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Department of
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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 premises that are recognised by AQIS as bona fide scientific premises, usually as evidenced by the existence of an "Animal Ethics Committee" or equivalent arrangement within the organisation.

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 (see Annex 2 below) 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 A copy of the Animal Health Certificate must be received (by fax is acceptable) 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 such as those 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 that 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 that 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: For a minimum of 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 by means of micro isolators or other similar biologically secure means. During this period and up to the time of export, there were no new introductions to the isolation unit and the animals remained clinically healthy and free from evidence of the diseases listed in clause 2.2.

2.5 Pre-export testing: The source colony of the animals for export or donors has been regularly tested for hantaviruses at intervals not exceeding 6 months.

Within the 6 months prior to the date of collection/export, the colony 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 1 below).

There were no new introductions of animals from untested colonies in the period between the most recent sampling and the time of isolation for export or collection of genetic material.

If alternative tests are proposed, these must be approved by AQIS beforehand. (Note 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 a minimum of 92°C for 3 minutes, eggs must be from specified pathogen free (SPF) flocks free of Newcastle disease, avian influenza, and infectious bursal disease. Any bovine serum albumin used must be derived from countries recognised by Australia as free or provisionally free of bovine spongiform encephalopathy (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 examined by the veterinarian in charge of the colony and found to be clinically healthy.

3 TRANSPORT

3.1 Animals or reproductive material should be transported in a container as specified under the 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 in a manner acceptable to AQIS.

4.2 The imported rats, mice or genetic material must be imported into premises which are recognised by AQIS as *bona fide* scientific premises, usually as evidenced by the existence of an "Animal Ethics Committee" or equivalent arrangement within the organisation.

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 separate from all other animals. Different consignments of imported animals may be kept separate from each other by micro isolators, 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 infected with 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 or 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 that are recognised by AQIS as *bona fide* scientific premises, usually as evidenced by the existence of an "Animal Ethics Committee" or equivalent arrangement within the organisation.

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

Annex 1

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.

Population size	Number of animals to be sampled to detect 25% prevalence
10	10
15	10
20	11
40	13
60	14
80	15
100	15
150	16
200	16
∞	16

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

Annex 2

Model Animal Health Certificate for the EXPORT OF LIVE LABORATORY RODENTS AND GENETIC MATERIAL TO AUSTRALIA [1]

Exporting Animal Facility:	Name of Importer:
Address of Exporting Facility:	Address of Importer:
Contact Person:	Species:
AQIS permit number:	Number of animals: Genetic Material: Container seal numbers for genetic material:

CERTIFICATION by veterinarian responsible for the source colony.

I, ... (name) being the veterinarian in charge of the colony from which the animals or embryos were derived certify as follows:

1. The animals for export or the donors of genetic material have been bred and housed for their lifetime in premises that are part of a *bone fide* scientific institution.

2. The colony[2] of origin is housed in accommodation that precludes access by wildlife, including rodents and insect vectors, and is free of infestation with ectoparasites.

3. 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

4. In the 30 days prior to the date of collection/export, the animals to be exported or donors of genetic material and any animals in contact with them have remained isolated by means of micro isolators or other similar biologically secure means from animals not of equivalent health status. During this period there were no new introductions to the isolation unit and the

[1] Each page of this Health Certificate must be signed and bear an Official stamp.

[2] The term "colony" refers to the entire group of animals that 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.

animals remained clinically healthy and free from evidence of the diseases listed in point 3 above.

5. The source colony was tested for hantaviruses during the 6 months prior to the date of collection/export. ……..... (YES/NO).
(*If NO, the animals will be quarantined on arrival in Australia.*)

6. Testing of the source colony (delete as appropriate):
   - Testing was by ELISA (or, if by another method, a copy of the AQIS approval is attached)
   - All results were negative
   - The animals were at least 8 weeks old at the time of testing
   - No animals were introduced to the colony from the time of testing until the date of collection/export
   - The laboratory report is attached.

7. The testing was conducted on colony members or sentinels (delete one)
   - Number of animals in colony……
   - Number tested……
   - Date of introduction of sentinels (if applicable)……
   - Date of sampling……..

8. Embryos/ova in the consignment were collected and processed in accordance with Appendix 3.3.5. of the OIE Animal Health Code "Laboratory rodent and rabbit embryos/ova".

9. Reproductive material was processed using only products which met the following minimum standards:
   - milk: heat-treated at 92°C or above for at least 3 minutes
   - eggs: from SPF flocks free of Newcastle disease, avian influenza and infectious bursal disease
   - bovine serum albumin: from countries recognised by Australia as free or provisionally free of BSE in accordance with the definition of the OIE animal health code
   - liquid nitrogen: fresh
   - storage and transport containers: sterilised and containing no biological material not of equivalent health status.

10a. Live animals: Within the 48 hours prior to loading, each animal for export was examined by me and was free from evidence of infectious and contagious disease and ectoparasites.

10b. Genetic material: At the time of collection of genetic material, the donors were clinically healthy.

Signature of veterinarian responsible for the source colony:……

CERTIFICATION by official (government employed) veterinarian

I,……(*name*), being an official veterinarian of the ……. (*country of export*) government, hereby certify that:

1. The colony[3] of origin is housed in accommodation that precludes access by wildlife, including rodents and insect vectors, and is free of infestation with ectoparasites.

2. 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

3. The exporting institution is a *bone fide* scientific institution as evidenced by the existence of an Animal Ethics Committee (Animal Care and Use Committee or equivalent).

4. Reproductive material was processed using only products which met the following minimum standards:
   - milk: heat-treated at 92°C or above for at least 3 minutes
   - eggs: from SPF flocks free of Newcastle disease, avian influenza and infectious bursal disease
   - bovine serum albumin: from countries recognised by Australia as free or provisionally free of BSE in accordance with the definition of the OIE animal health code
   - liquid nitrogen: fresh
   - storage and transport containers: sterilised and containing no biological material not of equivalent health status.

[3] The term "colony" refers to the entire group of animals that 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.

5. From my knowledge of the facility and following due enquiry (including examination of the testing history and the laboratory reports here attached), I have no reason to doubt the validity of the statement of …….(*name*), the veterinarian responsible for the exporting facility.

Signature of official veterinarian……

Official Position…….....

Name of Government Authority…….

Address of government authority:

…….

…….

…….

Date……

Official Stamp