

IMPORT HEALTH STANDARD FOR MICROORGANISMS FROM ALL COUNTRIES

This standard is issued pursuant to Section 22 of the Biosecurity Act 1993

Dated: 28 July 2009

The information in this import health standard is in four parts:

Part A. GENERAL INFORMATION describes the legal basis for this import health standard and your general responsibilities as an importer.

Part B. IMPORTATION PROCEDURE outlines whether a permit to import is required, the conditions of eligibility, and documentation that may need to accompany your consignment.

Part C. CLEARANCE PROCEDURE describes the clearance requirements at the New Zealand border and, if necessary, whether the consignment must go to a transitional facility or containment facility.

Part D. IDENTITY CERTIFICATION contains model certification of identity and culture purity which may be required to accompany the application for a permit to import.

PART A. GENERAL INFORMATION

1 IMPORT HEALTH STANDARD

- 1.1 Pursuant to section 22 of the Biosecurity Act 1993, this document is the import health standard for the importation of microorganisms from all countries.
- 1.2 To be eligible for biosecurity direction or biosecurity clearance, the consignment must meet the requirements of this import health standard.

2 IMPORTER'S RESPONSIBILITIES

- 2.1 It is the responsibility of the importer or agent to ensure that they are compliant with the current relevant import health standard at the time of importation. Current versions of import health standards are available online at:
<http://www.biosecurity.govt.nz/ihs/search>

A register of import health standards is also publicly available for inspection at the office of the Director-General of the Ministry of Agriculture and Forestry, Pastoral House, 25 The Terrace, Wellington, New Zealand.

- 2.2 The costs to MAFBNZ in performing functions relating to the importation of microorganisms must be recovered in accordance with the Biosecurity Act and any

regulations made under that Act. All costs involved with documentation, transport, storage and obtaining biosecurity clearance or biosecurity direction must be covered by the importer or agent

3 DEFINITIONS

biosecurity clearance

A clearance under section 26 of the Biosecurity Act 1993 for the entry of goods into New Zealand. (Explanatory Note: Goods given a Biosecurity Clearance by an Inspector may be released to the importer without restriction).

biosecurity direction

Written authority from an Inspector, given under section 25 of the Biosecurity Act 1993, to move uncleared goods from a transitional facility, containment facility or biosecurity control area to another transitional facility, containment facility or biosecurity control area, or to export those goods from New Zealand.

Chief Technical Officer

A person appointed a chief technical officer under section 101 of the Biosecurity Act 1993

consignment

Unaccompanied goods being moved from one country to another covered by a consignment note or waybill

containment facility

A place approved in accordance with section 39 of the Biosecurity Act 1993, for holding organisms that should not, whether for the time being or ever, become established in New Zealand

equivalence

Acceptance by MAF that the health status of the consignment is equivalent to the health status of a consignment that complies with the requirements of the import health standard

ERMA

Environmental Risk Management Authority

HSNO

Hazardous Substances and New Organisms Act 1996

Inspector

A person appointed under section 103 of the Biosecurity Act 1993 to undertake administering and enforcing the provisions of the Biosecurity Act (Explanatory Note: An Inspector is appointed to undertake administering and enforcing the provisions of the Biosecurity Act and controls imposed under the Hazardous Substances and New Organism Act 1996).

Institutional Biosafety Committee (IBSC)

Committees with delegated authority from ERMA New Zealand, under sections 19, 40 and 42 of the HSNO Act 1996, to assess applications for the:

- (a) development of low-risk genetically modified organisms in containment, and
- (b) importation of low-risk genetically modified organisms into containment.

MAFBNZ

Ministry of Agriculture and Forestry Biosecurity New Zealand

microorganism

A microscopic organism including protozoa, fungi, bacteria, viruses and unicellular algae

new organism

A new organism is defined in section 2 of the HSNO Act 1996 as:

- (a) an organism belonging to a species that was not present in New Zealand immediately before 29 July 1998:
- (b) an organism belonging to a species, subspecies, infrasubspecies, variety, strain, or cultivar prescribed as a risk species, where that organism was not present in New Zealand at the time of promulgation of the relevant regulation:
- (c) an organism for which a containment approval has been given under this Act:
 - (ca) an organism for which a conditional release approval has been given:
 - (cb) a qualifying organism approved for release with controls:
 - (d) a genetically modified organism:
 - (e) an organism that belongs to a species, subspecies, infrasubspecies, variety, strain, or cultivar that has been eradicated from New Zealand.

permit to import (import permit)

a written order issued by the Director General of MAF authorising the importation of risk goods to a specified facility

transitional facility

Means (a) any place approved as a transitional facility in accordance with section 39 [of the Biosecurity Act 1993] for the purpose of inspection, testing, storage, treatment, holding or destruction of uncleared goods; or (b) a part of a port declared to be a transitional facility in accordance with section 39 [of the Biosecurity Act 1993]

unwanted organism

Any organism that a chief technical officer believes is capable or potentially capable of causing unwanted harm to any natural and physical resources or human health (Biosecurity Act 1993). For further reference please use the link below to view our website and the unwanted organisms register: <http://www.biosecurity.govt.nz/pests/registers/uor>

4 EQUIVALENCE

- 4.1 The import health standard has been agreed as suitable for trade between the exporting and the importing countries. It is expected that the consignment will meet the conditions in every respect.

4.2 Occasionally it may be found that, due to circumstances beyond the control of the importer or exporter, a consignment does not comply with the specific requirements in this import health standard, but may meet the outcomes sought. In such cases, a permit to import application may be made, an equivalence granted and import permit issued at the discretion of MAF Biosecurity New Zealand. The following information must be forwarded by the certifying government's veterinary authority for an equivalence to be considered:

- which clause/s of the import health standard cannot be met and how this has occurred;
- the reason the consignment is considered to be of an "equivalent health" status;
- the reasons why the veterinary authority of the country of origin believe this proposal should be acceptable to the New Zealand Ministry of Agriculture and Forestry and their recommendation for its acceptance.

PART B - IMPORTATION PROCEDURE

5 PERMIT TO IMPORT

5.1 A permit to import is required for all microorganisms imported under this standard and must be issued prior to importation. A permit to import can include multiple microorganisms.

5.2 An application form to apply for a permit to import can be obtained from our website: <http://www.biosecurity.govt.nz/forms/imports-biologicals-microorganisms>

5.3 Application for a permit to import must be made in writing to:

Animal Imports
Border Standards
MAF Biosecurity New Zealand
Ministry of Agriculture and Forestry
PO Box 2526
Wellington
New Zealand

Phone: 0800 008333
Fax: +64 4 894 0733
Email: animalimports@maf.govt.nz

5.4 An application for a permit to import must provide the following information for each

microorganism listed:

- **Importer and Exporter:**
 - name and address of importer, the name of the importer should be an individual
 - name and address of the end user if different from the importer
 - country of origin and name and address of exporter (if known), and
 - name and address of the transitional or containment facility to which the consignment is to proceed (if the microorganism is eligible for biosecurity clearance then it will not be directed by MAFBNZ to either type of facility).

- **Microorganism Description:**
 - latin binomial (incl. taxonomic authority),
 - common name,
 - type of microorganism (e.g. bacterium, virus, fungus),
 - strains and genotype, if relevant,
 - intended use of microorganism,
 - unwanted organisms status – yes or no (see section 3 definitions), and,
 - new organism status – yes or no (see section 3 definitions).

To assist risk assessment MAFBNZ may request additional information including a Certificate of Identity and Cultural Purity from the exporter (a model certificate is provided in part D).

- **For unwanted organisms:**
 - chief technical officer approval issued by MAFBNZ, authorising the unwanted organisms to be imported

- **For new organisms:**
 - HSNO Act approval number issued by ERMA or an IBSC, authorising the new organisms to be imported

6. ELIGIBILITY

6.1 This import health standard includes microorganisms that are:

- 6.1.1 new organisms, having HSNO Act approval from ERMA or IBSC;
- 6.1.2 unwanted organisms, having chief technical officer approval, and;
- 6.1.3 microorganisms that are not new or unwanted organisms.

6.3 Microorganisms that are **new** organisms can be given biosecurity direction provided the following requirements are met:

- 6.3.1 The product is accompanied by a permit to import, listing the HSNO approval number.
- 6.3.2 All the conditions on the permit to import are met.
- 6.3.3 All the conditions and purpose of the HSNO Act approval are met.
- 6.3.4 The containment facility listed on the permit to import is approved at the time of import to MAF Regulatory Authority Standard 154.03.02 - *Facilities for Microorganisms and Cell Cultures 2007a* and any subsequent amendments to that standard. This standard is available from our website <http://www.biosecurity.govt.nz/regs/trans/stds>.
- 6.4 Microorganisms (including unwanted organisms) can be given biosecurity direction provided the following requirements are met:
- 6.4.1 The consignment is accompanied by a permit to import.
- 6.4.2 All the conditions on the permit to import are met.
- 6.4.3 The transitional facility listed on the permit to import is approved at the time of import to MAF Regulatory Authority Standard 154.03.02 - *Facilities for Microorganisms and Cell Cultures 2007a* and any subsequent amendments to that standard. This standard is available from our website <http://www.biosecurity.govt.nz/regs/trans/stds>.
- 6.5 Microorganisms assessed by MAFBNZ not to be risk goods, or are assessed to be risk goods with an acceptable level of risk without conditions, can be given biosecurity clearance provided that **all** of the following requirements are met:
- 6.5.1 The consignment is accompanied by a permit to import;
- 6.5.2 All the conditions on the permit to import are met.
- 6.6 Microorganisms assessed by MAFBNZ as presenting unacceptable risks to biosecurity in New Zealand will not be eligible for import.

7. DOCUMENTATION ACCOMPANYING THE CONSIGNMENT

- 7.1 The consignment must be accompanied by appropriately completed original documentation. It is the importer's responsibility to ensure that any documentation is original (unless otherwise specified) and clearly legible. Failure to do so may result in rejection of consignments or delay in obtaining biosecurity clearance and/or biosecurity direction.
- 7.2 Copies of the documentation accompanying a consignment should also be securely

attached to the outside of the package.

- 7.3 Documentation must be in English, but may be bilingual (language of exporting country and English).

8 TRANSPORT OF MICROORGANISMS

- 8.1 It is the importers responsibility to ensure that microorganisms are transported according to the requirements of the International Air Transport Association (IATA) Dangerous Goods Regulations. These are available at <http://www.iata.org/>
- 8.2 The minimum requirement is for products to be packaged according to Packing Instruction No. 650 of the IATA Dangerous Goods Regulations.
- 8.3 Microorganisms that fit the definition of a Category A Infectious Substance, as defined in the IATA Dangerous Goods Regulations, must be packaged according to Packaging Instructions No. 602 of the IATA Dangerous Goods Regulations.
- 8.4 All non-infectious genetically-modified material must be packaged according to Packaging Instructions No. 913 of the IATA Dangerous Goods Regulations.

PART C – BIOSECURITY DIRECTION/CLEARANCE PROCEDURES

9 BIOSECURITY CLEARANCE AND DIRECTION

- 9.1 Upon arrival in New Zealand an Inspector must inspect the documentation accompanying the consignment. The Inspector may also inspect the consignment, or a sample of the consignment.
- 9.2 Microorganisms may be eligible for biosecurity clearance pursuant to section 26 of the Biosecurity Act 1993, or biosecurity direction to move to the facility named in the permit to import pursuant to section 25 of the Biosecurity Act 1993 provided the consignment is accompanied by a permit to import and complies with the conditions of that permit and the conditions of ELIGIBILITY.
- 9.3 The transitional facility or containment facility must be operating according to MAF Regulatory Authority Standard 154.03.02 - *Facilities for Microorganisms and Cell Cultures 2007a* and any subsequent amendments to that standard at the time of import.

PART D - IDENTITY CERTIFICATION

10 CERTIFICATION OF IDENTITY AND CULTURE PURITY

- 10.1 The following model Certificate of Identity and Culture Purity may be required by

MAF to accompany applications for a permit to import microorganisms into New Zealand from all countries.

PROVISIONAL

MODEL CERTIFICATION OF IDENTITY AND CULTURE PURITY

COMMODITY:

ORIGIN OF THE CONSIGNMENT

Name and Address of Institute/Organisation:

.....

Director/Manager:

Country:

MICROORGANISM DESCRIPTION:

Latin Binomial (incl. taxonomic authority):

Common Name:

Type of Microorganism (e.g. bacterium, virus):

Strain/Genotype (if relevant):

IF NEW ORGANISMS:

ERMA/IBSC Decision Code:

CONSIGNMENT INFORMATION

Name and Address of Exporter:

.....

Name and Address of New Zealand Importer:

.....

PURITY OF CULTURE INFORMATION

I , declare responsibility for ensuring, to the best of my ability, that the microorganisms listed on this permit to import application:

- will be imported as pure cultures (containing only one kind of microorganism, without any contaminants), except where the microorganisms are, (a) field collections (containing mixed and/or unidentified microorganisms generally isolated from a particular environment), or (b) part of a recognised quality assurance testing programme (provided that no highly infectious exotic organisms are included), as prescribed in the permit application,
- have been approved for importation by the Environmental Risk Management Authority, if they are new organisms
- will be been packaged according to the International Air Transport Association (IATA) Dangerous Goods Regulations.

Signature of Institute/Organisation/Company Director/Manager:

Date:

AI00-500

MICROIC.ALL