificate.

4.1. Embryos are derived from donors bred and housed for their lifetime in premises that are part of a bona fide scientific institution (evidenced by the existence of an Animal Ethics Committee or equivalent arrangement within the organisation) and all preparation and processing of donors and embryos occurred within the same facility.

NOTE: The term ‘donors’ refers to donors of all reproductive material including, embryos, ova and semen.

4.2. The donors were housed in a facility for which there was a control program in place designed to preclude access by wildlife, including rodents and insect vectors.

4.3. There is no clinical, epidemiological or other evidence of the following diseases or infectious agents in any barrier maintained room where the donor mice were bred or housed during the 12 months before, or 30 days after, the date of collection :

- hantaviruses
- ectromelia virus
- rabies.

NOTE: The term ‘barrier maintained room’ refers to an individual room within the facility with protocols in place to exclude any potential sources of unwanted microbiological contamination.

4.4. Reproductive tracts (uteri, oviducts, ovaries, testes, epididymis and vas deferens) were removed either at a site separate from the embryo processing laboratory or within a biological safety cabinet before processing.

4.5. Collection of reproductive material including ova and sperm and embryo recovery was performed in aseptic conditions.

4.6. During processing of embryos for export no embryos from donors of a lesser health status or of other species were handled.

4.7. After washing the zona pellucida of each embryo was examined over its entire surface at not less than 50X magnification and was intact and free from adherent material.

4.8. Biological product of animal origin used in the media and solutions for collection, processing, washing or storage of embryos were free of pathogenic micro-organisms. Media and solutions used in the collection and storage of embryos were sterilised by approved methods according to the latest edition of the International Embryo Transfer Society (IETS) Manual and handled in such a manner as to ensure that sterility is maintained. Antibiotics may be added to collection, processing, washing and storage media.

4.9. All equipment used to collect and process reproductive material (embryos, ova or semen) and which the reproductive material (embryos, ova or semen) comes into direct contact with was new or sterilised before use as recommended in the latest edition of the IETS Manual.

4.10. The embryos were frozen and stored in sealed, sterile ampoules, straws or vials. Only embryos from donors of the same health status are stored together in the same ampoule, vial or straw.

4.11. Ampoules, straws or vials were sealed at the time of freezing and are clearly identified with a unique legible and non-erasable identifier according to, or similar to, the system described in the IETS manual. The following details were recorded and are included with the veterinary certificate:

- species and strain of the donors
- collection date
- number and developmental stage of the embryos
- laboratory of origin.

4.12. At the time of embryo collection the donors were examined under the direction of the veterinarian in charge of the colony and found to be clinically healthy.

5. Transport

5.1. The transport container must be sealed in a tamper proof manner using either official seals or seals supplied by the source institution.

5.2. The shipping container was new.

or

Before loading, the shipping container was emptied and inspected and any loose materials/receptacles removed. The shipping container including all surfaces in contact with the straw, ampoules or vials were disinfected with one of the following disinfectants: 2% available chlorine (chlorine bleach), Virkon® or irradiated at 50kGray.

(The veterinary certificate must indicate the option that applies. For used shipping containers the date of disinfection, the disinfectant used and its active chemical must be recorded on the veterinary certificate.)

5.3. Only new liquid nitrogen was added to the tank.

6. Post-arrival procedures

6.1. The imported embryos must be imported into a laboratory facility with management standards and practices that comply with the *Australian code of practice for the care and use of animals for scientific purposes* and, if applicable, relevant state or territory legislation.