IMPORT HEALTH STANDARD FOR THE IMPORTATION OF BIOLOGICAL PRODUCTS INTO NEW ZEALAND

Draft pursuant to Section 22 of the Biosecurity Act 1993
Dated: 22 June 2006

USER GUIDE

The information in MAF import health standards is presented in numerically ordered sections with descriptive titles. Sections are grouped into one of three alphabetical parts.

Part A - GENERAL INFORMATION
Contains sections of general interest, including those relating to the legal basis for MAF import health standards and the general responsibilities of importers of biological products.

Part B - IMPORTATION PROCEDURE
Contains sections that outline the requirements to be met prior to and during importation.

Part C – BIOSECURITY DIRECTION/CLEARANCE PROCEDURES
Contains sections describing the requirements to be met at the New Zealand border and, if necessary, in a transitional facility in New Zealand prior to any consignment being given biosecurity clearance.

Part D - SANITARY CERTIFICATION
Contains model health certification that may be required and must be completed by the appropriate personnel as indicated. This certification must accompany the consignment to New Zealand.

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 biological products into New Zealand that do not have their own specific import health standard.

1.2 This import health standard is for biological products imported from all countries not covered by another import health standard.

1.3 Obtaining biosecurity direction for a consignment of biological products imported into New Zealand is dependent upon the consignment meeting the requirements of this import health standard.
1.4 This import health standard may be reviewed, amended or revoked if there are changes in New Zealand’s import policy or the animal health status of the originating country, or for any other lawful reason, or as directed by the Manager, Biosecurity Standards Group, Biosecurity New Zealand.

2 IMPORTER'S RESPONSIBILITIES

2.1 The importer must obtain the necessary documentation before proceeding with importation.

2.2 All costs associated with documentation, transport, storage and obtaining a biosecurity direction and/or a biosecurity clearance must be borne by the importer or agent (see Part B: Importation Procedure).

2.3 The costs of MAF in performing functions relating to the importation of biological products must be recovered in accordance with the Biosecurity Act 1993 and any regulations made under that Act.

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

**biosecurity direction**
Direction authorised by an inspector, given under section 25 of the Biosecurity Act 1993, to move uncleared goods to a transitional facility, containment facility or biosecurity control area

**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

**inspector**
A person appointed under section 103 of the Biosecurity Act to undertake administering and enforcing the provisions of the Biosecurity Act

**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:
(a) Cause unwanted harm to natural and physical resources or human health in New
Zealand; or
(b) Interfere with the diagnosis, management, or treatment, in New Zealand, of pests
or unwanted organisms

transitional facility
(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 ACRONYMS
MAF Ministry of Agriculture and Forestry

5 EQUIVALENCE
5.1 If the requirements of this import health standard are not met in every respect, an
application for equivalence, accompanied by supporting information may be submitted
to MAF for consideration.

PART B - IMPORTATION PROCEDURE

6 PERMIT TO IMPORT
6.1 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.

6.2 An application for a permit to import must be made in writing to:

[Animal or Plant] Imports Group
Biosecurity New Zealand
Ministry of Agriculture and Forestry
PO Box 2526
Wellington
NEW ZEALAND
6.3 An application for a permit to import must provide the following information for each biological product listed:

- name and address of importer\(^1\),
- country of origin and name and address of exporter (if known),
- name of the biological products to be imported,
- description of biological products,
- intended use of biological products,
- if appropriate, the name and address of the transitional facility to which the consignment is to proceed following importation.

6.4 The permit may require a Sanitary Certificate for one or more products from the exporter, depending on the outcomes of the risk assessment (section 8). A model certificate is shown in Part D of this standard. For plant biological products a phytosanitary certificate produced in accordance with ISPM 12 may be more appropriate.\(^2\)

7 ELIGIBILITY

7.1 All requirements of this import health standard must be met for biological products to be eligible for importation.

8 ASSESSMENT OF RISK

8.1 Each biological product included in a permit to import application will be assessed for risk based on criteria set by MAF, including that described and outlined in MAF’s risk analysis\(^3\).

8.2 Outcomes of the risk assessment:

8.2.1 General Permit to Import

If the biological product is not a risk good, or a risk good with an acceptable level of risk without conditions, a general permit to import will be issued and the product will be eligible for a biosecurity clearance.

8.2.2 Restricted Permit to Import

If the biological product is a risk good and has an acceptable level of risk for use under specific conditions, a restricted permit to import will be issued with those conditions attached. A Sanitary Certificate will be required. The product will be directed to a

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1 The name of the importer should be an individual and must be specific as to the destination of the biological product.
2 ISPM 12: Guidelines for Phytosanitary Certificates
3 Risk Analysis for the Importation of Non-Viable Biological Products, Microorganisms and Cell Cultures into New Zealand.
transitional facility approved to either MAF Regulatory Authority Standard 154.02.17 - Transitional Facilities for Biological Products or a MAF Standard for the relevant biological product.  

8.2.3 **No Permit to Import**

If the biological product is considered to present an unacceptable risk to biosecurity in New Zealand, the product will not be allowed to be imported.

8.3 If the applicant is not satisfied with the outcome of the risk assessment they can submit an application for the development of an import health standard specific to the biological product of concern, to:

[Animal or Plant] Imports Group  
Biosecurity New Zealand  
Ministry of Agriculture and Forestry  
PO Box 2526  
Wellington  
NEW ZEALAND.

9 **DOCUMENTATION ACCOMPANYING THE CONSIGNMENT**

9.1 The permit to import and the completed Sanitary Certificate (if required) must accompany the consignment.

9.2 Documentation must be in English, but may be bilingual (language of exporting country/English).

9.3 It is the importer’s responsibility to ensure that any documentation presented in accordance with the requirements of this import health standard is original (unless otherwise specified) and clearly legible. Failure to do so may result in delays in obtaining biosecurity direction and/or biosecurity clearance or rejection of consignments.

PART C – BIOSECURITY DIRECTION/CLEARANCE PROCEDURES

10 **BIOSECURITY DIRECTION**

10.1 Upon arrival in New Zealand an inspector must inspect the documentation accompanying the consignment at the port of arrival. The inspector may also inspect the consignment, or a sample of the consignment.

10.2 Provided that the documentation requirements are met, a biosecurity direction must be given by an inspector pursuant to section 25 of the Biosecurity Act 1993 authorising the consignment to move to the transitional facility named in the permit to import,

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1 Or any subsequent amendments to these Standards.
10.3 The transitional facility must be operating according to MAF Regulatory Standard 154.02.17 - Transitional Facilities for Biological Products or a MAF Standard for the relevant biological product¹.

11 BIOSECURITY CLEARANCE

11.1 Provided that the consignment meets the conditions of the general permit to import and the conditions of this import health standard, the consignment may, subject to sections 27 and 28 of the Biosecurity Act 1993, be given a biosecurity clearance pursuant to section 26 of the Biosecurity Act 1993.

¹ Or any subsequent amendments to these standards.
PART D - SANITARY CERTIFICATION

The following model Sanitary Certificate contains the information required by MAF to accompany imports of biological products into New Zealand from all countries.

[MODEL] SANITARY CERTIFICATION

COMMODITY: ...........................................................................................................................................

CERTIFYING AUTHORITY: .........................................................................................................................

Director: ....................................................................................................................................................

Institute of Origin: .....................................................................................................................................

Country: ....................................................................................................................................................

ORIGIN OF THE CONSIGNMENT

Name and Address of Institute: ....................................................................................................................

CONSIGNMENT DESCRIPTION

BIOLOGICAL PRODUCT DESCRIPTION:

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

Common Name of Source: ..........................................................................................................................

Strain/Genotype (if relevant): ......................................................................................................................

Type of Biological Product: ........................................................................................................................

NUMBER OF PACKAGES: ............................................................................................................................

CONSIGNMENT INFORMATION

Name and Address of Exporter: ....................................................................................................................

Name and Address of New Zealand Importer: .............................................................................................
PURITY OF BIOLOGICAL PRODUCT INFORMATION

I ........................................................................................................................................... certify that, to
the best of my knowledge:

▪ the consignment contains only the biological product(s) as described above,

▪ the biological products are free from adventitious 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.

Signature of Institute Director: ........................................................................................................

Date: ....................................................