

# IMPORT HEALTH STANDARD FOR CELL CULTURES 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 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 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 the importation of cell cultures from all countries.
- 1.2 To be eligible for biosecurity direction, 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 cell cultures 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 direction must be covered by the importer or agent

### **3 DEFINITIONS**

#### **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.

#### **cell culture**

Cells derived from tissues grown *in vitro*. These include and generally are cell lines.

#### **cell line**

A population of cells that can be propagated indefinitely *in vitro* derived from a single common ancestor cell.

#### **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 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.

#### **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

### **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 cell cultures imported under this standard and must be issued prior to importation. A permit to import can include multiple cell cultures.
- 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](mailto:animalimports@maf.govt.nz)

- 5.4 An application for a permit to import must provide the following information for each cell culture:
- 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
    - name and address of exporter; and country of origin, and

- name and address of the transitional or containment facility to which the consignment is to proceed.
- Cell Culture Description:
  - Cell line name (eg, 6-23 clone 6)
  - Latin binomial (incl. taxonomic authority) of the organism the cell culture is derived from (eg, *Rattus norvegicus Berkenhout*),
  - Common name of the organism the cell culture is derived from (eg, Rat),
  - Cell type (eg, thyroid),
  - Morphology (eg, epithelial)
  - Intended use of cell culture,
  - 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 manufacturer's declaration from the exporter (a model declaration 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 The following items are NOT eligible for importation under this import health standard:

6.1.1 tissue cultures derived from plants

Note:

Importation of these commodities is covered in MAF Biosecurity New Zealand Standard 155.02.06: Importation of Nursery Stock. This standard is available from our website: <http://www.biosecurity.govt.nz/regs/imports/plants/nursery>

6.2 This import health standard includes cell cultures that are:

6.2.1 derived from **new** organisms, having HSNO Act approval from ERMA or an IBSC to be imported into containment

Note:

For the purpose of this standard, cell cultures that are derived from tissues of new organisms, as defined above, are deemed 'new organisms'.

6.2.2 derived from **not new** organisms (including unwanted organisms).

6.3 Cell cultures (including cell lines) derived from **new** organisms may be eligible for biosecurity direction provided the following requirements are met:

6.3.1 The consignment 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 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 Cell cultures (including cell lines) derived from **not new** organisms (including unwanted organisms), assessed by MAFBNZ to be risk goods may be eligible for 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.

6.6 Cell cultures 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 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 CELL CULTURES**

- 8.1 It is the importers responsibility to ensure that cell cultures 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 cell cultures to be packaged according to Packing Instruction No. 650 of the IATA Dangerous Goods Regulations.
- 8.3 Cell cultures that fit the definition of 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 cell cultures must be packaged according to Packaging Instructions No. 913 of the IATA Dangerous Goods Regulations.

## **PART C – BIOSECURITY DIRECTION PROCEDURE**

### **9 BIOSECURITY 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 Cell cultures (including cell lines) may be eligible for biosecurity direction pursuant to section 25 of the Biosecurity Act 1993 authorising the consignment to move to the facility named in the permit to import, 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 or containment facility have current approval to operate 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. MANUFACTURER'S DECLARATION**

### **10 MANUFACTURER'S DECLARATION**

- 10.1 The following model Manufacturer's declaration may be required by MAF to accompany applications for a permit to import cell cultures into New Zealand from all countries.

PROVISIONAL

# MODEL MANUFACTURER'S DECLARATION

COMMODITY: .....

## ORIGIN OF THE CONSIGNMENT

Name and Address of Institute/Organisation: .....

.....

Director/Manager: .....

Country:.....

## CELL LINE DESCRIPTION:

Cell Culture/Line Name: .....

Latin Binomial (incl. taxonomic authority) of Source Organism: .....

.....

Common Name of Source Organism: .....

Cell Type (eg, human acute myeloid leukaemia):.....

Morphology (eg, epithelial): .....

Intended Use of Cell Culture:.....

.....

## IF NEW ORGANISMS:

ERMA/IBSC Decision Code:.....

## CONSIGNMENT INFORMATION

Name and Address of Exporter: .....

.....

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

.....

**SANITARY INFORMATION**

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

- will be imported as pure cell cultures (without any contaminants),
- have been approved for importation by the Environmental Risk Management Authority, if they are new organisms, and
- will be packaged according to the International Air Transport Association (IATA) Dangerous Goods Regulations.

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

Date: .....

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