

IMPORT HEALTH STANDARD FOR CELL CULTURES FROM ALL COUNTRIES

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

Dated: 31 January 2010

The information in this import health standard is in three 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 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 and grown *in vitro*. These include and generally are cell lines. [Note: Cell cultures derived from humans that have not been genetically modified are exempt from this import health standard and cell cultures derived from plants are not eligible for importation under this import health standard, see section 6.1]

cell line

A population of cells that can be propagated indefinitely *in vitro* and that are 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 Act 1996

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).

IBSC

Institutional Biosafety Committee appointed by ERMA to have 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, or
- (e) an organism that belongs to a species, subspecies, infrasubspecies, variety, strain, or cultivar that has been eradicated from New Zealand.

For the purpose of this standard cell cultures that are derived from tissues of new organisms as defined above are deemed 'new organisms' unless a HSNO Act determination from ERMA is provided stating these cell lines are not new organisms. For advice on new organism status contact ERMA New Zealand (www.ermanz.govt.nz).

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.

risk good

means 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

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 the purpose of this standard cell cultures that are derived from tissues of unwanted organisms are deemed 'unwanted organisms'. For further reference please use the link below to view 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 country and New Zealand. 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 permit to import issued at the discretion of MAFBNZ. The following information must be forwarded by the certifying government's veterinary authority for an equivalence to be considered:

- which requirement/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 MAFBNZ 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 the MAFBNZ website: <http://www.biosecurity.govt.nz/forms/imports-biologicals-microorganisms>;

5.3 The following information must be provided on the application form for each cell culture:

- Importer and Exporter:
 - name and address of importer (if the importer is not an individual (e.g. a

company or institution), then the name of an authorised contact person must be supplied),

- name and address of the end user (if known), if different from the importer,
 - country of origin, and name and address of exporter (if known), the exporter may be listed as 'various' on the permit to import if the biosecurity risk is negligible, and
 - name and address of the transitional or containment facility to which the consignment is to proceed.
- Cell Culture Description:
 - Latin binomial (incl. taxonomic authority) of the organism the cell culture is derived from (eg, *Rattus norvegicus* (Berkenhout, 1769)),
 - Common name of the organism the cell culture is derived from (eg, Rat),
 - unwanted organisms status – yes or no (see section 3 definitions), and
 - new organism status – yes or no (see section 3 definitions).
 - 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.

To assist risk assessment MAFBNZ may request additional information.

6 ELIGIBILITY

6.1 The following items are NOT eligible for importation under this import health standard:

6.1.1 Cell cultures derived from humans that have not been genetically modified are exempt from this import health standard. These products can be given biosecurity clearance.

Note:

Cell cultures derived from humans that have been genetically modified are new organisms under the HSNO Act and must meet the conditions of this import health standard.

6.1.2 All 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 the MAFBNZ website:

<http://www.biosecurity.govt.nz/regs/imports/plants/nursery>

6.2 The following products may be eligible for import under this standard:

6.2.1 Cell cultures that are derived from not-new organisms (including unwanted organisms).

Note:

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

6.2.2 Cell cultures that are derived from new organisms, having HSNO Act approval from ERMA or an IBSC to be imported into a containment facility.

Note:

For the purpose of this standard cell cultures that are derived from tissues of new organisms as defined above are deemed 'new organisms' unless a HSNO Act determination from ERMA is provided stating these cell lines are not new organisms.

6.3 Cell cultures (including cell lines) derived from **not-new organisms** (including unwanted organisms) are risk goods and may be eligible for **biosecurity direction** provided the following requirements are met:

6.3.1 The consignment is accompanied by a copy of the permit to import.

6.3.2 All the conditions on the permit to import are met.

6.3.3 The transitional facility listed on the permit to import is approved at the time of import to MAF and ERMA New Zealand Standard: *Facilities for Microorganisms and Cell Cultures 2007a* and any subsequent amendments to that standard.

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

6.4.1 The consignment is accompanied by a copy of the permit to import, listing the HSNO Act approval number.

6.4.2 All the conditions on the permit to import are met.

6.4.3 All the controls and the purpose of the HSNO Act approval are met.

6.4.4 The containment facility listed on the permit to import is approved at the time of import to MAF and ERMA New Zealand Standard: *Facilities for Microorganisms and Cell Cultures 2007a* and any subsequent amendments to that standard. This standard is available from the MAFBNZ website <http://www.biosecurity.govt.nz/regs/trans/stds>

6.5 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 documentation. It is the importer's responsibility to ensure that any documentation is 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 of consignments of cell cultures 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 has current approval to operate to MAF and ERMA New Zealand Standard: *Facilities for Microorganisms and Cell Cultures 2007a* and any subsequent amendments to this standard at the time of import.

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