Environmental Protection Authority
Te Mana Rauhī Taiao

Summary of approval

July 2019

Application Number	NOC05006
Approval Holder	Institute of Geological & Nuclear Sciences
Application category	**Import into Containment any New Organism under the Hazardous Substances and New Organisms (HSNO) Act 1996**
Purpose of the Approval	This application is for the importation for research purposes including taxonomy, ecology, biodiversity and biotechnology studies, of groups of non-pathogenic extremophilic microorganisms
Date of Approval	20 October 2005
Amendment Number	APP203756
Date of Amendment	29 July 2019
Considered by	Committee of the Authority
Purpose of the Amendment	To correct a technical error in the description of the scope of the approval set out in the decision on the application numbered NOC05006 (which relates to non-pathogenic, extremophilic microorganisms)

Decision summary

The application to import into containment "non-pathogenic extremophilic microorganisms" is approved, with controls (as detailed in Appendix 1 of this decision), having being considered in accordance with the relevant provisions of the Hazardous Substances and New Organisms (HSNO) Act 1996 (the Act) and the HSNO (Methodology) Order 1998 (the Methodology). This approval applies only to non-pathogenic, extremophilic microorganisms that were not present in New Zealand immediately before 29 July 1998.

Dr Nick Roskruge	29 July 2019
Chair, Decision-Making Committee **Environmental Protection Authority**	**Date**

Appendix 1: Controls

In order to satisfactorily address the matters detailed in the *Third Schedule Part II: Containment controls for new organisms excluding genetically modified organisms*[1] of the Act, and other matters in order to give effect to the purpose of the Act, the approved organisms are subject to the following controls:

1 To limit the likelihood of any accidental release of any organism or any viable genetic material[2]:

1.1 The approved organisms shall be imported into and maintained within a containment facility which complies with these controls.

1.2 The construction, operation, and management of the microorganism containment facility shall be in accordance with the:

a) Ministry of Agriculture and Forestry (MAF) Biosecurity Authority/ERMA New Zealand Standard 154.03.02[3]: *Containment Facilities for Microorganisms*.

b) Australian New Zealand Standard AS/NZS 2243.3:2002[3] *Safety in Laboratories*: Part 3: (*Microbiological aspects and containment facilities*).

c) Physical Containment Level 1 (PC1) requirements of the above Standards.

1.3 The person responsible for a particular research area and/or the person responsible for the operation of the containment facility shall inform all personnel involved in the handling of the organisms of the Authority's controls.

1.4 The containment facility shall be approved by Ministry of Agriculture and Forestry (MAF), in accordance with section 39 of the Biosecurity Act and the MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.02[5]: Containment Facilities for Microorganisms.

2 To exclude unauthorised people from the facility:

2.1 The identification of entrances, numbers of and access to entrances, and the security requirements for the entrances and the facility shall be in compliance with the standards listed in Control 1.2 of this document.

3 To control the effects of any accidental release or escape of an organism:

3.1 Construction and operation of the containment facility shall comply with the requirements of the standards listed in Control 1.2 relating to the control of the effects of any accidental release or escape of an organism.

3.2 If a breach of containment occurs, the facility operator must ensure that the MAF Inspector responsible for supervision of the facility has received notification of the breach within 24 hours.

3.3 In the event of any breach of containment of the organism, the contingency plan for the attempted retrieval or destruction of any viable material of the organism that has escaped shall

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[1] Bold headings refer to matters to be addressed by containment controls for new organisms excluding genetically modified organisms, specified in the Third Schedule (Part II) of the HSNO Act 1996.

[2] Viable Genetic Material is biological material that can be resuscitated to grow into tissues or organisms. It can be defined to mean biological material capable of growth even though resuscitation procedures may be required, eg when organisms or parts thereof are sublethally damaged by being frozen, dried, heated, or affected by chemical.

[3] Any reference to this standard in these controls refers to any subsequent version approved or endorsed by ERMA New Zealand

be implemented immediately. The contingency plan shall be included in the containment manual in accordance with the requirements of standards listed in Control 1.2.

3.4 Any person exercising this approval shall comply with the requirements of the standards listed in Control 1.2 listed above relating to the maintenance of records demonstrating compliance with the Standard 154.03.02[5], as required by the quality assurance programme, and documented in the containment manual.

4 Inspection and monitoring requirements for containment facilities:

4.1 The inspection and monitoring requirements for the containment facility shall be in compliance with the standards listed in Control 1.2.

4.2 The containment manuals shall be updated, as necessary, to address the implementation of the controls imposed by this approval, in accordance with the MAF/ERMA New Zealand Standard 154.03.02[5].

5 Qualifications required of the persons responsible for implementing these controls:

5.1 The training of personnel working in the facility shall be in compliance with the standards listed in Control 1.2.

6 Additional controls:

6.1 All 'open container' manipulations involving organisms imported under this approval shall be performed in a biological safety cabinet that is operated in accordance with the requirements of the Australian/New Zealand Standard 2243.3:2002[5]: Safety in Laboratories Part 3: Microbiological aspects and containment facilities, fifth edition, until such times that the user has assessed and documented, including any methods and results, to demonstrate that aerial dispersed propagules are not formed by the isolate being examined. Once such evidence is documented the tested isolate can be manipulated outside of the biological safety cabinet.

6.2 Each application to MAF Biosecurity New Zealand for a permit to import any isolate shall be accompanied by a written declaration that the isolate(s) are non-pathogenic to humans and are extremophilic microorganisms.

6.3 ERMA New Zealand shall be notified in writing within five working days if any new information on pathogenicity becomes available, and work on the organism shall cease while this information is assessed. Any imported organisms that become known to be pathogenic shall be considered outside this approval. The organism can be held in storage while a new application is made and a decision is reached under the Hazardous Substances and New Organisms Act 1996. Storage is limited to one year from the date that ERMA New Zealand is notified at which time the stored isolate should then be destroyed, unless an application has been formally received by ERMA New Zealand.

6.4 All packages of organisms imported in accordance with this approval shall be clearly labelled with the ERMA New Zealand approval code and the direction that the package should not be opened at the border, and shall only be opened within a registered containment facility. The package should also be accompanied by the appropriate documentation specifying this direction and attached to the package in such a way that the package does not have to be opened to access the documentation.

6.5 Any person using this approval for the first time shall notify ERMA New Zealand and the MAF Inspector responsible for supervision of the facility of their intention to do so in writing.