ENVIRONMENTAL RISK MANAGEMENT AUTHORITY DECISION

Amended under s67A on 6 September 2007 and 30 August 2011

26 November 2004

Application code:	NOC04016
Application category:	Import into Containment any New Organism under the Hazardous Substances and New Organisms (HSNO) Act 1996
Applicant:	Victoria University of Wellington P O Box 600 Kelburn Parade Wellington 6015
Applicant contact:	Ken Ryan
Purpose:	To import into containment samples of Antarctic water (both fresh and marine in all states) and soil, sediments and rocks containing unidentified micro-organisms for identification and long term culture
Date application received:	23 September 2004
Consideration date:	29 October 2004
Considered by:	Committee of the Authority

1 Summary of Decision

The application to import into containment the following samples which are likely to contain new organisms 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):

- Prokaryotic (primarily bacteria, archaea, cyanobacteria[1]) and eukaryotic microorganisms[2] (algae, phytoplankton, zooplankton[3], protozoa, and micro-

[1] Cyanobacteria are also referred to as "blue-green algae" or "blue-green bacteria". These organisms were originally grouped with algae because of their photosynthetic ability. It is now realised that they are bacteria and not related to any of the algae.

[2] Organisms that may only be observed under a microscope.

[3] Zooplankton are a community of floating, aquatic, minute animals and non-photosynthetic protists.

invertebrates) present in water[4], soils/sediments, rock and microbial mat samples taken from Antarctic marine and freshwater environments.

2 Legislative Criteria for Application

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 under Part II of the Act. Unless otherwise stated, references to section numbers in this decision refer to sections of the Act.

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.

Application Process

The application was formally received and verified on 23 September 2004.

Under section 53(2) of the Act 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 it was considered that there would not be significant public interest which might warrant notification of this application, having regard to guidelines referred to above.

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 Authority were notified and provided with an opportunity to comment on the application. Comments from both DoC and MAF, and the applicant's responses to those comments, are included in the Evaluation and Review (E&R) Report prepared by the Agency.

The Authority, with the consent of the applicant, under section 59 (5) also waived the requirement to notify the applicant that further information (contained in the E&R Report) was available for inspection no less than ten working days before the commencement of the consideration (section 58(2) of the Act). The E&R Report was provided to the applicant nine working days prior to the consideration and a response was obtained before the consideration.

Information Available for Consideration

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

[4] Including water in all states: such as sea ice, snow and sea water

- Application NOC04016 (form 2N);
- Scientific references cited in the application;
- Quarantine and Containment Manual for the School of Biological Sciences (Version number 4) that meet the MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.02 (Containment Facilities for Microorganisms).
- Evaluation and Review (E&R) Report prepared by the Agency to assist and support the Committee's decision-making including comments on the application from DoC and MAF.

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.

Decision Making Committee

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 Max Suckling (Chair), Associate Professor Marie Dziadek, Dr Kieran Elborough.

3 Sequence of the Consideration

In accordance with clause 24 of the Methodology, the approach adopted by the Committee was to look sequentially at identification, assessment and evaluation of risks, costs and benefits. Interposed with this was the consideration of the adequacy of the proposed containment regime, and the ability of the organism to escape and to form self-sustaining populations. Management techniques were considered in relation to the identified risks and those risks identified as significant were assessed (clause 12 of the Methodology). Costs and benefits were assessed in accordance with clause 13 of the Methodology.

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.

4 Purpose of the Application

The Committee was satisfied that the purpose of the application fell under section 39(1)(h) of the Act: The importation of any new organism into containment for such other purposes as the Authority thinks fit.

The purpose of the application was to allow Victoria University to import into containment samples containing micro-organisms such as bacteria, algae, phytoplankton, zooplankton, protozoa, foraminifera, and micro-invertebrates collected from Antarctica. The resulting micro-organisms would then be identified with a view to determining Antarctic microbial diversity, monitoring natural changes or cycles in microbial communities and compiling a bio-inventory of the micro-organisms in ice covered regions of the Ross Sea. It is also intended to study the physiological requirements of these organisms in order to determine the effect of ecological and climate changes in the Antarctic. These studies will contribute to the development of policy for the protection of Southern Ocean marine ecosystems.

5 Adequacy of the Containment Regime

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 probability 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.

Ability to adequately contain the organisms

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

i. biological characteristics of the organisms;

ii. ability of the organisms to establish a self-sustaining population

iii. containment regime;

iv. potential pathways for escape of the organisms from the containment facility.

(i) Biological characteristics of the organism

The biological characteristics of the organisms likely to be isolated from these samples are described in detail in section 4 of the E&R Report. Samples will be collected from a number of habitats in Antarctica and the surrounding Southern Ocean including soils, sea ice, snow, sea water, small stones and sediments from the sea floor, freshwater habitats and associated aquatic materials namely sediments, stones, underlying soil and rock, and

microbial mats**.** It should be noted that sea ice brines have temperatures from -2ºC to -15ºC and salinity that varies from that of seawater to several times more concentrated than seawater. The seawater temperature under sea ice is -1.8ºC to -1.9ºC. Benthic[5] samples will also be exposed to similar temperatures as that for seawater. Some samples will be taken from soils with a temperature range of -40ºC to 5ºC, particularly those from around bird colonies. Therefore, the Committee consider it is likely that the microorganisms identified from these environments will be psychrophilic[6] and are unlikely to inhabit temperate environments. The organisms likely to be isolated from these samples can be grouped into several kingdoms including:

- protista, eukaryotic organisms including unicellular and multicellular algae, slime molds, and unicellular or simple colonial protozoans,
- bacteria,
- archaea, a super-classification of odd bacteria, initially thought to be a very ancient group differing from bacteria and eukaryotes in their cell wall structures and chemistry, lipidic membrane structure and metabolism,
- animalia, specifically micro-invertebrates.

As this approval is for unidentified organisms an additional control was imposed that requires users of the approval to forward to ERMA New Zealand any publication in which any unidentified organism imported in accordance with this approval, (and which are not already recorded on the ERMA New Zealand Register of new organisms), is assigned a taxonomic classification. (Control 6.1)

(ii) Ability of the organism to establish a self-sustaining population

The Committee considered the ability of the microorganisms likely to be isolated from samples to form a self-sustaining population and the ease of eradication of such a population. The Committee noted that due to the wide range of organisms likely to be isolated their ability to form a self-sustaining population varied.

The Committee considered that organisms isolated from extreme cold and/or hypersaline environments would be unlikely to form a self-sustaining population within New Zealand temperate waters, however, those isolated from less extreme environments could. The Committee also noted that should such a population establish it may be difficult to detect and will be nearly impossible to eradicate.

[5] From the sea floor

[6] Organisms that require cold environments such as 0°C (32°F) for growth.

(iii) Containment regime

The applicant samples will be imported into the Transitional Facilities for Biological Products and Containment Facilities for Microorganisms at the School of Biological Sciences, Victoria University of Wellington. The School's containment facilities include both PC1 and PC2 laboratories registered by MAF according to the MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.02 (Containment Facilities for Microorganisms). The applicant proposes to hold and work with the samples in a PC1 laboratory in accordance with the Australian/New Zealand Standard Safety in Laboratories Part 3: Microbiological aspects and containment facilities (AS/NZS 2243.3:2002) and MAF/ERMA Standard 154.03.02.

On the basis of the biological characteristics of microorganisms likely to be isolated from the samples the Committee considered the containment level of PC1 to be adequate. The Committee did note that the Australian/New Zealand Standard 2243.3:2002 also requires the use of a biological safety cabinet where there is a significant risk from production of aerosols[7] that may be hazardous to laboratory workers or the environment. As terrestrial soil and Antarctic freshwater algae can produce desiccation-resistant airborne spores which may be capable of long distance dispersal, an additional control (control 6.2) was imposed to mitigate the risk of this potential exposure pathway. Control 6.2 states that all manipulations involving samples that may contain terrestrial or freshwater algal spores should be performed in a biological safety cabinet that is operated in accordance with the requirements of AS/NZS 2647.

The Committee considered that there is some limited uncertainty regarding the potential for Risk Group 2 organisms to be isolated due to the exact taxonomic identification of the organisms being unknown at the time of import. An additional control (control 6.3) is imposed that states that in the improbable event that a microorganism known to cause human, plant or animal disease is identified in the samples (i.e. Risk Group 2) it should be moved to the appropriate containment level (i.e. PC2) or destroyed as described in the AS/NZS Standard 2243.3:2002 as soon as practically possible.

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

The Committee identified four potential pathways of escape including:

i. escape during transport to containment facilities;

ii. escape from the containment facilities by accidental/unintentional or deliberate removal by staff

[7] Suspension in air of finely dispersed solids or liquids

iii. escape from the containment by accidental/unintentional or deliberate removal by unauthorised persons;

iv. escape from the containment following natural disaster (flood, earthquake etc.) or fire.

The Committee considered that adherence to the regulations set out in the MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.02 regarding transportation of the samples would make escape during transport highly improbable.

The Committee considered that adherence to operational procedures detailed in the MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.02, which covers all aspects of laboratory management including operation and management of the facility, control of access, vermin control, waste disposal, and staff training would make escape due to accidental/unintentional or deliberate removal by staff highly improbable.

The Committee considered that restricted access to the containment facility as specified in the MAF/ERMA Standard 154.03.02, which limits the opportunity for unauthorised persons to aid escape from containment is adhered to, escape by accidental/unintentional or deliberate removal by unauthorised persons is highly improbable.

The Committee considered that the contingency plan provided included appropriate procedures to prevent escape following power failure and fire. However, the Committee noted the need for the applicant to develop a contingency plan to prevent adverse effects occurring should an accidental release or spillage of microorganisms, sabotage or theft occur in order to comply with the MAF/ERMA Standard 154.03.02.

In conclusion, the Committee considered that based on the proposed containment regime (that is physical facilities and operational procedures) and the biology of the organism, escape during transport, accidental or deliberate removal by staff and/or unauthorised persons and/or natural disaster is highly improbable.

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

In accordance with clause 9(c) of the Methodology, the Committee in association with the applicant 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 requirements of clauses 12, 13, and 14 of the Methodology, 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 of the Methodology. The degree of uncertainty attached to evidence is taken into account, as required under clauses 25, 29 and 30 of the Methodology.

Potential for the organisms to be pathogenic or toxic to plants or animals in New Zealand

While it is noted that algae can cause blooms that result in aquatic "dead zones" due to oxygen depletion or toxin production, algae likely to be isolated from these samples will not encounter the necessary conditions (i.e. melting of huge volumes of sea ice and up-welling of cold nutrient rich water at the ice edge) in New Zealand waters for this to occur. Also most of the organisms likely to be isolated obtain energy via photosynthesis and none of the species of microorganisms isolated from Antarctica to date are known to be pathogenic to plants or animals. Based on this information the Committee considered that the risk to New Zealand flora and fauna via formation of algal blooms, toxins or pathogenicity in the remote event of escape from containment to be negligible.

Potential for disruption of New Zealand's microflora environment through competition with and displacement of native microorganisms

The Committee noted that as organisms capable of forming self-sustaining populations likely to be isolated from the samples are probably already present in New Zealand and no adverse effects have been realised. As a result the Committee considered that the risk of disruption of New Zealand's microflora environment through competition with and displacement of native microorganisms is negligible.

Potential for the microorganisms to be pathogenic or toxic to humans

The Committee noted the majority of organisms in the families represented by those likely to be isolated from Antarctic samples (such as Archaea, Eubacteria, Protista, and Animalia) are not known to cause any human disease. Of the few exceptions to this none have been isolated from Antarctic region. Also in the unlikely event of escape these organisms are not expected to form self-sustaining populations so the adverse effect would not be realised. Any occupational exposure will be prevented provided that requirements of the MAF/ERMA standard and additional controls are adhered to. The Committee considers that the risk posed by the microorganisms to be pathogenic or toxic to humans is negligible.

Māori and their culture and traditions

The Committee considers that as the risks of escape from containment and establishment of the microorganisms likely to be isolated from the Antarctic samples are negligible, the potential risks to the mauri of native flora, fauna and ecosystems are also negligible.

The market economy

The Committee considers that as the risks of escape from containment and establishment of the microorganisms likely to be isolated from the Antarctic samples are negligible, the potential risks to the market economy via the seafood industry are also negligible.

7 Identification and assessment of potentially significant beneficial effects

In accordance with clause 9(c) of the Methodology, the Committee has identified potential beneficial effects. These beneficial effects have been considered in terms of the requirements of clauses 13, and 14 of the Methodology, including the probability of occurrence and the magnitude of beneficial effects, whether or not they are monetary, the distribution of benefits over time, space and groups in the community.

The Committee considered that the main benefits of approving this application would be:

- Potential for facilitation of scientific collaborations and increased international scientific reputation for New Zealand scientists
- Potential for contribution to education of New Zealand students
- Development of a bio-inventory of Antarctic aquatic microorganisms
- Improved understanding of the ecology and biodiversity of microorganisms in Antarctica.

The Committee agrees with the analysis of these benefits as set out in the E&R report. The benefits are highly likely to be realised and of some importance to the users of this approval. The Committee therefore considers these benefits to be non-negligible.

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

Clause 33 of the Methodology requires the Authority to have regard for the extent to which a specified set of risk characteristics exist when considering applications. This provision 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 application being "in containment" and the conclusion that the containment provisions and other controls will reduce most biological and physical risks to a low level.

In relation to the biological and physical risks considered (and 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 of the microorganisms likely to be isolated from the Antarctic samples and the establishment of an undesirable self sustaining population. Given the Committee's finding that the risk of escape from containment occurring is improbable, as is the establishment of a self-sustaining population, the extent

to which these risk characteristics are present does not warrant caution additional to that required by section 7 of the Act.

9 Overall Evaluation of Risk, Costs and Benefits

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.

The Committee considered that the risks as a whole are negligible, so therefore the decision is made in accordance with clause 26 (not clause 27) of the Methodology.

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 organism can be adequately contained, and that it is evident that the benefits of the application outweigh the costs.

10 Decision

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, being section(s) 39(1)(h): Such other purposes as the Authority thinks fit.

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 the following organisms are outweighed by the benefits:

   Prokaryotic (primarily bacteria, archaea, cyanobacteria[8]) and eukaryotic microorganisms[9] (algae, phytoplankton, zooplankton[10], protozoa, and micro-

[8] Cyanobacteria are also referred to as “blue-green algae” or “blue-green bacteria”. These organisms were originally grouped with algae because of their photosynthetic ability. It is now realised that they are bacteria and not related to any of the algae.

[9] Organisms that may only be observed under a microscope.

[10] Zooplankton are a community of floating, aquatic, minute animals and non-photosynthetic protists.

invertebrates) present in water[11], soils/sediments, rock and microbial mat samples taken from Antarctic marine and freshwater environments. The organisms proposed for import are likely to be Risk Group 1[12] organisms for which it is highly improbable that they will be pathogenic or have any significant adverse effect on New Zealand's native and valued introduced flora or fauna.

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.

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 2, matters to be addressed by containment controls for new organisms.

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 23 – obtaining further information;
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.

[11] Including water in all states: such as sea ice, snow and sea water

[12] As defined in AS/NZS 2243.2:2002 as "a microorganism that is unlikely to cause human, plant or animal disease".

6. The application for importation into containment of is thus **approved**, **with controls**, as set out in Appendix 1.

_____ 26 November 2004

Dr Max Suckling Date

Chairperson of Decision-making Committee

Approval code: NOC002379

Amendment: November 2006
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
- Removal of the control regarding inspection of facilities by the Authority, its agent or enforcement officers

_____ Date: 6 September 2007

Dr Max Suckling
Chair, New Organisms Standing Committee

Amendment: August 2011
Changes to controls:

- Removal of Control 6.1, which required the person using the approval to forward to ERMA New Zealand any publication in which any unidentified organism imported in accordance with this approval, (and which are not already recorded on the ERMA New Zealand Register of new organisms), is assigned a taxonomic classification.
- Standardisation of the wording of control 6.2 regarding the identification of a Risk group 2 organism.

_____ 30 August 2011

Richard Woods Date

Chair, Decision Making Committee
Environmental Protection Authority

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*[13] 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[14]:

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)/ERMA New Zealand Standard 154.03.02[15]. Containment Facilities for Microorganisms.

b) Australian New Zealand Standard AS/NZS 2243:3 2002[15] *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[15]: 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.

[13] 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.

[14] 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.

[15] 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 The applicant 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[15], 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 of this document.

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[15].

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 manipulations involving samples that may contain terrestrial or freshwater algal spores should be performed in a biological safety cabinet that is operated in accordance with the requirements of AS/NZS 2647[16].

[16] AS 2647 *Biological safety cabinets-Installation and use*

6.2 In the even that the organism is found to be a Risk Group 2[17] organism, the EPA and the MAF Inspector responsible for supervision of the facility must be notified immediately and all research involving the organism must cease. The organism can be held in storage for up to one year while a new approval is sought. If a new approval is not obtained within a year, the organism must be destroyed.

[17] Risk Group 2 (moderate individual risk, limited community risk)- a pathogen that can cause human, plant or animal disease, but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment, laboratory exposures may cause infection, but effective treatment and preventive measures are available, and the risk of spread is limited.