



File: 99/3287

August, 2002

QUARANTINE REQUIREMENTS FOR THE IMPORTATION OF LIVE LABORATORY RATS AND MICE AND THEIR REPRODUCTIVE MATERIAL

1 GENERAL

- 1.1 These requirements apply to the importation of *Rattus rattus* (black rat), *R. norvegicus* (brown rat) and *Mus musculus* (house mouse) and genetic material derived from these species. Genetic material means embryos, ova, and semen.
- 1.2 Laboratory rats and mice or their reproductive material may be imported from countries approved by the Australian Quarantine and Inspection Service (AQIS). AQIS will consider applications to import from a country, subject to an evaluation and acceptance of the Veterinary Administration's ability to provide health certification for laboratory rats and mice according to the principles of the International Animal Health Code of the Office International des Epizooties (OIE).
- 1.3 These conditions apply only to laboratory rats and mice bred and housed for their lifetime in an institution under the supervision of an animal care and use committee (or similar body accepted by AQIS as being equivalent to an Australian "Animal Ethics Committee").
- 1.4 Under the Environment Protection & Biodiversity Conservation Act 1999, permission to import any live animal, other than those exempted under that Act, must be obtained from Environment Australia. *Rattus rattus* (black rat), *R. norvegicus* (brown rat) and *Mus musculus* (house mouse) are exempted. Other species may not be exempted. Further information may be obtained from:

The Director
Wildlife Protection
Environment Australia
GPO Box 787
Canberra ACT 2601
Australia
Ph (02) 6274 2291 Fax (02) 6274 1921
E-mail wps@ea.gov.au
<<http://www.ea.gov.au>>

- 1.5 The importation of genetically modified laboratory animals is subject to guidelines published by the Office of the Gene Technology Regulator (OGTR) which can be contacted through:

Office of the Gene Technology Regulator (MDP 54)
PO Box 100
Woden ACT 2606
Australia

Email ogtr@health.gov.au
<<http://www.health.gov.au/ogtr/index.htm>>

- 1.6 A valid Permit to Import Quarantine Material into Australia, obtained from the Australian Quarantine and Inspection Service (AQIS) office in the State of import, must accompany each consignment. A processing fee will be charged for the permit. The exporter must ship the consignment to the Australian importer care of AQIS in the State of import.
- 1.7 Each consignment must be accompanied by an **Animal Health Certificate** signed by the Official Veterinarian and the veterinarian in charge of the donor colony. An Official Veterinarian is a veterinarian authorised by the Veterinary Administration of the country to certify on behalf of that administration in conformity with the provisions of the OIE Animal Health Code. Each page of the Health Certificate should bear an Official stamp.
- 1.8 The Animal Health Certificate must:
 - provide details of the certifying authority, identification of the animals, place of origin of the animals, consignor and consignee, destination and means of transport;
 - in the case of reproductive material, provide the dates on which the material was collected;
 - contain the certification statements listed in Section 2 below.
- 1.9 The Animal Health Certificate must be received by the AQIS officer in charge at the port of entry prior to shipment of the animals/genetic material.
- 1.10 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.
- 1.11 The importer or agent must nominate a person who will be accessible to AQIS officers and who will accept responsibility for ensuring that all import requirements are met.
- 1.12 Fees may be applied by AQIS to cover costs associated with inspection, collection, testing, processing, or quarantine and any Australian Government veterinary supervision of the consignment.
- 1.13 Nothing in these conditions prevents importers from specifying their own disease-freedom or testing requirements, as part of a commercial contract.

2 CERTIFICATION

The following certification statements must be provided on the Animal Health Certificate.

The term "date of collection/export" in these conditions means the date on which live animals were transported to the point of export or, in the case of reproductive material, the date on which the material was collected.

The term "colony" refers to the entire group of animals which are in contact. The members of the group may be in different cages within the same room provided they share airspace, handlers and equipment and there is no air filter or any similar physical barrier between.

- 2.1 Housing: The colony of origin of the animals for export or colony of origin of the donors is housed in accommodation which precludes access by wildlife, including rodents and insect vectors, and is free of infestation with ectoparasites.
- 2.2 History: There has been no clinical or other evidence of the following diseases or infectious agents in the colony of origin during the 12 months prior to the date of collection/export:
 - hantaviruses
 - ectromelia virus
 - rabies
- 2.3 In the case of embryos or ova, the collection and processing was in accordance with Appendix 3.3.5. of the OIE Animal Health Code "Laboratory rodent and rabbit embryos/ova".
- 2.4 Pre-export isolation: In the 30 days prior to the date of collection/export, the animals to be exported or donors of genetic material and the animals in contact with them have remained isolated and have remained clinically healthy and free from evidence of the diseases listed in clause 2.2. There have been no new introductions of animals later than 30 days prior to the last sampling up to the time of export or collection of genetic material.
- 2.5 Pre-export testing: The colony containing the animals for export or donors has been sampled within the 6 months prior to collection/export as follows:
 - Hantaviruses: The colony has been regularly tested for hantaviruses at intervals not exceeding 6 months; and, within the 6 months prior to the date of collection/export, has been sampled and tested by ELISA using a sample size sufficient to give a 99% confidence that less than 25% of the animals have demonstrable antibodies to the agent (see Annex);
 - Ectromelia virus (mice only): The colony has been tested by ELISA using a sample size sufficient to give a 99% confidence that less than 5% of the animals have demonstrable antibodies to the agent (see Annex).

If alternative tests are proposed, these must be approved by AQIS beforehand. (See clause 1.9 above).

Animals must be at least 8 weeks of age at the time of testing. A report containing the test methods, the name of the testing laboratory, and numbers of animals tested must be attached to the certification. Test methods other than those mentioned may be used with prior approval from AQIS.

If it is not possible to test the colony of origin prior to export, they may be tested in post arrival quarantine at an AQIS-approved premise as described in section 5 below.

- 2.6 Testing using sentinels: Where immunocompromised animals are involved or animals are otherwise unsuited to be tested directly, sentinel animals may be used for serology. Sentinels must be of the same species, 8-12 weeks of age, and must be in the boxes with the imported animals or in contact in a manner acceptable to AQIS. They must remain there for a minimum of 45 days but not more than 120 days prior to testing for the diseases listed above. The number of sentinels to be placed in contact with the colony is calculated from the number of animals in the original colony to give the required sampling rate (see Annex). A few additional animals should be added to the colony to allow for incidental losses.
- 2.7 Collection of reproductive material: Whenever milk, egg yolk or any other animal protein is used in preparing the material, the product must be free of pathogens or suitably treated: milk must be heat-treated at minimum 92°C for 3 minutes, eggs must be from SPF flocks free of Newcastle disease, avian influenza, and infectious bursal disease. Any bovine serum albumin used must be derived from countries recognised as free or provisionally free of BSE in accordance with the definition in the OIE Animal Health Code.

Liquid nitrogen must be fresh and reproductive material must be stored in sterilised containers in which no biological material, other than material of equivalent health status, is held.
- 2.8 Pre-export examination: In the case of live animals, each animal for export has been examined by the veterinarian in charge of the donor colony within the 48 hours prior to loading and is free from evidence of infectious and contagious disease and ectoparasites. In the case of genetic material, at the time of collection of genetic material, the donors were clinically healthy.

3 TRANSPORT

- 3.1 Animals or reproductive material should be transported in a container as specified under International Air Transport Association (IATA), Live Animal Regulations.
- 3.2 Containers of reproductive material must be sealed in a tamper proof manner using either official seals or seals supplied by the source institution.

4 POST-ARRIVAL PROCEDURES

- 4.1 On arrival, all litter in the containers must be destroyed under the direction of an AQIS officer. The materials should be disposed of at the receiving facility.
- 4.2 The imported rats, mice or genetic material must be imported into premises which are under the supervision of an "Animal Ethics Committee".

5 POST-ARRIVAL QUARANTINE AND RELEASE FROM QUARANTINE

- 5.1 If pre-export testing as stipulated in clauses 2.5 or 2.6 above has not been undertaken for any reason, the rats and mice or the genetic material must be imported into quarantine premises (Section 46A of the Quarantine Act 1908) approved and registered for that purpose by AQIS and with procedures for biosecurity and disease reporting which are approved by AQIS.
- 5.2 Within approved quarantine premises, imported animals must be kept physically separated from all other animals. Different consignments of imported animals may be kept separate from each other by microisolators, which must be of a level of individual security acceptable to AQIS. Any animals introduced into the quarantine room for breeding or for use as sentinels will also remain in quarantine until the imported animals are released from quarantine.
- 5.3 If, while in post arrival quarantine, any imported animal or in-contact animal is diagnosed as, or suspected to be, affected by disease due to infection with a hantavirus, ectromelia virus, or rabies, the manager of the import facility must notify AQIS immediately.
- 5.4 Imported animals, animals derived from imported genetic material and the progeny of either, will be released from quarantine only if they have been tested in a manner equivalent to the pre-export testing described in clauses 2.5 and 2.6 above. This testing must be applied to recipients of genetic material as well as any progeny if any, and should be conducted within 3 months of importation.
- 5.5 The animals may be released from quarantine only into premises, which are under the supervision of an "Animal Ethics Committee".

6 REVIEW

- 6.1 These conditions may be reviewed at any time with the approval of the Director of Quarantine.

David Banks
General Manager
Animal Biosecurity

Sample size required for detecting disease with 99% confidence

Table 1: Minimum number of animals required to give a 99% confidence of detecting disease if it is present at 25% prevalence or 5% prevalence.

Population size	Number of animals to be sampled to detect 25% prevalence	Number of animals to be sampled to detect 5% prevalence
10	10	10
15	10	15
20	11	20
40	13	36
60	14	46
80	15	54
100	15	59
150	16	68
200	16	73
∞	16	90

Source: Cannon RM and Roe RT (1982) Livestock disease surveys - a field manual for veterinarians. Australian Government Publishing Service, Canberra.