

IMPORT HEALTH STANDARD FOR BIOLOGICAL PRODUCTS 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 the general responsibilities of the importer.

Part B. IMPORTATION PROCEDURE outlines whether a permit to import is required, the conditions of eligibility, and documentation that may need to accompany the 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. MANUFACTURER'S DECLARATION contains a model manufacturer's declaration 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 biological products 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 biological products 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 a biosecurity clearance must be covered by the importer or agent

3 DEFINITIONS

biological product

Non-viable products derived from living organisms

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.

consignment

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

equivalence

Acceptance by MAFBNZ 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

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: Goods given a Biosecurity Clearance by an Inspector are released to the importer without restriction).

MAFBNZ

Ministry of Agriculture and Forestry Biosecurity New Zealand

permit to import (import permit)

A written order issued by the Director-General of MAF authorising the importation of risk goods

risk goods

Any organism, organic material, or other thing, or substance, that (by reason of its nature, origin, or other relevant factors) it is reasonable to suspect constitutes, harbours, or contains an organism that may:

- Cause unwanted harm to natural and physical resources or human health in New Zealand, or
- Interfere with the diagnosis, management, or treatment, in New Zealand, of pests or

unwanted organisms

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]

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, 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 biological products imported under this standard and must be issued prior to importation. A permit to import may include multiple biological products.
- 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 biological product listed:

- Importer and Exporter:
 - name and address of importer, if the importer is not an individual (e.g. a company), the name of an authorised contact person
 - 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 facility to which the consignment is to proceed (if the biological product is eligible for biosecurity clearance then it will not be directed to a transitional facility).
- Biological Product Description:
 - name of the biological products to be imported,
 - description of biological products,
 - intended use of biological products,

To assist risk assessment MAFBNZ may request additional information, including a manufacturer's declaration (a model declaration is provided in Part D).

6 ELIGIBILITY

6.1 Biological products that meet another import health standard need to be imported under that import health standard and are not eligible for import under this standard. For other import health standards please refer to the MAF Biosecurity New Zealand website: <http://www.biosecurity.govt.nz/ihs/search>

6.2 Biological products are eligible for biosecurity clearance provided that **all** of the following requirements are met:

6.2.1 The products are non-viable

6.2.2 The consignment is accompanied by a permit to import

6.2.3 All the conditions on the permit to import are met

6.3 Biological products assessed by MAFBNZ to be risk goods and have an acceptable level of risk for use under specific conditions, can be given biosecurity direction provided the following requirements are met:

6.3.1 The products are non-viable

6.3.2 The consignment is accompanied by a permit to import

6.3.3 All the conditions on the permit to import are met

6.3.4 The transitional facility listed on the permit to import is approved at the time of import to either MAF Regulatory Authority Standard MAF Regulatory Authority Standard:

- 154.02.17 - *Transitional Facilities for Biological Products*; or
 - BNZ-STD-TFGEN - *Standard for General Transitional Facilities for Uncleared Risk Goods - ANNEX G: Holding of Biological Products*.
- and any subsequent amendments to those Standards at the time of import.

These standards are available from our website:

<http://www.biosecurity.govt.nz/regs/trans/stds>.

6.4 Biological products that are 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).

PART C. BIOSECURITY DIRECTION/CLEARANCE PROCEDURES

8 BIOSECURITY CLEARANCE AND DIRECTION

- 8.1 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.
- 8.2 Biological products may be eligible for biosecurity clearance pursuant to section 26 of the Biosecurity Act 1993, or biosecurity direction to move to the transitional 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.
- 8.3 The transitional facility must be operating according to MAF Regulatory Authority Standard:
- 154.02.17 - *Transitional Facilities for Biological Products*; or
 - BNZ-STD-TFGEN - *Standard for General Transitional Facilities for Uncleared Risk Goods - ANNEX G: Holding of Biological Products*.
- and any subsequent amendments to those Standards at the time of import.

PART D. MANUFACTURER'S DECLARATION

9 MANUFACTURER'S DECLARATION

- 9.1 The following model Manufacturer's declaration may be required by MAF Biosecurity New Zealand for a permit to import biological products from all countries.

MODEL MANUFACTURER'S DECLARATION

COMMODITY:

ORIGIN OF THE CONSIGNMENT

Name and Address of Institut/Organisation:

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Director/Manager:

Country:.....

BIOLOGICAL PRODUCT DESCRIPTION:

Source of Biological Product (Latin Binomial incl. taxonomic authority):

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Common Name of Source:

Strain/Genotype (if relevant):

Type of Biological Product:

CONSIGNMENT INFORMATION

Name and Address of Exporter:

.....

Name and Address of New Zealand Importer:.....

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PURITY OF BIOLOGICAL PRODUCT INFORMATION

I , declare responsibility for ensuring, to the best of my ability, that the biological product(s) listed on this permit to import application:

- will be the only biological product(s) imported, and
- will be free from viable microorganisms, except where the biological products are field collections (containing mixed and/or unidentified biological products generally isolated from a particular environment), as prescribed in the permit application.

Signature of Institute/Organisation/Company Director/Manager::.....

Date:

PROVISIONAL