ENVIRONMENTAL RISK MANAGEMENT AUTHORITY DECISION

Amended under s67A on 6 September 2007, and on 29 July 2019

31 October 2005

Application code:	**NOC05006**
Application category:	**Import into Containment any New Organism under the Hazardous Substances and New Organisms (HSNO) Act 1996**
Applicant:	Institute of Geological & Nuclear Sciences
Applicant contact:	**Matthew Stott**
Purpose:	**This application is for the importation for research purposes including taxonomy, ecology, biodiversity and biotechnology studies, of groups of non-pathogenic extremophilic microorganisms**
Date application received:	26 September 2005
Consideration date:	20 October 2005
Considered by:	Committee of the Authority

1 Summary of Decision

1.1 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.

2 Legislative Criteria for Application

2.1 The application was lodged pursuant to section 40(1)(a) of the Act. The application was determined in accordance with section 45, having regard to the matters specified in section 44 and other matters relevant to the purpose of the Act, as specified in Part II of the Act. Unless otherwise stated, references to section numbers in this decision refer to sections of the Act.

2.2 Consideration of the application followed the relevant provisions of the Methodology, as specified in more detail below. Unless otherwise stated, references to clause numbers in this decision refer to clauses of the Methodology.

3 Application Process

Application receipt

3.1 Application NOC05006 was determined to be in compliance with section 40(2) of the Act and was formally received on 26 September 2005.

Notification

3.2 Under section 53(2) of the Act the Environmental Risk Management Authority (the Authority) has discretion as to whether to publicly notify an application to import into containment any new organism. In this case the application was not publicly notified (following ERMA New Zealand guidelines) because the organisms are not considered to be novel in a way that would generate public interest beyond that which would accompany a full release application, nor are they considered as having a high level of associated risk, nor are they iconic or of cultural importance.

3.3 In accordance with section 58(1)(c) of the Act and clauses 2(2)(e) and 5 of the Methodology, the Department of Conservation (DoC) and the Ministry of Agriculture and Forestry (MAF) Biosecurity New Zealand were notified and provided with an opportunity to comment on the application.

Decision Making Committee

3.4 The application was considered by a sub-Committee of the New Organisms (Non-GMO) Committee of the Authority appointed in accordance with section 19(2)(b) of the Act. The Committee comprised the following members: Dr Kieran Elborough (Chair), Prof. George Clark and Ass. Prof. Marie Dziadek.

Information Available for Consideration

3.5 The documents available for the consideration of the application by the Committee were:

- application NOC05006 (Form NO2N): Import into Containment any New Organism that is not genetically modified;
- scientific papers cited in the application;
- the Institute of Geological Sciences Containment Manual;
- a memo from the Agency to the Committee to assist and support the Committee's decision-making; and
- comments on the additional controls from MAF.

3.6 DoC did not respond with formal comments on the application. However they raised a general concern with the Agency regarding broad organism descriptions. The Committee noted that DoC are currently deciding whether they support or oppose broad organism descriptions.

3.7 MAF commented on the additional controls by email on 19 October 2005. They raised a concern with additional control 6.4 (see Appendix 1 of this report), which states that all packages of organisms imported in accordance with this approval shall not be opened at the border and shall only be opened in a containment facility. MAF noted that inspectors have the right to open any package presented at the border but that they would not open the primary receptacle. The Committee considers that additional control 6.4 is appropriate to mitigate the risk of escape during transport to the containment facility (as discussed in section 6.17 of this decision). The Committee noted that the Agency is working with MAF on this issue, with the view that in future all packages containing new organisms are only opened within an appropriate containment facility.

3.8 Recognised techniques were used in identifying, assessing, and evaluating the relevant information, as required under clause 24 of the Methodology. Techniques for identifying and preparing information on risks, costs and benefits were based on internal procedures as specified in the ERMA New Zealand Technical Guide publications.

4 Sequence of the Consideration

4.1 In accordance with clause 24 of the Methodology, the approach to the consideration adopted by the Committee was first to examine the scope and purpose of the application, and the range of organisms applied for, then to look sequentially at identification, assessment and evaluation of risks, costs and benefits. Those risks identified as significant were assessed in accordance with clause 12 of the Methodology. Costs and benefits were assessed in accordance with clause 13 of the Methodology. Qualitative scales used by the Committee to measure likelihood and magnitude of risks, costs and benefits are provided in Appendix 2 of this decision.

4.2 Combined with the assessment of risks, costs and benefits was the consideration of the adequacy of the proposed containment regime, and the ability of the organisms to escape and establish self-sustaining populations (as required by sections 37 and 44 and clause 10(e)). Management techniques were considered in relation to the identified risks. The containment regime was considered in the context of a risk management regime for controlling the identified risks and costs (clauses 12(d) and 24). In doing so, the Committee set controls to satisfactorily provide for the matters in the Third Schedule (Part II) of the Act and additional controls were considered in relation to residual risks that required further consideration.

4.3 Benefits associated with this application were considered in accordance with clauses 9, 10, 13 and 14 of the Methodology and section 6(e) of the Act.

4.4 Finally, taking account of the risk characteristics established in accordance with clause 33 of the Methodology, the combined impact of risks, costs and benefits was evaluated in accordance with clause 34. The approach to the consideration follows the decision path outlined in Appendix 3 of this decision.

5 Purpose of the Application

5.1 The Institute of Geothermal and Nuclear Sciences wish to import a number of non-pathogenic extremophilic microorganisms for use as a reference collection to allow identification of isolates recovered from the New Zealand environment. In addition, basic ecological studies will be undertaken to better understand the biology of these potentially valuable organisms.

5.2 The Committee was satisfied that the application was for a valid purpose under section 39(1)(h) of the HSNO Act being "such other purposes as the Authority thinks fit".

6 Adequacy of the Containment Regime

Ability to adequately contain the organisms

6.1 In carrying out its consideration, the Committee considered the adequacy of containment in accordance with section 45(1)(a)(iii) of the Act, and, the magnitude and likelihood of the risks, costs and benefits alongside each other and in an integrated fashion. This is because the former interact with the latter and this is recognised in clause 12(d) of the Methodology and in section 45(1)(a)(ii) of the Act. For convenience in setting out the decision the adequacy of containment is discussed first.

6.2 In considering the ability of the organisms to escape from containment, the Committee considered the:

- biological characteristics of the organisms;
- containment regime; and
- potential pathways for escape of the organisms from the containment facility.

(i) Biological characteristics of the organisms

6.3 The Committee notes that the approval covers a broad organism description. This was due to the large number of different organisms that the applicant wishes to import and the changing nomenclature associated with this group. The Committee considered this an appropriate approach due to the organisms having very similar risk profiles, being low risk and held in containment, which will limit the exposure pathway for any adverse effects.

6.4 Extremophile means "someone who loves extremes" (Shostak, 2005), and the term is often used interchangeably for the domain or superkingdom Archaea. This taxon was proposed to differentiate this group of organisms as an evolutionary 'middle ground' between Bacteria and Eukarya (Woese and Fox, 1977). While Archaea are prokaryotes they share some similarity with eukaryotes. This is particularly evident in the way in which genetic material is produced in the processes of transcription,

translation and replication as demonstrated by the similarity of the sequences of the proteins involved (Makarova and Koonin, 2003).

6.5 No member of Archaea, at this time, are known to cause disease of humans, plants or animals (Todar, 2005). This reflects their extreme habitat in which they do not come into contact with 'normal' living organisms so that there has not been any opportunity for the natural selection of pathogenic traits. It is noted that some extremophiles have adapted through natural selection to the anerobic and acidic conditions of animal digestive system, though they are not disease causing.

6.6 More recently the prevalence of Bacteria in these so called extreme conditions has been recognised (Maloney, no date) and as noted by the applicant their specialised living requirements have restricted exposure to and therefore the ability to infect plants, animals or humans.

6.7 The extremophiles are grouped by their environmental requirements. The applicant identified several groups of organisms as examples of extremophiles as listed below accompanied by their specific growth requirements:

- thermophiles (Bacteria and Archaea found at high temperatures 60°C or greater);
- acidophiles (Bacteria found at a low pH, less than or equal to 3);
- barophiles (Bacteria and Archaea found at high fluid pressure);
- alkaliphiles (Bacteria and Archaea found at high pH, greater than or equal to pH of 9); and
- halophiles (Archaea found at high salt concentration, greater than 0.2 M NaCl) (Roberts, 1998).

6.8 While not meeting the phylogenetic definition of extremophiles, there are also microorganisms, which on a functional basis have been classed as extremophiles such as:

- methanotrophs: Bacteria utilising methane as a carbon source, found mainly in soil but also aquatic environments (Knowles, 2005);
- methanogens: Archaea utilising a range of carbon sources to produce methane, found in anaerobic environments such as the guts of ruminants (Whitford et al., 2001); and
- nitrifiers: Bacteria and Archaea able to convert nitrogen gas into a form accessible by other organisms – ammonia (The BioWeb Group, 2000).

6.9 It should be noted than an individual organism may exhibit a number of these features (for example *Picrophilus oshimae*, which was isolated from a hot spring, grows optimally at 60°C when the pH is 0.7 so it is both a thermophile and an acidophile) (Maloney, no date).

6.10 The Committee recognises that some of the organisms (in particular the gram-positive bacteria) likely to be imported under this approval have the capacity to produce endospores. Endospores are survival structures produced during times of

stress (such as nutrition deficiency or exposure to environmental conditions outside the optimum for normal growth). Endospores are more tolerant or resistant to the affects of heat and disinfectants which helps to protects the genetic material within (Madigan et al., 1997).

6.11 The Committee notes that conditions that are conducive to endospore formation are unlikely to occur when these organisms are held in containment because the applicant intends to maintain actively growing cultures. Also, adherence to section 4.6 of the ERMA New Zealand/MAF Biosecurity Authority Standard 154.03.02: *Containment Facilities for Microorganisms* (Standard 154.03.02) which the containment facility must be registered in accordance with), details the requirements for disposal of biological waste, will, in the unlikely event of endospores being produced, mitigate the risk of any endospores leaving the containment facility in a viable state.

6.12 To ensure that the organisms and endospores produced are contained at all times the Committee has imposed an additional control (6.1) that requires any person exercising the approval to perform all 'open container' manipulations of all organisms imported in accordance with this approval in a biological safety cabinet that is operated in accordance with the requirements of Australian/New Zealand Standard 2243.3:2002: *Safety in Laboratories Part 3: Microbiological aspects and containment facilities,* fifth edition 2002 (AS/NZS Standard 2243.3:2002). Open container manipulations are procedures whereby the culture is exposed to the atmosphere and includes plating and subculturing. However, if the user of the approval has assessed and documented, including test methods and results, to demonstrate that aerial dispersed propagules are not formed by the isolate being examined, then the isolate can be manipulated outside of a biological safety cabinet.

6.13 Given the wide organism description, and to ensure that MAF is aware of what organisms are covered by the approval, the Committee has imposed an additional control (6.2) which requires users of the approval to declare that the isolate(s) that they wish to import are extremophilic microorganisms that are non-pathogenic, when they apply to MAF for an import permit. The Committee notes that this puts the onus on the applicant to ensure that the organisms that they wish to import are within the organism description. In support of this control, the Committee considers that opportunities to utilise any microorganisms NOT meeting this description will be limited, eg the publication of data associated with non-compliant strains will provide an avenue for discovery and enforcement action.

(ii) Containment regime

6.14 The Committee notes that as all the microorganisms are to be non-pathogenic they will meet the definition of Risk Group 1 in the AS/NZS Standard 2243.3:2002. On this basis the Committee considers that Physical Containment level 1 (PC1) and compliance with the requirements of Standard 154.03.02 in conjunction with the additional controls imposed is adequate to contain the microorganisms.

6.15 The Committee recognises that from time-to-time with the discovery of new information users of this approval may learn they have inadvertently imported a strain outside of the scope of the organism description. For this reason the Committee has imposed an additional control (6.3) where in the event that new information on pathogenicity becomes available, ERMA New Zealand shall be notified and work 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 Act. 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.

(iii) Potential pathways for escape of organisms from the containment facility

6.16 The Committee considered potential pathways of escape of the microorganisms. Three pathways were identified and the associated mitigating factors prescribed under the Standard 154.03.02 are discussed below.

6.17 The potential for escape during transport to containment facilities was considered. The Committee noted that under Standard 154.03.02 cultures are required to be transported in packaging meeting the requirements of the International Air Transport Association that are specificially designed to maintain the integrity of parcels in transit, hence preventing accidental escape. To prevent escape of the organisms during transport to the containment facility, the Committee has imposed an additional control (6.4) requiring packages containing the organisms to be clearly labelled with the ERMA New Zealand application code and the direction that the package should not be opened at the border, and shall only be opened within a registered containment facility. This control also stipulates that the package should be accompanied by the appropriate documentation specifying this direction and such documentation should be accessible without opening the package.

6.18 The potential for accidental/unintentional or deliberate removal by people was considered. The Committee noted that Standard 154.03.02 specifies operating procedures, in particular relating to access and disposal that are designed to prevent removal and ensuring that all people who work in the facility are familiar with the operating procedures and the principles of containment.

6.19 The potential for escape from containment following accidental spillage, natural disaster (flood, earthquake etc.) or fire was considered. The Committee noted that under AS/NZS Standard 2243.3:2002 detailed procedures for dealing with spills are specified and under Standard 154.03.02 approval users are required to develop a contingency plan that is specifically designed to prevent further releases and where possible destroy any escaped organisms.

6.20 The Committee concluded that escape of the organisms via any of these pathways is highly improbable provided the relevant controls are complied with. The Committee

is satisfied that adherence to the requirements of Standard 154.03.02 and the additional controls proposed is sufficient to manage these risk pathways.

Conclusion on the adequacy of the containment regime

6.21 The Committee has considered the ability of the microorganisms to escape containment given their biological characteristics, the proposed containment regime and the potential pathways of escape. Taking all of these considerations into account the Committee concludes that it is highly improbable that the microorganisms would be able to escape from containment.

6.22 The Committee has imposed an additional control (6.5 requiring all users of the approval to notify ERMA New Zealand and MAF when they first exercise the approval. This is for compliance monitoring purposes and to ensure that ERMA New Zealand is aware of all users of the approval are known in case a reassessment[1] or amendment[2] of the approval is warranted.

7 Ability of the organism to establish a self-sustaining population

7.1 In accordance with sections 44 and 37 and clause 10(e) the Committee considered the ability of the microorganisms to form a self-sustaining population should they escape from containment, and the ease of eradication of such populations.

7.2 In the event of an escape from containment, organisms would only survive in those specific environments to which they are adapted. While these environments do exist in New Zealand in order to reach them the microorganisms would need to be specifically transported to them in relatively large quantities. If this highly improbable series of events did occur a self-sustaining population is likely to form.

7.3 The Committee acknowledge that in the highly improbable event of the formation of a self-sustaining population the microorganisms would be difficult to eradicate and to do so may cause more harm to the existing microflora than the escaped organism. If eradication was attempted, determining the success of such an attempt would in practice be very difficult.

8 Identification and assessment of potentially significant adverse effects (risks and costs)

8.1 In accordance with clause 9(c) the Committee has categorised potential adverse effects into environmental, human health, Māori culture, market economy and social categories. These adverse effects have been considered in terms of the

[1] Section 62 of the Act.

[2] Section 67A of the Act.

requirements of clauses 12, 13, and 14 including the probability of occurrence and the magnitude of adverse effects, whether or not they are monetary, the distribution of costs and benefits over time, space and groups in the community. Risk characteristics are considered in terms of clause 33. The degree of uncertainty attached to evidence is taken into account, as required under clauses 25, 29 and 30.

The Environment

8.2 The Committee considered the potential for the non-pathogenic, extremophilic microorganisms to cause adverse effects to the environment. Given that they are non-pathogenic, the only exposure pathway for an adverse effect to be realised is in competition with and displacement of native microorganisms.

8.3 In assessing this effect the Committee notes that in order for this effect to be realised the microorganisms would need to form a self-sustaining population, which would require a large volume of culture to be removed from the containment facility undetected and deliberately transported to a suitable environment. In order for an adverse effect to be realised the escaped microorganism would need to out-compete the existing microflora for resources resulting in displacement. In conducting this assessment the Committee recognised that there is a high probability, given the highly specialised nature of these microorganisms, that they may already be present in these environments. This is a theory proposed by Fenchel and Finlay and based on their observation that 'habitat properties alone are needed to explain the presence of a given microbe, and historical factors are irrelevant'.

8.4 Taking this into account the Committee considered that it is highly improbable that the organisms will cause any adverse impacts to the environment and any such impacts are likely to be minimal in magnitude. Therefore the Committee considered the potential for any adverse effects to the environment resulting from the importation into containment of these organisms to be negligible.

Human health and safety

8.5 The Committee notes that by definition the microorganisms are non-pathogenic as discussed in sections 6.5-6.6, and that there is no information to suggest that they produce any toxins. On the basis of this information the Committee did not identify any adverse effects to human health and safety.

Māori and their culture and traditions

8.6 The Committee has considered the potential Māori cultural effects in accordance with clauses 9(b)(i) and 9(c)(iv) and sections 6(d) and 8 of the Act using the assessment framework contained in the ERMA New Zealand User Guide "Working with Māori under the HSNO Act 1996" in assessing this application.

8.7 The Committee considered the only potential adverse Māori cultural effects would be through the flow-on effects to mauri from displacement of native species. Given

the assessment presented in section 8.3 the Committee considers this adverse effect to be negligible.

Social and community effects

8.8 The Committee considered the information available and did not identify any adverse effects to society and the community.

The market economy

8.9 The Committee considered the information available and did not identify any adverse effects to the market economy.

9 Identification and assessment of potentially significant beneficial effects

9.1 The Committee considered the potential beneficial effects associated with the application, in accordance with sections 5 and 6(e) of the Act and clauses 9(c), 10, 13, and 14 of the Methodology. The Committee identified the following beneficial effects:

- collaboration with overseas researchers adding to New Zealand's international reputation in this discipline; and
- increased scientific knowledge of these types of microorganisms including a better understanding of our native microorganisms.

9.2 The Committee considers that the benefits are likely to be realised and are of minor to moderate value and hence non-negligible.

9.3 The Committee recognises the medium-term benefits identified by the applicant such as the potential to develop biotechnology of relevance to medical and environmental science. However, these benefits were not assessed as they were not considered to directly result from this application.

10 Establishment of the Approach to Risk in the Light of Risk Characteristics

10.1 Clause 33 requires the Authority to have regard to the extent to which a specified set of risk characteristics exist when considering applications. This provides a route for determining how cautious or risk averse the Authority should be in weighing up risks and costs against benefits. In the present application, clause 33 is influenced by the organism being "in containment" and the conclusion that the containment provisions and other controls will reduce most biological and physical risks to a low level.

10.2 In relation to the biological and physical risks considered (including the risks to human health), the containment measures limit the extent to which exposure to the

risks is involuntary. The Committee also consider that there are no significant risks which are not known or understood by the general public. It is considered that the potentially significant risks are dependant upon escape from containment and the establishment of an undesirable self-sustaining population. Given the Committee's finding that the risk of escape from containment occurring is highly improbable, and that it is also highly improbable that any self-sustaining population would be undesirable, the extent to which these risk characteristics are present does not warrant caution additional to that required by section 7 of the Act.

11 Associated approvals

11.1 The Committee noted the need for the applicant to obtain an import permit from the Ministry of Agriculture and Forestry which will require adherence to the relevant Import Health Standard designed to mitigate the risk of any associated organisms.

12 Overall Evaluation of Risk, Costs and Benefits

12.1 The overall evaluation of risks, costs and benefits set out below was carried out in accordance with section 45 of the Act and clause 26 of the Methodology, having regard to clauses 22 and 34 of the Methodology.

12.2 The Committee has assessed the potential risks of importing these organisms into containment as being negligible.

12.3 The Committee considers that the benefits are likely to be realised and are non-negligible.

12.4 The Committee acknowledges the possibility that a self-sustaining population of the microorganisms may establish, however, the Committee considers it highly improbable that such a population would be undesirable. The proposed containment regime, based on Standard 154.03.02 and additional controls are considered to be adequate considering the risks posed by the organism. Additionally, it is considered highly improbable that the organisms would be able to escape from this containment system.

12.5 The Committee was unable to find common units of measurement with which to combine risks, costs, and benefits in accordance with clause 34(a) and there were no dominant sources of risk (clause 34(b)). Because the risks as a whole are negligible, the decision is made in accordance with clause 26 (not clause 27).

12.6 The Committee considered all of the controls, set out in Appendix 1 taking into account the cost effectiveness of the control in preventing the escape of the organisms and effectively managing any risks. The Committee, having regard to these matters, is satisfied that the organisms can be adequately contained, and that it is evident that the benefits of the application outweigh the costs.

13 Decision

13.1 Pursuant to section 45(1)(a)(i) of the Act, the Committee is satisfied that this application is for one of the purposes specified in section 39(1) of the Act, namely 39(1)(h): such other purposes as the Authority thinks fit.

13.2 Having considered all the possible effects in accordance with sections 45(1)(a)(ii), 45(4) and 44 and pursuant to clause 26 of the Methodology, and based on consideration and analysis of the information provided and taking into account the application of risk management controls specified in this decision, the view of the Committee is that the risks (or costs) of adverse effects associated with the importation into containment of non-pathogenic, extremophilic microorganisms are outweighed by the benefits.

13.3 The Committee is satisfied that the containment regime, as set out in Appendix 1, will adequately contain the organisms as required by section 45(1)(a)(iii) of the Act.

13.4 In accordance with clause 36(2)(b) of the Methodology the Committee records that, in reaching this conclusion, it has applied the balancing tests in section 45 of the Act and clause 26 of the Methodology and has relied in particular on the criteria set out in the following sections of the Act:

- section 44 additional matters to be considered;
- section 45 determination of application;
- section 37 additional matters to be considered; and
- the Third Schedule (Part II), matters to be addressed by containment controls for new organisms.

13.5 The Committee has also applied the following criteria in the Methodology:

- clause 9 – equivalent of sections 5, 6 and 8;
- clause 10 – equivalent of sections 36 and 37;
- clause 12 – evaluation of assessment of risks;
- clause 13 – evaluation of assessment of costs and benefits;
- clause 20 – information produced from other bodies;
- clause 21 – the decision accords with the requirements of the Act and regulations;
- clause 22 – the evaluation of risks, costs and benefits – relevant considerations;
- clause 24 – the use of recognised risk identification, assessment, evaluation and management techniques;
- clause 25 – the evaluation of risks;
- clause 26 – the risks are negligible and it is evident benefits outweigh costs;
- clause 29 and 32 – considering uncertainty;
- clause 33 – the risk characteristics; and
- clause 34 – the aggregation and comparison of risks, costs and benefits.

13.6 The application for importation into containment of non-pathogenic, extremophilic microorganisms is thus **approved**, **with controls**, in accordance with section 45(1)(a) of the Act. As required under section 45(2) the approval is subject to the controls listed in Appendix 1 of this decision.

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Kieran Elborough Date 31 October 2005
Chairperson of Decision-making Committee
Approval code: NOC002454

First amendment: November 2007
Changes to controls:

- Addition of footnotes to the containment facility references and the Australian/New Zealand containment facility references to "future proof" the decision
- Standardise the wording of the breach of containment control
- Standardise the wording for the notification of the first time use of this approval
- Removal of the control regarding inspection of facilities by the Authority, its agent or enforcement officers

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Dr Max Suckling Date 6 September 2007
Chair, New Organisms Standing Committee

Second amendment pursuant to section 67A of HSNO Act: 29/07/2019
To correct a technical error in the description of the scope of the approval by adding:
In paragraph 1.1 "*This approval applies only to non-pathogenic, extremophilic microorganisms that were not present in New Zealand immediately before 29 July 1998*."

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

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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*[3] 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[4]:

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[5]: *Containment Facilities for Microorganisms*.

b) Australian New Zealand Standard AS/NZS 2243.3:2002[5] *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] 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.

[4] 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.

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

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 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.

Appendix 2: Qualitative scales for describing adverse effects

Qualitative Risk Assessment

Risks and benefits are assessed by estimating the magnitude of the possible effects and the likelihood of their occurrence. For each effect, the combination of these two components determines the level of that effect, which is a two dimensional concept. Risk assessment may be qualitative or quantitative. Qualitative assessment is informed by quantitative data where this is available.

Qualitative matrices are used to prioritise risks (and benefits), and to identify any risks that are unacceptable. The measure of the level of risk (combination of magnitude and likelihood) is specific to the application therefore measures of level of risk should not be compared between applications. However, the measures (descriptors) for different types of risk (human health, ecological etc) should be established so that they represent relative orders of magnitude.

Magnitude of effect

The magnitude must be a measure of the endpoint (specified by the Act and the Methodology), and is described in terms of the element that might be affected. The magnitude of the effect is not the same as the effect itself. The qualitative descriptors for magnitude of effect are surrogate measures that should be used to gauge the end effect or the 'what if' element.

Tables 1 and 2 contain generic descriptors for magnitude of adverse effects (risks and costs) and beneficial effects (benefits). These descriptors are examples only, and their generic nature means that it may be difficult to use them in some particular circumstances. They are included here simply to illustrate how qualitative tables may be used to represent levels of risk.

Table 1 Magnitude of adverse effect

Descriptor	Examples of descriptions
Minimal	Mild reversible short term adverse health effects to individuals in highly localised area Highly localised and contained environmental impact, affecting a few (less than ten) individuals members of communities of flora or fauna, no discernible ecosystem impact Low dollar cost of containment/cleanup/repair (<$5,000) No social disruption6
Minor	Mild reversible short term adverse health effects to identified and isolated groups7 Localised and contained reversible environmental impact, some local plant or animal communities temporarily damaged, no discernible ecosystem impact or species damage Dollar cost of containment/cleanup/repair in order of $5,000-$50,000 Potential social disruption (community placed on alert)
Moderate	Minor irreversible health effects to individuals and/or reversible medium term adverse health effects to larger (but surrounding) community (requiring hospitalisation) Measurable long term damage to local plant and animal communities, but no obvious spread beyond defined boundaries, medium term individual ecosystem damage, no species damage Dollar cost of containment/cleanup/repair in order of $50,000-$500,000, Some social disruption (e.g. people delayed)
Major	Significant irreversible adverse health effects affecting individuals and requiring hospitalisation and/or reversible adverse health effects reaching beyond the immediate community Long term/irreversible damage to localised ecosystem but no species loss Dollar cost of containment/cleanup/repair in order of $500,000-$5,000,000 Social disruption to surrounding community, including some evacuations
Massive	Significant irreversible adverse health effects reaching beyond the immediate community and/or deaths Extensive irreversible ecosystem damage, including species loss Dollar cost of containment/cleanup/repair greater than $5,000,000 Major social disruption with entire surrounding area evacuated and impacts on wider community

The economic effects category has been given a surrogate magnitude. This is for demonstration as a means of illustrating the type of magnitudes that might be encountered.

[6] The concept of social disruption includes both physical disruption, and perceptions leading to psychological disruption. For example, some chemicals may have nuisance effects (through odour) that result in communities feeling threatened.

[7] Note that the reference to 'groups' and 'communities' in the context of human health effects includes the notion of groups defined by health status.

Table 2 Magnitude of beneficial effect

Descriptor	Examples of descriptions
Minimal	Mild short term positive health effects to individuals in highly localised area Highly localised and contained environmental impact, affecting a few (less than ten) individuals members of communities of flora or fauna, no discernible ecosystem impact Low dollar benefit (<$5,000) No social effect
Minor	Mild short term beneficial health effects to identified and isolated groups Localised and contained beneficial environmental impact, no discernible ecosystem impact or species damage Dollar benefit in order of $5,000-$50,000 Minor localised community benefit
Moderate	Minor health benefits to individuals and/or medium term health impacts on larger (but surrounding) community and health status groups Measurable benefit to localised plant and animal communities expected to pertain to medium term. Dollar benefit in order of $50,000-$500,000, Local community and some individuals beyond immediate community receive social benefit.
Major	Significant beneficial health effects to localised community and specific groups in wider community Long term benefit to localised ecosystem(s) Dollar benefit in order of $500,000-$5,000,000 Substantial social benefit to surrounding community, and individuals in wider community.
Massive	Significant long term beneficial health effects to the wider community Long term, wide spread benefits to species and/or ecosystems Dollar benefit greater than $5,000,000 Major social benefit affecting wider community

Likelihood of effect occurring

Likelihood in this context applies to the composite likelihood of the end effect, and not either to the initiating event, or any one of the intermediary events. It includes:

- the concept of an initiating event (triggering the hazard), and
- the exposure pathway that links the source (hazard) and the area of impact (public health, environment, economy, or community).

The likelihood term applies specifically to the resulting effect or the final event in the chain, and will be a combination of the likelihood of the initiating event and several intermediary likelihoods[8]. The frequency or probability solely of the initial incident or hazard event should not be used (as it sometimes is in the safety discipline).

[8] Qualitative event tree analysis may be a useful way of ensuring that all aspects are included.

The best way to determine the likelihood is to specify and analyse the complete pathway of the "chain of events" from source to the final environmental impact or effect. Each event in the chain is dependent upon the previous event occurring in the first place.

Likelihood may be expressed as a frequency or a probability. While frequency is often expressed as a number of events within a given time period, it may also be expressed as the number of events per head of (exposed) population. As a probability the likelihood is dimensionless and refers to the number of events of interest divided by the total number of events (range 0-1).

Table 3 Likelihood (adverse effect)

	Descriptor	Description
1	Highly improbable	Almost certainly not occurring but cannot be totally ruled out
2	Improbable (remote)	Only occurring in very exceptional circumstances.
3	Very unlikely	Considered only to occur in very unusual circumstances
4	Unlikely (occasional)	Could occur, but is not expected to occur under normal operating conditions.
5	Likely	A good chance that it may occur under normal operating conditions.
6	Very likely	Expected to occur if all conditions met
7	Extremely likely	Almost certain

Table 3 provides an example of a set of generic likelihood descriptors for adverse and beneficial effect. Note that when estimating these likelihoods, the impact of default controls should be taken into account.

The table is not symmetrical. This is to allow for classification of very low probability adverse effects.

In practical terms, where the exposure pathway is complex, it may be conceptually difficult to condense all the information into a single likelihood. For any risk where the likelihood is other than 'highly improbable' or 'improbable', then an analysis of the pathway should include identifying the 'critical points'; the aspects that are the most vulnerable, and the elements where controls might be used to 'cut' the pathway.

Calculating the level of risk

Using these qualitative descriptors for magnitude of effect and likelihood of the event occurring, an additional two-way table representing a level of risk (combined likelihood and measure of effect) can be constructed as shown in Table 4, where six levels of effect are allocated: A, B, C, D, E and F. These terms have been used to emphasise that the matrix is a device for determining which risks (benefits) require further analysis to determine their significance in the decision making process. Avoiding labels such as 'low', 'medium', and 'high' removes the aspect of perception.

The lowest level (A) may be deemed to be equivalent to 'insignificant'. In this table 'A' is given to three combinations; minimal impact and an occurrence of improbable or highly improbable, and minor impact with a highly improbable occurrence. In some cases where there is high uncertainty it may be preferable to split this category into A1 and A2, where only A1 is deemed to equate to insignificant.

For negative effects, the levels are used to show how risks can be reduced by the application of additional controls. Where the table is used for positive effects it may also be possible for controls to be applied to ensure that a particular level of benefit is achieved, but this is not a common approach.

Table 4 Calculating the level of risk (benefit)

	Magnitude of effect				
Likelihood	**Minimal**	**Minor**	**Moderate**	**Major**	**Massive**
Highly improbable	A	A	B	C	D
Improbable	A	B	C	D	E
Very unlikely	B	C	D	E	E
Unlikely	C	D	E	E	F
Likely	D	E	E	F	F
Very likely	E	E	F	F	G
Extremely likely	E	F	F	G	G

The table presented here is symmetric around an axis from highly improbable and minimal to massive and extremely likely, however, this will not necessarily be the case in all applications.

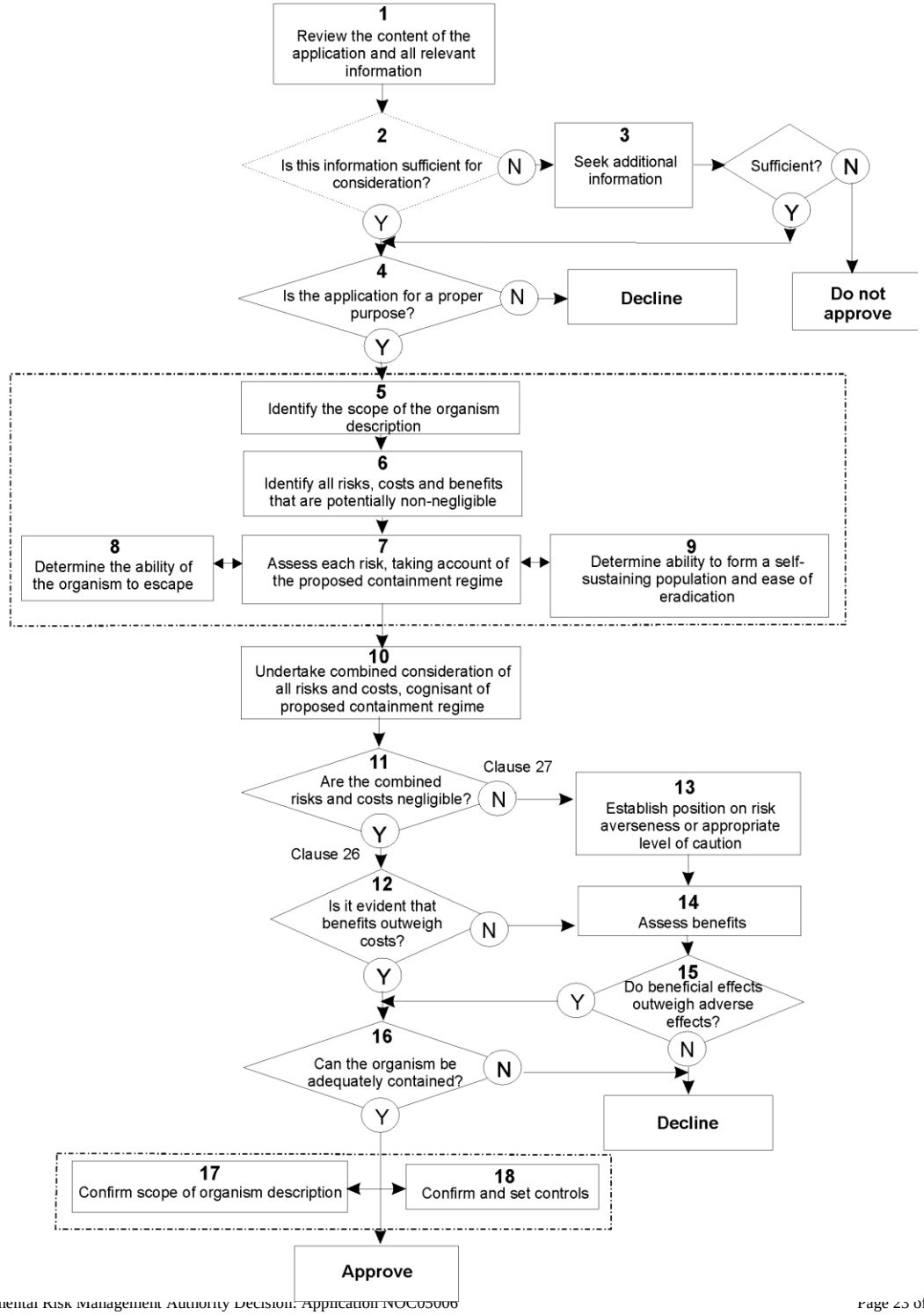
Impact of uncertainty in estimates

Uncertainty may be taken into account in two ways. Firstly, when describing a risk a range of descriptors may be used. For example, a risk may be allocated a range of very unlikely-improbable, and minor-major. This would put the range of the risk as B through E. Alternatively, the level of risk (or benefit) may be adjusted *after* it has been estimated on the grounds of uncertainty.

Appendix 3: Decision Pathway and explanatory notes

Figure 9: Decision path for applications to import into containment a new organism (non GMO) (application made under Section 40 of the Act and determined under Section 45 of the Act)

THE DECISION PATH MUST BE READ TOGETHER WITH THE ATTACHED NOTES



NOTES to Figure 9- Decision path for applications to import into containment a new organism (non GMO) (application made under Section 40 of the Act and determined under Section 45 of the Act)

An application may include a number of organisms or may be for a "generic" application. In both of these cases the organisms having similar risk profiles should be grouped into categories. Each category should be considered separately via the path below.

Items 1, 2 & 3:	Information that should be reviewed includes that in the application, the advice from the Agency, from experts and in submissions (where relevant). Review should occur in terms of section 40(2) of the Act and clauses 8, 15, 16, 20 and 22 of the Methodology. Additional information may need to be sought under s58 of the Act. If the applicant is not able to provide sufficient information for consideration then the application is not approved. In these circumstances the Authority may choose to decline the application, or the application may lapse.	
Item 4:	Acceptable purposes are set out in section 39 of the Act	
Item 5:	Clearly identify the scope of the organism description with particular reference to where the application is generic, or refers to a number of organisms.	
Item 6:	The range of risks, costs and benefits to be identified should be that covered by clauses 9, 10 and 11 of the Methodology. This is a two step process.	
	Step 1:	Identify all possible risks, costs and benefits
	Step 2:	Eliminate those risks, costs and benefits that can be readily concluded to be negligible
Item 7:	The assessment of risks and costs should be carried out in accordance with clauses 12 to 14, 22, 25, and 29 to 32 of the Methodology. The process of risk assessment includes the estimation of the likelihood and magnitude of each effect. The assessment is carried out with the controls proposed by the applicant and any controls required to meet the provisions of the 3rd Schedule of the Act in place. The assessment also includes the following steps.	
	Step 1:	Consideration of the extent to which the risk will be mitigated by the default controls.
	Step 2:	Consideration of how risk averse or cautious the Authority should be in giving weight to the residual risk (clause 33 of the Methodology), where residual risk is the risk remaining after the imposition of controls.
	Note that only risks and costs are assessed at this stage, since assessment of benefits depends on whether the decision follows the clause 26 or clause 27 path.	
	The process of risk assessment is not linear. It is very iterative. In essence all of the steps (including the steps in items 8 & 9) must be repeated until a satisfactory conclusion is reached.	
Item 8:	Determine the ability of the organism to escape from containment and consider any addition controls that might be imposed that would reduce the likelihood of escape (Section 44).	
Item 9:	Determine the ability of the organism to form a self-sustaining population and ease of eradication of this occurred (Section 37)	

Item 10:	Once the risks and costs have been assessed individually, consider all risks and costs together, taking account of the proposed controls (item 7) and any additional controls proposed in Item 8.
Item 11:	Consider whether any residual risks are negligible. An holistic perspective should be adopted, taking into account the particular characteristics of the substance and the feasibility of the proposed controls.(if necessary, review the controls).
Item 12:	This item constitutes a decision made under clause 26 of the Methodology. If risks are negligible and there are no external costs (costs accrue only to the applicant), then the fact that the application has been submitted is deemed to demonstrate existence of benefit, and no further benefits need be considered. However, if external costs exist then all benefits need to be assessed.
Item 13:	Although 'risk averseness' is considered as a part of the assessment of individual risks, it is good practice to consolidate the view on this if risks are non-negligible. Clause 33 of the Methodology applies, as does section 7 of the Act dealing with caution in the face of scientific and technical uncertainty.
Item 14:	Assess benefits in terms of clause 13 of the Methodology.
Item 15:	In weighing up adverse and beneficial effects, clause 34 of the Methodology applies. Where this item is taken in sequence from items 13 and 14 (i.e. risks are not negligible) it constitutes a decision made under clause 27 of the Methodology, and adverse effects comprise risks and costs. Where this item is taken in sequence from items 12 and 14 (i.e. risks are negligible, and costs do not accrue only to the applicant) it constitutes a decision made under clause 26 of the Methodology, and adverse effects comprise costs only. At this step the scope of the organism description for generic application should be reviewed. If changes are made to the organism description, items 6 to 14 above should be repeated for the revised organism description. Then the weighing up process in this item for the revised organism description should also be repeated.
Item 16:	The meaning of the phrase "adequacy of containment" needs to be extended so that it covers both the satisfactory biological and/or physical containment of the organisms. If the organism description was revised in item 15, the considerations in this item should relate to the revised organism description. If, as a result of this consideration, further revision of the organism description is required, the determination as to whether the organisms can be adequately contained should be repeated for the new organism description.
Item 17:	The scope of the organism description has been identified in item 5. This step in the decision-making process confirms the scope of the organism description in such a way that the risk boundaries are defined.
Item 18:	Controls have been considered at the earlier stages of the process (items 7, 8, 10 and 16). However, this step confirms and sets the controls. Controls flow from, but are considered in conjunction with, the organism description. If controls are changed at this point, the previous steps need to be repeated.