

NEW ORGANISMS AND RESTRICTED BIOLOGICAL PRODUCTS PROCEDURE

Section	Health and Safety
Contact	University Health and Safety Manager
Last Review	August 2014
Next Review	December 2017
Approval	AVC Research, Academic and Enterprise or University Research Committee

Purpose:

To provide for safe and responsible use of New Organisms (including Genetically Modified Organisms) and Restricted Biological Products at Massey University in a way that protects the environment and the health and safety of people and communities.

All staff and students conducting research or teaching involving the importation or development of low risk genetically modified organisms (GMOs) in containment must ensure that their work is carried out in such a way that any adverse effect on the environment is minimised as specified in the Hazardous Substances and New Organisms (HSNO) Act 1996.

Procedure:

This procedure covers the use of New Organisms (including Genetically Modified Organisms) and Restricted Biological Products undertaken in appropriate facilities at Massey University.

Definitions:

A new organism is defined as:

- a) An organism that arrived in New Zealand after 29 July 1998.
- b) An organism that became extinct before July 29 1998.
- c) An organism with approval to be in containment.
- d) An organism with approval to be released with controls.
- e) A qualifying organism approved for release with controls.
- f) A genetically modified organism.
- g) An organism that was present in New Zealand before 29 July 1998 in contravention of the Animals Act 1967 or the Plants Act 1970 (except for the rabbit haemorrhagic disease virus (rabbit calicivirus)).
- h) A risk species.

A restricted Biological Product is defined as:

A non-viable product derived from an organism requiring direction to a Transitional Facility as under direction of an Import Health Standard (Biosecurity Act 1993).

Environmental Protection Agency (EPA) Approval:

Almost all work involving New Organisms requires an approval under the HSNO act from the EPA, any approval gained will stipulate specific controls that must be followed, it is the responsibility of the applicant to ensure all approval conditions are met.

Additional approvals/controls:

In addition to HSNO approval from EPA, the importation or transfer of New Organisms is subject to Ministry of Primary Industries (MPI) authorisation under the Biosecurity act. Some New Organisms may also be classified as controlled or unwanted organisms under the Biosecurity act; work with these organisms also requires special approval from MPI.

Appropriate Facilities at Massey University:

MPI approved Transitional and Containment Facilities have been established at Massey University to ensure teaching and research involving the import and development of new organisms (including genetically modified organisms), and imported biological products is undertaken in accordance with the Biosecurity Act 1993 and the HSNO Act 1996.

A Ministry of Primary Industries (MPI) approved Transitional and Containment Facility is a grouping of physical containment laboratories and storage areas under a single management structure where work with New Organisms and Restricted Biological Products is undertaken.

Scope of Transitional and Containment Facilities at Massey University:

Transitional and Containment Facilities ensure compliance with (where applicable):

- The Biosecurity Act 1993
- The Hazardous Substances and New Organisms (HSNO) Act 1996

MPI STANDARDS

- 154.02.17 Transitional Facilities for Biological Products
- 154.02.08 Transitional and Containment Facilities for Invertebrates
- 154.03.03 Containment Facilities for Vertebrate Laboratory Animals

MPI/EPA STANDARDS

- Facilities for Microorganisms and Cell Cultures: 2007a
- Containment Facilities for Plants: 2007

Management Structure and Quality Management System:

Transitional and Containment facilities must have an MPI approved Operator charged with overall responsibility for that Facility. The operator may delegate their responsibilities to a suitable person or persons to assist in management of the facility.

Each Transitional and Containment Facility has a Management structure and Quality Management System (QMS) approved by MPI, as well as documented procedures for use and movement of goods, training, physical and operational containment; these are documented in the Transitional and Containment Facility Manual for each of the respective Facilities.

The Operator (or delegate) ensures that:

- An up-to-date manual is maintained for the Facility
- The MPI Facility Inspector holds, or has access to, a current copy of the manual
- All Users of the Facility have easy access to the current Containment Manual.

Relevant Legislation:

Hazardous Substances and New Organisms Act 1996
Biosecurity Act 1993

Related Procedures:

[Genetically Modified Organisms Procedures](#)

Document Management Control:

Prepared By: University Health and Safety Manager
Owned By: Assistant Vice Chancellor – People and Organisational Development
Authorised By: AVC Research, Academic and Enterprise or University Research Committee
Date Issued: August 2014
Last Reviewed: August 2014
Next Review: December 2017