



Import Health Standard

Laboratory Animals and
Laboratory Animal Germplasm

LABANIIC.ALL

4 October 2013

Issuing Authority

This standard is issued under section 24A of the Biosecurity Act 1993.

Dated at Wellington this 4th day of October 2013

Howard Pharo
Manager Import and Export Animals
For the Director General
Ministry for Primary Industries
(Under delegated authority)

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Import Health Standard for Laboratory Animals and Laboratory Animal Germplasm

23 December 2013

The following relates to Chief Technical Officer Direction: CTO 2013 094

IMPORTANT INFORMATION FOR IMPORTERS

Jackson Laboratory, United States of America – the following equivalent Veterinary Certificate should be used for importing laboratory animals from Jackson Laboratory under this import health standard:

[New Zealand Certificate for Jackson Laboratory](#)  (98 KB)

Part A: Introduction

Background

1. This document, issued under section 24A of the Biosecurity Act 1993, is the import health standard (IHS) for the importation into New Zealand of animals and germplasm for laboratory purposes.

Scope

2. This standard specifies the requirements that must be met to import, into New Zealand, animals and germplasm for laboratory purposes.

Importer's responsibilities

3. It is the responsibility of the importer to ensure that the consignment is accompanied by a permit to export, if required, in accordance with the legislation of the country of origin and the Convention on the International Trade in Endangered Species (CITES) <http://www.cites.org>. The importer is advised to clarify the status of the species of animal in relation to international agreements on their trade prior to export. Material arriving in New Zealand without the correct CITES certification may be subject to seizure by the New Zealand Department of Conservation. [Note: Any requirement for CITES or other conservation-related documentation must be met by the exporter/importer and is independent of this certification.]
4. The importer must obtain a permit to import prior to proceeding with importation.

5. The importer must notify the date, expected time, port of arrival and the flight number to MPI at the airport of entry at least 72 hours in advance of each consignment being imported.

Definitions

| Import Health Standard Term | Definition |
|--|--|
| Animals for laboratory purposes | A group of animals used in laboratories for research, sourced from colonies maintained for scientific purpose. Species commonly imported into New Zealand are mice, rats, guinea pigs, rabbits and zebrafish (<i>Danio rerio</i>). |
| Colony | The entire group of animals that is in direct or indirect contact (includes uncontrolled airspace, handlers and equipment) with the animals to be exported, or donors of the reproductive material to be exported. |
| Competent Authority | The Veterinary Authority or other governmental authority of an OIE member having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations in the OIE Code in the whole territory. |
| Germplasm | Ova, semen or embryos collected from animals that are eligible for importation under this import health standard. |
| IATA | The International Air Transport Association. |
| New organism | The full definition is as defined in the Hazardous Substances and New Organism Act. For the purposes of this import standard, a new organism is one that is not present in New Zealand apart from in containment. |
| Official Veterinarian | A veterinarian authorised by the Veterinary Administration of the country to perform certain designated official tasks associated with animal health and/or public health and inspections of commodities and, when appropriate, to certify in conformity with the provisions of the Section 5.2 of the OIE Terrestrial Code pertaining to principles of certification. |
| OIE | World Organisation for Animal Health. |
| OIE Code | The World Organisation for Animal Health (OIE) <i>Manual of Diagnostic Tests and Vaccines for Terrestrial Animals</i> (the <i>Manual</i>), available at the OIE website: Terrestrial Manual Online Access - OIE - World Organisation for Animal Health |
| Restricted organism | Any organism for which a containment approval has been granted under the Hazardous Substances and New Organism Act. |

Part B: General Requirements

Eligibility

6. Only laboratory animals and laboratory animal germplasm from colonies maintained for scientific use under veterinary supervision may be imported.
7. The animals and donor animals of germplasm and the colony must have been free of quarantine restrictions for at least 90 days prior to the date of export.
8. Species commonly imported are rats, mice, rabbits, guinea pigs and zebrafish (*Danio rerio*). Other species may be considered under the Equivalence section of this standard.

Permit to Import

9. A permit to import is required prior to the importation of animals and germplasm for laboratory purposes into New Zealand.

An application form for a permit to import can be obtained from the MPI website:
<https://www.mpi.govt.nz/dmsdocument/3137-Permit-to-Import-Semen-or-Embryos>

Email the completed form to: animal.imports@mpi.govt.nz

10. The importer must supply the following information:
 - name and address of importer;
 - name and address of exporter/s;
 - breed/strain/type or description of the animals/germplasm;
 - name and address of the containment facility in New Zealand to which the consignment/s is to proceed following importation;
 - if the animal is a new organism, evidence to show that approval has been given by the Environmental Protection Authority for the organism to be held in containment, and the containment controls that apply.
11. The permit to import may be issued for multiple consignments for a period of up to 6 months.

Documentation accompanying the consignment

12. Documentation presented in accordance with the requirements of this import health standard must be original (unless otherwise specified), in English, and clearly legible. Inadequate documentation may result in delays in obtaining biosecurity authorisation or rejection of the consignment.
13. The consignment must be accompanied by:
 - a signed copy of the permit to import; AND

- veterinary certification that meets the requirements of Part C. Specified Requirements.
14. The Official Veterinarian of the exporting country must sign, date and stamp each page of the veterinary certificate and any documents that form part of the extended certificate.

Transport

15. Animals must be transported in a container that meets the standards prescribed in the International Air Transport Association (IATA) Live Animal Regulations.
16. The importer must notify biosecurity inspectors at the airport of arrival at least 72 hours before the expected time of arrival of the animals/germplasm, flight number and arrival time. Contact details can be found at the following MPI website:
[Steps to importing laboratory animals | Import | NZ Government \(mpi.govt.nz\)](http://mpi.govt.nz/steps-to-importing-laboratory-animals)

Biosecurity authorisation

17. On arrival of the consignment in New Zealand, an MPI biosecurity inspector must inspect the documentation accompanying the consignment.
- 17.1 Germplasm: The biosecurity inspector is not required to open the shipping container at the port of arrival. Contents of the shipment must be inspected by the biosecurity inspector in the containment facility at the time the seal is broken on the shipper.
- 17.2 Live animals: The transport box containing the animals must not be opened at the port of arrival unless for animal welfare reasons.
18. The biosecurity inspector will authorise movement of the consignment to the facility named in the permit to import approved to the MPI Standard 154.03.03 [Containment Facilities for Vertebrate Laboratory Animals](#).
19. If documentation is not compliant, the facility operator must forward the correct paperwork to the biosecurity inspector at the port of first arrival as soon as possible, and if the correct paperwork is not confirmed the consignment may be reshipped or destroyed.

Post arrival quarantine

20. On arrival at the facility the animals or germplasm must be moved to a quarantine area in the containment facility. The quarantine requirements for laboratory animals and germplasm are detailed in Appendix 1 of this IHS.

Containment facility

21. On successful completion of all terms of this IHS, a biosecurity inspector may give the consignment clearance pursuant to section 26 of the Biosecurity Act 1993.
22. Restricted organisms will not be given biosecurity clearance. On authorisation from the biosecurity inspector, they may be moved from quarantine but must remain in the containment facility.

Incorporation of material by reference

23. The following international standards are incorporated by reference in this import health standard under section 142M of the Biosecurity Act:
 - The International Air Transport Association (IATA) Live Animals Regulations (LAR): a copy is available for reading free of charge at MPI, Pastoral House, 25 The Terrace, Wellington.
 - The OIE Code is available on the OIE website free of charge: [Terrestrial Manual Online Access - OIE - World Organisation for Animal Health](#)
 - All Ministry for Primary Industries (MPI) standards are available on the MPI website free of charge: [All import health standards | NZ Government \(mpi.govt.nz\)](#)
24. Under section 142O (3) of the Biosecurity Act it is declared that section 142O(1) does not apply; that is, a notice under section 142O(2) of the Biosecurity Act is not required to be published before material that amends or replaces the above listed standards has legal effect as part of these documents.

Equivalence

25. This IHS has been agreed as suitable for trade between New Zealand and the exporting countries. It is expected that the consignment will meet the requirements of this IHS in every respect.
26. The requirements for laboratory animals and laboratory animal germplasm are met if, in the opinion of the Director-General, the measures taken for managing the risks associated with the importation are equally effective at managing those risks as the requirements specified in this standard. If an equivalence measure(s) is approved MPI will issue a permit to import (under Section 24 (D)(2) of the Biosecurity Act).

Part C: Specified Requirements

The animals and germplasm for laboratory purposes must be accompanied by:

1. An original certificate identifying the animals and germplasm in the consignment, including number, and species/breed/strain/type, consistent with the permit to import.

2. A declaration from the director or supervising veterinarian of the institute of origin named in the permit to import, stating that:
 - (i) the premises of origin of the animals/donor animals are under veterinary supervision, the health of the animal(s) is monitored so that disease incursions are identified, and control and/or eradication measures are applied. For all animals other than fish, a health monitoring programme should include microbiological and parasitological tests and necropsies;
 - (ii) the animals/donor animals were born in the institution and have not been in contact with any diseased animals, and at the time of export/germplasm collection the animals/donor animals were clinically healthy, including free of ectoparasites;
 - (iii) the primary containers for importation were appropriately cleaned and disinfected prior to use;
 - (iv) in addition, for rodent/rabbit embryos, ova and semen:
 - a. collection and processing was in accordance with the OIE Code chapter for *Collection and processing of laboratory rodent and rabbit embryos/ova*;
 - b. germplasm was identified and stored since collection only with material of equivalent health status, and under supervision of the facility veterinarian;
 - c. the germplasm was placed in new or disinfected transport containers. For frozen material the containers were filled with fresh (previously unused) liquid nitrogen;
 - d. the facility veterinarian or senior officer sealed the transport container with an official seal prior to shipment, and the number of the seal was recorded on the veterinary certificate.
3. A certificate from an Official Veterinarian of the country of origin certifying that after due enquiry he/she is satisfied that the animals/donor animals/germplasm has not been in contact with any animal or germplasm carrying infectious diseases, other than pathogens screened by the exporting facility and acceptable to the importer and MPI.

NOTE: The Model Veterinary Certificate below includes all the Specified Requirements.

Model Veterinary Certificate

COUNTRY: X

| | | | |
|--------------------------------|--|--|--|
| PART I: Details of consignment | Exporting animal facility: | Name of importer: | Official Stamp: veterinary signature: |
| | Certificate reference number: | MPI permit number: | |
| | Address and email contact of exporting facility: | Address of importer: | |
| | Port of embarkation country of origin: | Port of arrival New Zealand: | |
| | Contact person in exporting facility: | Contact person in New Zealand: | |
| | Identification of animals: Total number of animals, total number of units (boxes or cages): Species and breed/type/strain: | Description/amount of germplasm: Germplasm species/breed/type/strain: Container seal numbers for genetic material: | |

I,, the director, manager or veterinarian responsible for the exporting facility of the above laboratory animals or germplasm certify as follows:

1. The animals/donor animals were born in the named institution, from colonies maintained for scientific use and under veterinary supervision, where the health of the animals is monitored so that incursions of disease are identified, and control and/or eradication measures can be applied. Other than for fish, the health monitoring programme includes microbiological and parasitological tests and necropsies.
2. The animals/donor animals have not been in contact with any diseased animals, and at the time of export/germplasm collection, the animals/donor animals were clinically healthy, including free of ectoparasites.
3. The primary containers for importation were appropriately cleaned and disinfected prior to use.
4. In addition, for mammalian embryos, ova and semen:
 - a. Collection and processing was in accordance with the OIE Animal Health Code *Collection and processing of laboratory rodent and rabbit embryos/ova*;
 - b. The germplasm was identified and stored since collection only with material of equivalent health status, and under supervision of the facility veterinarian;
 - c. The germplasm was placed in new or disinfected transport containers. For frozen material the containers were filled with fresh (previously unused) liquid nitrogen;
 - d. The facility veterinarian or senior officer sealed the transport container with an official seal prior to shipment, and the number of the seal was recorded on the veterinary certificate.

Name and position of director, manager or veterinarian responsible for facility:

Address:

Contact details:

Official declaration

I,, an Official Veterinarian of the country of origin, certify that after due enquiry I am satisfied that the animals/donor animals of germplasm have not been in contact with any animal with an infectious disease, other than pathogens screened by the exporting facility and acceptable to the importer and MPI.

Signature of Official Veterinarian:

Address and email contact:

Official stamp:

Appendix 1: Post Arrival Quarantine of Laboratory Animals and Laboratory Animal Germplasm

1. The imported animals, their progeny born in the quarantine period, progeny born directly from imported germplasm transfer, and any animals introduced to the quarantine area must remain in an MPI-approved quarantine area in the containment facility for no less than 30 days or for a longer period if required by the biosecurity inspector.
2. Full records must be kept of:
 - all morbidity and mortality during the quarantine period
 - any treatments given during the quarantine period
 - movement of animals into, during and out of the quarantine area.

These records must be reviewed by the biosecurity inspector prior to the animals being transferred from quarantine into containment, or clearance.

3. Quarantine must operate as all-in/all-out, with the quarantine period for all animals starting from the day that the last animal enters, unless MPI-approved measures are used to separate animals in the quarantine area.
4. Material imported with the animals (cages and bedding, shipping containers, water and packaging that has been in contact with water from imported fish or embryos) must be treated or destroyed as biosecurity waste if released prior to the end of quarantine. At the end of the quarantine period, if the biosecurity inspector has not raised any biosecurity concerns, cleaning and waste disposal do not need to follow biosecurity methods.
5. For laboratory fish and fish embryos, effluent water during the quarantine period must be treated to kill any biological agents present by EITHER:

5.1 Chlorination:

- All water must pass through a filter capable of removing suspended organic material prior to chlorination;
- Chlorine compound must be added to the effluent to achieve a minimum concentration of free residual chlorine of 200 ppm (200 mg per litre) at 1 hour post treatment;
- Before the treatment period commences, the chlorinated effluent must be brought to a pH between 5.0 and 7.0;
- Sodium hypochlorite (bleach) may be used at 1.6 millilitres of hypochlorite solution (12.5% available chlorine) per litre of water; calcium hypochlorite powder (eg Pool Chlor, 65-70% available chlorine) may be used at 0.3 gram of powder per litre of water;
- The tank must be agitated for a period of not less than 10 minutes to ensure thorough mixing of hypochlorite, and the hypochlorite retained for a period of not less than 1 hour;
- Tanks not achieving this free residual chlorine level at the allotted time must be re-treated until the requirement is met;

- The chlorine in the wastewater may be neutralised by adding sodium thiosulphate at a rate of 1.25 grams (2.5 ml of 50% sodium thiosulphate solution) per litre of treated wastewater, then agitated for not less than 10 minutes before discharge;
- Chlorination records must be maintained noting the:
 - amount of compound added
 - volume of effluent
 - time that the treatment period commenced
 - pH at the commencement of the treatment period.

OR

5.2 Ultraviolet (UV) light irradiation:

- All water to be treated must pass through a filter capable of removing suspended organic material and, where necessary, other filtration to ensure that the UV transmittance of the water is within manufacturer's specifications prior to irradiation;
 - Commercial UV water treatment units operating in the spectral range of 190-280 nm (254 nm recommended) delivering doses of at least 130 mW/cm² are required. The dose is calculated as the product of the intensity (mW/cm²) and the exposure time in seconds (s). Servicing and maintenance must be done at least as frequently as required by the manufacturer of the UV sterilisation system. The bulbs must be monitored regularly to ensure they are working.
6. While in the quarantine area, the animals may be subjected to such testing, treatments or procedures required by MPI as are reasonably necessary to determine the health status of the consignment.
 7. All imported germplasm must remain in an MPI-approved quarantine area in the facility. Waste associated with germplasm manipulations must be destroyed as biosecurity waste or sterilised (autoclaved 121°C for 15 mins or 134°C for 3 mins).
 8. The facility operator must notify the MPI Chief Technical Officer or their delegate when imported germplasm is transferred into a recipient animal. The recipient animal must remain in an MPI-approved quarantine area during the transfer and pregnancy. Any resultant progeny must undergo quarantine for no less than 30 days or for a longer period if required by the Chief Technical Officer.