

RESTRICTED ORGANISMS AND BIOLOGICAL PRODUCTS

Section	University Services
Contact	Director Occupational Health & Safety, Wellbeing
Last Review	June 2023
Next Review	June 2026
Approval	Director Occupational Health & Safety, Wellbeing

Purpose:

To provide for safe and responsible use of Restricted Organisms and Restricted Biological Products at Massey University in a way that protects the environment and the health and safety of people and communities and to meet our obligations under NZ and international legislation.

Scope:

This procedure covers the use of Restricted Organisms and Restricted Biological Products undertaken in appropriate facilities at Massey University.

Definitions:

A restricted organism is defined as:

- a) Any organism regulated under the Biosecurity act 1993 or the HSNO Act 1996.
 - i. An Unwanted Organism or Regulated Pest (section 52 and 53 of the Biosecurity acts 1993)
 - ii. A New Organism (section 2A of the HSNO act 1996).

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 hemorrhagic 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).

HSNO act Approval:

Almost all work involving New Organisms requires an approval under the HSNO act from the Environmental Protection Authority (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. The importation (including storage and use) of New Organisms must only take place with an appropriate HSNO approval in place. Refer to the New Organisms at Massey site for more information, and applications for permission to work under existing broad HSNO approvals.

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 regulated pests or unwanted organisms under the Biosecurity act; work with these organisms also requires an unwanted organism's approval from an MPI Chief Technical Officer (CTO) under section 52 and 53 of the Act.

In cases where restricted organisms or biological products are applied to plant or animals, specific HSNO act approval conditions for that work and/or an MPI CTO approval is also required.

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

MAF 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

MAF/ERMA STANDARDS

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

AS/NZS 2243.3 safety in laboratories Part 3 microbiological aspects and containment facilities.

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.

Related documents:

Relevant Legislation

- Hazardous Substances and New Organisms Act 1996
- Biosecurity Act 1993

Related Procedures

- Genetically Modified Organisms Procedures