MAF Biosecurity New Zealand
and ERMA New Zealand Standard

Containment Facilities for Plants: 2007

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO

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The Environmental Risk Management Authority (ERMA), in accordance with section 11(1)(fb) of the Hazardous and Substances and New Organisms Act 1996, approves this standard – **Containment Facilities for Plants: 2007**.

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Rob Forlong **Date**

Chief Executive
ERMA New Zealand
(for the Environmental Risk Management Authority)

MAF, in accordance with section 39 of the Biosecurity Act 1993, approves this standard – **Containment Facilities for Plants: 2007**.

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Clive Gower-Collins **Date**

Manager, Import Standards
MAF Biosecurity New Zealand
Ministry of Agriculture and Forestry

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Foreword

The Environmental Risk Management Authority (ERMA) is responsible for making decisions under the Hazardous Substances and New Organisms (HSNO) Act 1996 on applications to introduce and/or develop new organisms (including genetically modified organisms) in New Zealand.

MAF Biosecurity New Zealand (MAFBNZ), a division of the Ministry of Agriculture and Forestry (MAF), is the lead agency in New Zealand's biosecurity system. It is responsible for preventing the importation of unwanted pests and diseases, and for controlling, managing or eradicating them should they arrive.

MAFBNZ is also the agency responsible for enforcing the new organism provisions of the HSNO Act, including HSNO Act Approvals and associated containment controls.

The Import Standards Group of MAFBNZ develops import health standards and operational standards in order to exercise those enforcement responsibilities.

This standard – *Containment Facilities for Plants: 2007*, is a joint ERMA - MAF standard prepared by MAFBNZ (Import Standards Group) in collaboration with ERMA New Zealand.

This version cancels and replaces the previous version (standard 155.04.09: 12 May 2006 - *Containment Facilities for New Organisms (including genetically modified organisms) of Plant Species*.)

There are no significant amendments from the previous version.

Review and Amendment

This standard is subject to review and amendment at any time, to ensure that it continues to meet current needs.

Reviews and amendments, in the form of new versions, will be notified to Operators of facilities approved under this standard.

Operators are responsible for ensuring that the most recent version of this standard is being used.

This standard is accessible on:

www.biosecurity.govt.nz/commercial-transport-and-border-management/standards/forest-products

Contact Persons

For all operational issues, please contact the MAF Inspector responsible for your facility.

The person responsible for all matters relating to the review and amendment of this standard is a senior adviser within the Operations Team of MAFBNZ. This person can be contacted through the office below:

Biosecurity Operational Standards and Systems Team
Ministry of Agriculture and Forestry
PO Box 2526
WELLINGTON

Phone: (04) 894 0233
Fax: (04) 894 0662
Email: standards@maf.govt.nz

1. Introduction

This standard applies to plants that are new organisms (see definition on page 9). That is, those plant species that have not been approved for release in New Zealand (including genetically modified plants) but where approval has been given for them to be held in containment subject to controls imposed by the Environmental Risk Management Authority [the Authority], or under delegation from the Authority by the Institutional Biological Safety Committees (IBSC) in regard to low risk genetic modifications approved under the HSNO (Low-Risk Genetic Modification) Regulations 2003.

These new organisms are not eligible for release into New Zealand unless the Authority gives approval, and the primary purpose of containment is to prevent their escape. They are defined as 'restricted organisms' in the Biosecurity Act 1993 and are required to be held in a containment facility approved under this Act.

In general, and in addition to an approval from the Authority, before any new species of plants may be imported into New Zealand, a permit to import is required from MAF. Imported new organisms, approved by ERMA for importation into containment, may be directed by an inspector to a transitional facility to meet the import health requirements of an import health standard, and subsequently to a containment facility approved to this Standard. No biosecurity clearance will be issued in respect of any new organism except where that new organism has been approved for release by the Authority (without conditions).

2. Scope

This MAF Biosecurity New Zealand – ERMA New Zealand standard specifies the structural, operating and approval requirements for containment facilities holding plants that are new organisms under the Hazardous Substance and New Organisms Act 1996 (HSNO). The Standard applies to all genetically modified plants for which a prior approval to develop, field test, or import into containment is mandatory under the HSNO Act and its regulations.

3. References

The following publications are referred to:

- AS/NZS ISO 9001 [2000]: Quality management systems - requirements.
- AS/NZS Standard 2243.3: 2002 Safety in laboratories: Microbiological aspects and containment facilities.
- AS/NZS ISO17025: General requirements for the competence of testing and calibration laboratories.

- Biosecurity Act 1993
- Hazardous Substances and New Organisms Act 1996 (HSNO)
- Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 2003.
- MAF Biosecurity New Zealand standard 154.03.01: 2003 - Supervision of Containment Facilities
- MAF Biosecurity New Zealand - ERMA New Zealand standard - *Facilities for Microorganisms and Cell Cultures: 2007*.

4. Terms and Definitions

For the purposes of this standard the following terms and definitions apply.

approval
Approved by the Director-General, MAF, or his/her delegate. The contact people for this standard are listed on page 5.

audit
An evaluation to determine the degree of conformity with prescribed criteria and to provide a basis for ongoing improvement.

authorised movement
Authority from an Inspector, given under section 25 of the Biosecurity Act, to move uncleared goods to a transitional facility, containment facility or biosecurity control area.

biosecurity clearance
A clearance under section 26 of the Biosecurity Act for the entry of goods into New Zealand.

biosecurity direction
Written authority from an Inspector, given under section 25 of the Biosecurity Act 1993, to move uncleared goods from a transitional 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 (CTO)
The persons appointed by the Director-General as chief technical officers under section 101 of the Biosecurity Act 1993.

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.

controls (HSNO Act 1996)

Any obligations or restrictions imposed on any hazardous substance or new organism, or on any person in relation to any hazardous substance or new organism, by this or any other Act or any regulations, rules, codes, or other documents made in accordance with the provisions of this or any other Act for the purposes of controlling the adverse effects of that substance or organism on people or the environment.

corrective action request (CAR)
A request for a corrective action to remedy a non-compliance.

Director-General
The chief executive of the Ministry of Agriculture and Forestry.

enforcement officer
An enforcement officer appointed under section 98 or section 99(3) of the [HSNO] Act.

ERMA New Zealand
Is made up of the following three components:

(a) Environmental Risk Management Authority (ERMA) - a quasi-judicial decision-making body (and also the Governing Board of ERMA New Zealand), who make decisions on applications to import hazardous substances and new organisms (including genetically modified organisms) into New Zealand.

(b) Ngā Kaihautū Tikanga Taiao - a committee to advise and assist the Authority from a Māori perspective.

(c) ERMA New Zealand - the Agency that is the administrative support organisation for the Authority, including advising applicants and evaluating and reviewing applications to assist the Authority.

field test
Tests undertaken on the effects of the organism under conditions similar to those of the environment into which it is likely to be released, but from which the organism, or any heritable material arising from it, could be retrieved or destroyed at the end of the tests, including large-scale fermentation of microorganisms.

genetically modified organism (GMO)
Unless expressly provided otherwise by regulations, any organism in which any of the genes or other genetic material:

(a) have been modified by *in vitro* techniques; or

(b) are inherited or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by *in vitro* techniques.

import health standard (IHS)
A document issued under section 22 of the Biosecurity Act 1993, which specifies the requirements to be met for the effective management of risks associated with importation of risk goods, before those goods may be imported, moved from a biosecurity control area or a transitional facility, or given a biosecurity clearance.

Inspector

A person appointed under section 103 of the Biosecurity Act 1993 to undertake administering and enforcing the provisions of the Biosecurity Act.

Institutional Biological Safety 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.

IBSCs also assign containment levels for organisms as prescribed in the HSNO (Low-Risk Genetic Modification) Regulations 2003.

internal audit
An audit carried out by the company or organisation to evaluate its own performance in relation to the standard or prescribed criteria.

in vitro
The experimental reproduction of biological processes in artificial environments, usually outside living organisms.

Living Modified Organism (LMO)
Any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. This includes organisms produced by the fusion of cells from different taxonomic families, which overcomes natural physiological reproductive or recombination barriers, and which are not techniques used in traditional breeding and selection.

low-risk genetic modification
Refers to modifications as defined in the HSNO (Low-Risk Genetic Modification) Regulations 2003.

new organism
Under section 2 of the HSNO Act 1996, new organism means (with some qualifications):

(a) an organism belonging to a species that was not present in New Zealand 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 belonging to a species, subspecies, infrasubspecies, variety, strain, or cultivar that has been eradicated from New Zealand.

Operator

The person or organisation, approved by the Director-General, who has overall responsibility for a facility, under section 40 of the Biosecurity Act 1993.

organism
Under section 2 of the HSNO Act 1996, an organism:

(a) does not include a human being:

(ab) includes a human cell:

(b) includes a micro-organism:

(c) includes a genetic structure, [other than a human cell], that is capable of replicating itself, whether that structure comprises all or only part of an entity, and whether it comprises all or only part of the total genetic structure of an entity:

(d) includes an entity (other than a human being) declared to be an organism for the purposes of the Biosecurity Act 1993:

(e) includes a reproductive cell or developmental stage of an organism.

permit to import
A written order issued by the Director-General authorising the importation of risk goods to a specified facility.

pest
An organism specified as a pest in a pest management strategy.

procedure
A document that specifies, as applicable, the purpose and scope of an activity; what shall be done and by whom; when, where, and how it shall be done; what materials, equipment and documentation shall be used; and how it shall be controlled.

Quality Management System
The term "quality management system" in this standard means the quality, administrative and technical systems that govern the operations of a facility.

release
In relation to new organisms, means to allow the organism to move within New Zealand free of any restrictions other than those imposed in accordance with the Biosecurity Act 1993 or the Conservation Act 1987, and section 2 of the Hazardous Substances and New Organisms Act, 1996.

restricted organism
Any organism for which a containment approval has been granted in accordance with the Hazardous Substances and New Organisms Act 1996 (including any approval deemed to have been granted under sections 254(1), 254(3), 254(80(a), 255(1), 255(2), 256, 258(1), and 258(3)).

risk good

Any organism, organic material, or other thing, or substance, that (by reason of its nature, origin, or other relevant factors) may constitute, harbour, or contain 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.

risk species (HSNO Act 1996)
Any species, subspecies, infrasubspecies, variety, strain or cultivar prescribed as a risk species under section 140.

NOTE: *Section 140(1)(h) enables regulations that prescribe that a risk species may have adverse effects on the health and safety of people or the environment.*

supervisor
An Inspector appointed under the Biosecurity Act. This person, employed by the supplier, inspects containment facilities and audits the operation of containment.

The Authority
Environmental Risk Management Authority (ERMA), responsible for administering the Hazardous Substances and New Organisms Act 1996.

vermin
Organisms that are to be excluded from the facility, e.g. rodents, birds, invertebrates etc.

5. Acronyms

BACC	Biosecurity Authority Clearance Certificate
BCH	Biosafety Clearing House
CAR	corrective action request
CTO	chief technical officer
ERMA	Environmental Risk Management Authority
GMC	GMO for importation into containment
GMD	GMO for development in containment
GMO	genetically modified organism
HSNO	Hazardous Substances and New Organisms
IATA	International Air Transport Association
IHS	import health standard
IBSC	Institutional Biological Safety Committee
LMO	living modified organism

MAF	Ministry of Agriculture and Forestry
MAFBNZ	Ministry of Agriculture and Forestry Biosecurity New Zealand
NOC	new organism into containment
PC	physical containment
QMS	Quality Management System

6. Approval

6.1 Approval of a Facility

Containment facilities shall be approved in accordance with section 39 of the Biosecurity Act 1993. They shall have an approved operator and be constructed and operated in accordance with this standard.

In order to meet the requirements of this standard, the facilities shall comply with all of the controls specified by the Authority in the approval of new organisms to be contained in the facility.

[It is expected that the facility will comply with the requirements of the Resource Management Act, 1991, Building Act, 1991 and any other relevant legislation.]

A facility may not be approved unless there is an approved operator.

6.1.2 Procedure for Approval of a Containment Facility

Any person wishing to have a facility approved and to be approved as an operator shall establish contact with the MAF BNZ Inspector (refer contact details on page 5).

The Inspector shall consider applications before construction or alteration of a facility, in order to provide advice on whether the proposed facility is likely to comply with this standard. The following information should be provided:

- Information about the importation or development programme, origin of the plants, the species and maximum number of plants that the facility is designed to hold;
- Plans of the proposed facility and a description of how the facility will be constructed to meet the structural requirements of this standard;
- A site plan of the property showing the location of the containment facility on the site and all facility entrances and access points identified. Boundaries of neighbouring properties shall be shown. The physical location of the property shall be clearly shown in relation to roads in the area. The site must be able to meet the requirements as described in section 8.

When the operator considers the requirements of sections 7 & 8 of this Standard have been met, the Inspector will audit the Quality Management System and the facility. When the Inspector is satisfied that:

- the Operator has met the structural and operational requirements of a containment facility as required in this standard, which includes the requirement that the Operator has met, or made provision for, any containment controls specified by the Authority or the institutional biological safety committee,
- the Quality Management System (section 7) meets the requirements of this standard,
- the application form on page 30 of this standard has been completed satisfactorily by the prospective Operator,

then the application form and a copy of the Quality Management System manual shall be sent to the Contact Person, together with the Inspector's written recommendation for approval of a containment facility.

Approval of a containment facility will be in writing. A facility may be approved for an unspecified time, a specified time or until a specified event.

6.1.3 Modifications to an Approved Facility

If the facility is to be modified, subsequent to approval, the Contact Person shall be consulted so that the plans can be approved in principle. When the modifications have been completed they shall be inspected by the Inspector to check that they meet this standard and the Contact person advised so that central records can be updated.

6.2 Approval of the Operator

The Operator is responsible for the operation of a facility and ensuring that mechanisms are in place for resourcing the facility.

An Operator shall be approved in accordance with section 40 of the Biosecurity Act, 1993. If the Director-General is satisfied:

- that the applicant is a fit and proper person to be the Operator of the facility specified in the application; and
- the applicant is able to comply with the operating standards for that facility,

s/he may approve the applicant as the operator of the facility.

In order to meet the second criterion above, the operator shall satisfy the Inspector that they have the technical and financial resourcing mechanisms in place to maintain that facility.

The technical resources shall be provided by a person or persons in authority (identified in section 7.1.2) with the qualifications, training and experience for

ensuring that both the structure of the facility and the operating procedures used in the facility are technically appropriate for the containment of the species of plants being held.

The Inspector shall send the application forms on pages 27-33 to the Contact person together with their written recommendation for approval of the Operator.

Approval of the Operator will be in writing.

6.2.1 Leased facilities

If the facility is leased, the lessee responsible for the operation of the facility shall apply to be the Operator and the contract with the owner shall clearly identify who is responsible for the maintenance of the premises and the resourcing of the operation. The Operator shall ensure that the owner is aware of the containment conditions and complies with these requirements. No part of the lease contract shall override the requirements of this standard in the operation of containment. This lease shall be made available to the Inspector who shall be satisfied that the contract does not override the requirements of this standard.

6.2.2 Collection of Personal Information on Individuals

The Operator is required to fill in the application forms on pages 27-34, which includes a New Zealand Police consent form for disclosure of convictions.
In regard to any information being collected for operator approval, this is personal information [being information identifying or being capable of identifying an individual person]. Notification is hereby provided, in accordance with Principle 3 of the Privacy Act 1993, to individuals of the following matters:

- This information is being collected for the purposes relating to the approval as an operator as per section 40 of the Biosecurity Act, 1993.
- The recipient of this information, which is also the agency that will collect and hold the information, is the Ministry of Agriculture and Forestry, PO Box 2526, Wellington.
- You are reminded that under Principles 6 and 7 of the Privacy Act, 1993, you have the right of access to, and correction of, any personal information which has been provided.

6.2.3 Changes to Operator

The Inspector shall be notified of any proposed changes of facility Operator, and new application forms submitted as per section 6.2.2 above.

6.3 Cancellation of Approval

A facility is no longer approved when the time specified in the approval expires or an event specified in the approval occurs. In addition the Chief Technical Officer may cancel approval of a facility if:

- the facility no longer complies with this standard, including controls specified by the Authority,
- the Chief Technical Officer is satisfied that the facility is no longer used for the purpose or one or more of the purposes specified in the approval,
- the Operator ceases to be an operator of the facility,
- the Operator is no longer a fit and proper person,
- the Operator requests cancellation.

If the facility is to be decommissioned, the following issues shall be considered:

- all viable material held in the facility is to be either destroyed by a specified date, or transferred to another approved containment facility;
- if disinfection is required prior to decommissioning, treatments shall also be applied to equipment and benches in the facility. Any fumigation and cleaning that is required shall be to a standard appropriate for the organisms held in the facility, and to be inspected by the Inspector.

The Chief Technical Officer may cancel approval of an operator if:

- he/she is no longer satisfied that the facility is being operated according to this standard, including controls specified by the Authority,
- the Operator ceases to be an operator of the facility,
- the Operator is no longer a fit and proper person,
- the Operator requests cancellation.

Notice of cancellation shall be given in writing to the operator.

The Inspector shall inspect the facility prior to the facility being closed down.

7. Quality Management System

The Operator shall prepare, implement and maintain a quality management system and procedures based on the principles of AS/NZS ISO 9001, a code of good manufacturing practice or similar quality system. The quality management system and any amendments shall address the requirements of this standard. The QMS should be documented as a containment manual or in an alternative format that clearly documents requirements and enables ready access for practical use and inspection.

Facilities accredited to ISO 9001, ISO 17025 or IANZ's Code of Laboratory Management Practice, do not need a separate manual provided the requirements of this standard are covered in their quality system.

The Inspector must approve the QMS and have access to a current copy of the containment manual, or a copy of the documents describing the approved QMS

The minimum requirements for the containment manual or alternative quality system are listed below.

7.1 Specific Requirements

7.1.1 Containment

Describe the main functions of the organisation and the reasons for holding or working with the plants.

Document procedures to show how the containment facility will be operated to meet:

- the containment controls set by the Authority (reference the Third Schedule, HSNO Act), or the institutional biological safety committee (IBSC),
- section 8 of this Standard, and
- the requirements of the Import Health Standard or Import Health Permit (if any).

Provide a floor plan or site plan showing the general layout of the facility and show where the plants will be held.

7.1.2 Management

Identify the operator and technical advisor(s). Identify the manager who, irrespective of other responsibilities, shall ensure that the processes needed for the quality assurance system are established, implemented and maintained.

Specify and document the responsibilities of the Operator, manager and the technical advisor(s).

Identify a safety officer responsible for plants as described in section 2.2 of AS/NZS 2243.3. (This may be the same person as the technical advisor). The safety officer shall ensure that safe procedures are documented and put into practice. They shall ensure laboratory and field staff are supervised, and ensure maintenance is carried out in accordance with safe procedures.

Identify other approved users and their responsibilities.

Prior to the commencement of any new HSNO approval work in laboratories, the Operator (or someone with equivalent status) should inspect and endorse the work proceeding to verify that all required systems are in place.

7.1.3 Training

Nominate a person or position responsible for ensuring that all people who work in the facility are familiar with the principles of containment and the procedures of the facility which ensure containment. Management must also be included in the training sessions.

Describe how the training programme is to be implemented, the time scale for implementation and refresher courses. Document training records for all staff.

7.1.4 Internal Controls

Identify quality systems used in the facility.

The Operator shall carry out an internal audit at least once every six months to verify that the activities associated with the facility continue to comply with the requirements of the quality assurance programme. The internal audit should also check that the plants (new organisms) growing in containment reconcile with the plant registers (see section 8.3). Facilities with laboratory accreditation to ISO 9001, ISO 17025 or IANZ's Code of Laboratory Management Practice shall be subject to internal audit every 12 months.

The QMS adopted to satisfy the requirements of this standard shall be reviewed at least once a year by the management. This review shall ensure its continuing suitability and effectiveness and introduce any necessary changes or improvements.

All audit and review findings and any corrective actions that arise from them shall be documented.

7.1.5 Version

Record the version number and issue date of the containment manual or QMS on each page. A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the quality system shall be established and readily available to prevent unintended use of obsolete documents.

Documents must periodically be reviewed and, where necessary, revised to ensure continuing suitability and compliance with HSNO requirements. Updates are to be provided to the Inspector who shall also hold an up to date copy of the manual.

8. Structural and Operational Requirements

These requirements may be supplemented by additional species-specific controls specified by the Authority (or IBSCs) when approving new organisms in containment.

The plants may only be stored or used in an approved containment facility. It is expected that the facility will comply with the requirements of the Resource Management Act (1991), Building Act (1991) and any other relevant legislation.

8.1 Physical Containment

8.1.1 Laboratories and Plant Houses

The containment facility shall be constructed and operated in a manner to ensure that plants and viable plant material are securely contained and held only within the containment facility.

Any associated HSNO controls should be posted in the laboratory.

The physical containment level, as defined in AS/NZS 2243.3, shall be determined by the Authority. The IBSCs have delegated authority from the Authority to set the containment level through the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 2003. The Authority and IBSCs may specify additional containment measures. There may be additional conditions specified in the import health standard set by MAF.

Note: for flowering plants in containment appropriate screening is to be provided to separate them from other plants and to prevent pollen and/or seed being dispersed beyond the specified area/part within or escaping from the containment house.

Minimum requirements for Physical Containment 1 and 2 (PC1 and PC2) will be those identified in the *Australian/New Zealand Standard 2243.3: 2002 Safety in laboratories: Microbiological aspects and containment facilities.*

8.1.1.1 Access

Procedures shall be adopted to prevent unauthorised access to the containment facility. Where access is breached by unauthorised persons, causing a security alert, the Operator is required to report this to the Inspector immediately (within 24 hours).

The requirements for access for each physical containment level are described in AS/NZS 2243.3 or any containment conditions specified by the Authority.

A prominent sign shall be displayed at all entrances to indicate that the premises are a containment facility and that unauthorised entry is restricted. For example (laboratory and plant house containment):

PLANT CONTAINMENT FACILITY LEVEL PC (number as determined by the Authority or Institutional Biological Safety Committee)

MAF Registration Number:

Restricted Access - AUTHORISED PERSONNEL ONLY.

Name of Containment Facility Operator:

{*List, as appropriate, of applicable procedures, including emergency and maintenance procedures*}

The entrances to the facility shall be kept locked, except when in active use.

Access to the facility shall, in the main, be limited to those people identified in section 7.1.2. However, visitors essential for the operation of the facility may be permitted entry. They shall adhere to access procedures and be accompanied by the principal investigators (i.e. those people identified in 7.1.2). Procedures for access shall be available at the entrance. An access log shall be maintained.

No plants or viable plant material may be removed from the containment facility without prior approval from the Inspector. Procedures shall ensure that no accidental removal occurs.

All containers of GM plants and GM plant material must be clearly labelled to ensure that they are able to be distinguished from non-GM plant material.

8.1.2 Requirements for PC 2 Plant Containment Facilities.

The plant containment facility shall incorporate the following features:

- The PC2 facility floor shall be concrete.
- Any openings in the walls, roof or ceiling, such as windows, vents and airconditioning or ventilation inlets and outlets, shall be screened from insects at the containment boundary with fine mesh screens having apertures of no greater than 0.56 mm and a wire diameter of at least 0.28 mm.
  The mesh shall be stainless steel or an equally suitable material with regards to its
  - mechanical strength under the airflow load,
  - ability to remain undamaged with regular vigorous cleanings needed to remove dust, fibre, animal or plant sheddings,
  - corrosion resistance and resistance to attack by insects from either inside the containment facility or from the local environment outside the facility.
- The drainage exits shall be designed to avoid entry of rodents and insects. [11.3.2 (a) in AS/NZS 2243.3:2002]
- A sign identifying the type of plant containment facility and listing procedures applicable, including emergency and maintenance procedures shall be posted inside the facility near the entrance. [Replaces 11.3.2 (b) in AS/NZS 2243.3:2002]
- If the plant containment facility is freestanding, it shall have an anteroom for entry and exit. The anteroom shall be fitted with a sticky pest strip or automatic insecticide aerosol device designed to kill arthropods which gain entry.
  An anteroom is not necessary if the facility connects directly with a certified small or large scale containment facility. In these instances, sticky pest strips should be located inside the main entrances to the facility.
- A washbasin shall be located either within the anteroom or in the plant containment facility close to the entrance. (The basin may be located in the laboratory, if it is directly connected to the plant containment facility).

Genetically modified plant cell/ tissue cultures can be maintained at laboratory PC1 (physical containment 1) in accordance with MAFBNZ-ERMA New Zealand Standard "*Facilities for Microorganisms and Cell Cultures: 2007"*.

8.1.3 Field Tests

A containment facility, being the area of land set aside for the field test, shall be approved in accordance with section 39 of the Biosecurity Act, 1993. It shall have an

approved Operator and be constructed, prepared and managed in accordance with this standard and any containment conditions specified by the Authority.

Approvals by the Authority for field tests of genetically modified plants will have controls that are mandated by the HSNO Act. These controls will need to be explicitly addressed in the QMS.

No GM plants may be grown to flowering stage in PC1 containment unless prior approval has been obtained from The Authority.

Controls imposed by an approval shall specify inspection and monitoring requirements for containment facilities, including any inspection required before commencement of field testing.

8.1.3.1 Access

The requirements for access will be as described in any containment controls specified by the Authority. Procedures shall be adopted to prevent unauthorised access to the field test.

Access to the facility shall, in the main, be limited to those people identified in section 7.1.2. However, visitors essential for the operation of the test site may be permitted entry. They shall adhere to access procedures and be accompanied by the principal investigators (i.e. those people identified in 7.1.2).

No plants, viable or heritable plant material may be removed from the test site without prior approval by the Inspector, and in accord with conditions specified by the Authority in any HSNO controls. Procedures shall ensure that no accidental removal occurs.

8.2 Operational Containment

8.2.1 Importation of Plants Which Are Not Genetically Modified

If the plant is to be imported as a new organism and is not genetically modified, provide evidence of the approval and the HSNO controls set by the Authority.

8.2.2 Low-Risk Genetic Modification

If the modification is a low risk genetic modification as defined in the HSNO (Low-Risk Genetic Modification) Regulations 2003:

- provide a copy of the approval from the Authority or the Institutional Biological Safety, including a description of any additional containment measures required;
- describe the category to which the modification belongs;
- with reference to standard AS/NZS 2243.3, describe the physical containment level required and indicate which requirements are provided in the facility.

8.2.3 Non Low-Risk Genetic Modification

If the modification is not a low risk genetic modification as defined in the HSNO (Low-Risk Genetic Modification) Regulations 2003 provide a copy of the approval and the containment controls set by the Authority.

8.2.4 Exposure of Experimental Animals to Plants

Where plants or plant products are used on experimental animals the HSNO controls to ensure no escape from containment or other adverse effects will be determined by the Authority and the procedures for meeting these requirements shall be documented. The MAF BNZ - ERMA New Zealand standards *Containment facilities for vertebrate laboratory animals* and *Containment facilities for invertebrates describe the requirements for holding these animals*.

[Note: *any work involving the manipulation of animals shall be in accordance with a code of ethical conduct approved by the Minister of Agriculture. This requirement is independent of this standard*.]

8.2.5 Disposal of Plant and Biological Waste

Biological waste and plant material shall be disposed of as described in section 11, AS/NZS standard 2243.3 or in accordance with any conditions specified by the Authority.

All waste involving genetically manipulated organisms shall be disposed of in accordance with the requirements of the Authority. GM material shall only be disposed of if it has first been rendered non-viable.

8.2.6 Transfer to another Containment Facility

The Operator shall make a written application to the Inspector for transfer of plants or viable plant material to another containment facility on another site. The Inspector shall seek approval from the Chief Technical Officer for transfers of plants having a containment requirement of PC3 or above.

The HSNO approval must be checked for additional measures which may be specified by the Authority (e.g. for additional packaging requirements, transfer approval, or limits on the particular facilities that are approved to hold the new organisms).

The receiving facility must be registered as having the appropriate containment level to contain the plants or viable plant material.

The plants or viable plant material may be transferred if accompanied by a written authority from the Inspector. Written authority may be for single or multiple transfers within a specified time.

Transfer of plants, viable plant material, or plant cultures to a registered microorganism/ cell culture facility within the same organisation and site is permissible provided the receiving facility has the appropriate containment level to

contain plants or viable plant material. Plants that contain maturing or mature pollen or seeds shall not be transferred to another facility.

The shipping/ transferring container shall meet the requirements of 8.2.7 and shall be sealed before transfer.

The Operator of the receiving facility shall forward a report confirming receipt of the plants or viable plant material to the Inspector on completion of the transfer.

The transfer of the plants or viable plant material shall be noted in the registers of both facilities and the entry initialled by the Inspector who supervised the transfer.

8.2.7 Transport of Plants or Viable Plant Material

Transport of plant or viable plant material by all modes (air, land sea) shall be as described in AS/NZS Standard 2243.3 [section 13]. The minimum requirement is that products shall be packaged according to Packing Instruction No. 650 of the IATA Dangerous Goods Regulations.

8.2.8 Contingency Plans

The QMS shall describe the contingency plans in place to take account of:

- the accidental release of plants or viable plant material outside the facility,
- Fire or any other emergency (these may need to be discussed with local emergency services in order that inappropriate actions are avoided in emergency situations.
- Breakdown in air handling system, or power outage (where applicable).

Resources shall be identified and accessible for the contingency. If there is a release of plants or viable plant material from containment, action shall be immediately taken to prevent further release and where possible recover the released plants. The Inspector shall be advised as soon as possible.

8.3 Register of Plants

8.3.1 Laboratory and Plant House

A register shall be maintained of plant(s) held in the containment facility. The following records shall be made for each plant:

- the identity of plant(s) and details of genetic modification, if any,
- the identity of the person responsible for the plant(s),
- unique identification number allocated to the accession or modification,
- date of import or accession into the facility,
- date of development,
- place of storage,

- date of transfer of a plant or viable plant material to another facility and identity of receiving facility,
- date of receipt of a plant from another facility,
- date and method of final disposal of a plant.

8.3.2 Field Tests

A register shall be maintained of plant lines (e.g. species, cultivars, modifications) grown in the field test. The following records shall be made for each plant line:

- the identity of plant(s) and details of genetic modification, if any,
- the identity of the person responsible for the plant(s),
- date of planting or sowing,
- date of transfer of plant(s) or viable plant material to another facility and identity of receiving facility,
- date of receipt of plant(s) or viable plant material from another facility,
- date and method of final disposal of plants.

8.4 Identification of New Organisms

Under sections 44 and 46 of the Biosecurity Act 1993, every person has a duty to inform MAFBNZ, as soon as practicable, of the suspected or identified presence of a new organism, or a notifiable organism not normally seen or otherwise detected in New Zealand. If an Operator is made aware of such presence, the contact persons for this standard should be contacted.

If an unidentified organism is subsequently identified as a new organism **and** is to be stored and/or propagated for further work (including development under the HSNO Act 1996), application for a HSNO Act Approval must be lodged with ERMA New Zealand.

If an unidentified organism is subsequently identified as an unwanted organism, CTO permission under section 53 of the Biosecurity Act 1993 is required (section 8.6). In some instances, CTO permission and a HSNO Act Approval will be required since some unwanted organisms will be new organisms, and vice-versa.

8.5 Unwanted Organisms

Under sections 52 and 53 of the Biosecurity Act 1993, work involving an unwanted organism, including sale, propagation, spread, release or cause to be released, requires the permission of a CTO. A CTO may specify the PC level and any additional conditions if permission is granted.

Application forms for seeking permission from a CTO to work with an unwanted organism are available at:

http://www.biosecurity.govt.nz/commercial-imports/unwanted-organisms-register-

The Operator must hold documented evidence of CTO permissions for activities involving unwanted organisms.

8.6 Vermin Control Programme

The organisation shall have an effective insect and rodent control program. Depending on the assigned physical containment level the containment manual shall describe how vermin such as rodents, birds and invertebrates are to be excluded (where such exclusion is relevant for the purposes of containment), how surveillance for their presence is to be maintained and what control activities will be undertaken if detected.

8.7 External Audit

The operator shall provide the Contact Person, Inspector or any other representative of the Chief Technical Officer, access to the facility, records and documents for the purposes of inspection and/or audit. During audits by the Inspector the Operator shall be available to assist and ensure that all relevant procedures and records are made available.

Inspections and on-site audits will be conducted by the Inspector as specified in the MAF Biosecurity New Zealand standard - *Supervision of Containment Facilities*.

Laboratories that have been accredited by International Accreditation of New Zealand (IANZ) to ISO 9001, ISO17025, IANZ's Code of Laboratory Management Practice or other MAF BNZ approved standards will be subject to an annual visit.

MAF BNZ reserves the right to audit at any time. Additional audits will be conducted as required especially if non-compliance is found.

Incidents of non-compliance will be dealt with by issuing:

- a critical situation report for situations that may present a serious risk to biosecurity. The Chief Technical Officer may direct that all work using plants will cease immediately and may not be permitted to recommence until the non-conformity is rectified and measures taken to prevent recurrence.
- a corrective action request [CAR] or equivalent for a non-compliance which is not a serious risk to biosecurity. Work will be permitted to continue but the facility will be given a specified period of time to rectify the non-conformity.

In some circumstances HSNO enforcement action might apply (eg. illegal development of a GMO, or escape of a GMO into the environment) in which case, compliance orders under HSNO might be used.

8.8 Costs

The Operator is required to pay all reasonable costs associated with the approval and supervision of a facility in accordance with the Biosecurity (Cost) Regulations 2003.

8.9 Records

The Operator is required to demonstrate compliance with this standard by keeping records as required for the quality management system and documented in the containment manual. Such records should be kept for a minimum of five years after release approval, biosecurity clearance, export, or destruction of the plants and include as a minimum:

- Records of the containment facility and Operator approvals.
- Copies of permits to import, containment controls specified by the Authority, import health standards, release approvals, biosecurity clearances and biosecurity directions.
- Log of activities undertaken.
- Log of personnel access to the facility.
- Records of occasions when experimental animals have been exposed to plants.
- Records of internal audits and corrective actions.
- Records of external audits and corrective actions.

8.10 Reporting

The Operator will give immediate reports of any breach of containment, of non-compliance, or other incidents that have a bearing on the risk of escape of a "new organism" to the Inspector (at least within 24 hours).

9. Appendices

Appendix 1 Application for Approval of a Containment Facility for Plants

Appendix 2 Application for Approval of an Operator of a Containment Facility

Appendix 3 Consent to Disclosure of Information

Appendix 1 Application for Approval of a Containment Facility for Plants

Application for Approval of a Containment Facility

(pursuant to section 39 of the Biosecurity Act 1993)

An application for approval of a transitional or containment facility must be made to the Director-General, using this form. This application form is an approved form in accordance with section 39(2) of the Biosecurity Act 1993.

Send the completed form and other documentation to the Inspector responsible for supervision of the transitional or containment facility (contact details are listed in the relevant standard).

If there is any change to the contact details provided in this application, you must inform MAF Biosecurity New Zealand, PO Box 2526, Wellington, in writing.

Name of Facility: .....

.....

Purpose of Facility: .....

.....

.....

Physical Location (attach a site plan)[1]: .....

.....

Postal Address: .....

.....

Telephone No: ..... Facsimile: .....

E-mail: .....

Nature of the Goods to be held in the Facility: .....

.....

.....

Proposed Physical Containment level(s): .....

Full Name of Operator: .....

Full Name of Facility Manager[2]: .....

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[1] The site plan must show the relationship of the facility to other rooms or buildings

[2] If the operator is the Crown, corporation sole, or a body of persons.

Applicant Declaration:

I, ...
(full legal name)

being the applicant for the approval of the above containment facility and declaring that the above facility meets the requirements of:

.....
(*MAFBNZ or MAFBNZ/ERMA NZ standards*)

apply to have it approved by the Director-General as a containment facility for the purpose stated above.

I include with this application:

- a copy of the approved Containment Manual (describing the Quality Management System)
- a site plan of the facility showing the relationship of the facility to other rooms or buildings

Full Name of Applicant: .....

Signature of Applicant: .....

Date: .....

Appendix 2 Application for Approval of an Operator of a Facility

Application for Approval as an Operator of a Containment Facility

(pursuant to section 40 of the Biosecurity Act 1993)

An application for approval as an operator of a transitional or containment facility must be made to the Director-General, using this form. This application form is an approved form in accordance with section 40(1) of the Biosecurity Act 1993.

Send the completed application form and other documentation to the Inspector responsible for supervision of the transitional or containment facility (contact details are listed in the relevant standard).

If there is any change to the contact details provided in this application, you must inform MAF Biosecurity New Zealand, PO Box 2526, Wellington, in writing.

Name of Facility: .....

.....

Purpose of Facility: .....

.....

.....

Physical Location: .....

.....

Postal Address: .....

.....

Telephone No: ..... Facsimile: .....

E-mail: .....

Full Legal Name of Proposed Operator: .....

.....

Designation: .....

Full Legal Name of Facility Manager[3]: .....

.....

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[3] If the operator is the Crown, corporation sole, or a body of persons.

Applicant Declaration:

I, ...
(full legal name)

being the person (the proposed Operator) responsible for the facility named above, declare that:

(a) I am able to comply with the MAF Biosecurity New Zealand/ERMA New Zealand standards: .....

.....
(MAFBNZ or MAFBNZ/ERMA NZ standards)

(b) I will ensure that the operation of the facility is in accordance with this/these standard(s).

I hereby apply for approval as the Operator of the above facility.

I include with this application:

- evidence showing that I meet the requirements to be an Operator
- a signed copy of the consent to disclosure of information by the New Zealand Police

Signature of Applicant/Facility Manager: .....

Date: .....

Appendix 3 Consent to Disclosure of Information

Consent to Disclosure of Information

Licensing & Vetting Service Centre
Officer of the Commissioner
PO Box 3017
WELLINGTON

I, ...
[Surname] [Fore Names]

.....
[Maiden or any other names used]

Sex: [M/F] Date and Place of Birth: .....

Nationality:.....

Residential Address: .....

Suburb: .....

City: .....

New Zealand Drivers Licence Number:.....

hereby consent to the disclosure by the New Zealand Police of any information they may have pursuant to this application to be registered as an operator of a transitional or containment facility, to the Ministry of Agriculture and Forestry. I understand that any record of criminal convictions I might have will automatically be concealed if I meet the eligibility criteria stipulated in Section 7 of the Criminal Records (Clean Slate) Act 2004.

Signed:..... Date:.....

COMMENTS OF THE NEW ZEALAND POLICE

Collection of Personal Information on Individuals

In regard to any personal information being collected on this application for approval of an Operator of a transitional or containment facility under the Biosecurity Act 1993 (that is personal information about an identifiable individual), notification is hereby provided in accordance with Principle 3 of the Privacy Act 1993, to individuals of the following matters:

1. This information is being collected for purposes relating to approval of a transitional or containment facility and administration of the Biosecurity Act 1993.

2. The recipient of this information, which is also the agency that will collect and hold the information, is Biosecurity New Zealand, PO Box 2526, Wellington.

3. The collection of information is authorized under section 40 of the Biosecurity Act 1993. The provision of this information is necessary in order to process this application. Failure to provide information is likely to result in the return of this application form to the applicant and ultimately may result in a refusal by the Director-General, to approve the facility as a transitional or containment facility.

4. You are reminded that under Principles 6 and 7 of the Privacy Act 1993, you have the right of access to, and correction of, any personal information, which has been provided.