ENVIRONMENTAL RISK MANAGEMENT AUTHORITY DECISION

Amended under s67A on 6 September 2007, 28 June 2010, 16 February 2011 and 30 August 2011

Date Signed: 31 March 2006

Application code:	NOC06002
Application category:	Import into Containment any New Organism under the Hazardous Substances and New Organisms (HSNO) Act 1996
Applicant:	University of Auckland
Applicant contact:	David Jenkins
Purpose:	Importation into containment of non-pathogenic micro-organisms to form a reference collection for diagnostic and taxonomic research purposes
Date application received:	13 February 2006
Consideration date:	14 March 2006
Considered by:	Committee of the Authority

1. Summary of Decision

1.1. Application NOC06002 to import into containment the following organisms is approved, with controls (as detailed in Appendix 1 of this decision), having been 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):
'Risk Group 1 species (as defined in the Australia/New Zealand Standard 2243.3:2002: Safety in Laboratories Part 3: Microbiological aspects and containment facilities, fifth edition, or any equivalent subsequent editions) belonging to the taxonomic groups currently known as bacteriophages and Bacteria, Archaea and yeasts of the Order Saccharomycetales'.

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 NOC06002 was determined to be in compliance with section 40(2) of the Act and was formally received on 13 February 2006.

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. Both MAF and DoC responded with suggestions regarding additional controls which were discussed by the Committee as noted in this decision. Neither group opposed the application.

Decision Making Committee

3.4. The application was considered by a Committee of the Authority (the Committee), appointed in accordance with section 19(2)(b) of the Act and clause 43 of the First Schedule to the Act. For the purposes of determining this application the Committee comprised the following members: Dr Max Suckling (Chair), Dr Kieran Elborough and Ms Helen Atkins. Consideration was undertaken at a meeting on 14 March 2006.

Information Available for Consideration

3.5. The documents available for the consideration of the application by the Committee were:
Application NOC06002 (Form NO2N): Import into Containment any New Organism that is not genetically modified;
Scientific papers cited in the application;
University of Auckland's Containment Manual; and
Comments on the application from DoC and MAF.

3.6. The Committee determined that the information used for the consideration was sufficiently relevant and appropriate considering the scale and significance of the risks, costs and benefits associated with these microorganisms.

4. Associated Approvals

4.1. The Committee notes that this approval is not specific to the applicant and may be used by other importers. It is therefore desirable 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. For this reason the Committee has imposed an additional control (6.1, Appendix 1) that describes a one-off requirement for users to inform ERMA New Zealand and MAF of their intention to do so.

4.2. For clarity the Committee point out that any person exercising this approval must comply with all other relevant statutes, including the Biosecurity Act 1993.

5. Sequence of the Consideration

5.1. In accordance with clause 24 of the Methodology, the approach to the consideration adopted by the Committee was to look sequentially at the identification, assessment and evaluation of risks, costs and benefits. 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. Those risks identified as significant were assessed in accordance with clause 12 of the Methodology. Management techniques were considered in relation to the identified risks. 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 were provided in the E&R Report. The approach to the consideration followed the decision path outlined in the E&R Report.

5.2. 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.

5.3. The Committee set controls to satisfactorily provide for the matters in the Third Schedule (Part II) of the Act. Additional controls have been included as noted elsewhere in this decision.

5.4. 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.

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[1] Section 62 of the Act.

[2] Section 67A of the Act.

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.

6. Purpose of the Application

6.1. The purpose of this application is to seek approval to import into containment new organisms under section 40(1)(a) of the Act, for research purposes including taxonomy, ecology, biodiversity and biotechnology studies. The Committee considers that this falls within the scope of section 39(h) of the Act.

7. Adequacy of the Containment Regime

7.1. 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.

Ability to adequately contain the organisms

7.2. 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.

Biological characteristics of the organisms

7.3. This approval is for a broad organism description so covers a wide range of microorganisms. The Committee considered that it was still possible to do a risk assessment of the whole group due to the limitation that they meet the Australia/New Zealand Standard 2243.3:2002: Safety in Laboratories Part 3: Microbiological aspects and containment facilities, fifth edition, or any equivalent subsequent editions definition of Risk Group 1 microorganisms that is they are 'unlikely to cause human, plant or animal disease'. This restriction is enforced by additional control 6.2 (Appendix 1) which requires any users of this approval to provide a written declaration to MAF at the time of applying for a permit to import.

7.4. In recognition of the potential for new information to reveal that a microorganism does not meet the Risk Group 1 definition, additional control 6.3 (Appendix 1) requires any user of this approval, in that situation to cease work and inform both MAF and ERMA New Zealand. In support of this control additional control 6.4 (Appendix 1) is designed to aid information sharing by requiring any users of this approval to record in their register of organisms the name of the institute or individual who supplied the culture. This has been done so that if suppliers of organisms publicise new information regarding an organism (for example observation of

pathogenecity, misidentification or contamination) users of this approval will be able to determine if they are affected.

7.5. The potential to import microorganisms meeting the Risk Group 1 definition but having other undesirable traits such as negative environmental impacts is limited by additional control 6.5 (Appendix 1) which prohibits the importation of organisms declared 'unwanted' under the Biosecurity Act 1993.

7.6. Section 20 of the Act requires the Authority to maintain a register of all applications including a unique identifier of approved organisms. Given the broad organism description it is not possible to know in advance what species will be imported so additional control 6.6 (Appendix 1) requires any users of this approval to provide ERMA New Zealand with these details as they become available.

7.7. Four main groups of microorganisms are captured by this approval – Bacteria, Archaea, yeasts and bacteriophages. The kingdom Bacteria represents a large number of genetically diverse organisms that occupy a wide range of environmental niches, utilise various organic compounds for energy, have many structural forms and reproduce in many ways. All bacteria are prokaryotes, that is they have no true nucleus or membrane bound organelles reproduce through binary fission in which cells are 'pinched off' forming clones.

7.8. Members of the domain or superkingdom Archaea are advanced prokaryotes. Many of the members of this group occupy extreme environments such as high temperature, very low or very high pH, high fluid pressures and high salt concentrations. No members of this group have been observed to behave in a pathogenic manner towards humans, plants or animals.

7.9. The term yeasts has been taken to include members of the order Saccharomycetales of the class currently known as Ascomycetes which are generally unicellular and reproduce by budding or fission. This order includes the genus Saccharomyces which are used in the fermentation processes. Due to additional issues relating to escape from containment raised by other fungi additional control 6.7 (Appendix 1) specificially excludes the importation of fungi other than this order.

7.10. Bacteriophages are members of the so called seventh kingdom of viruses. While not truly living, viruses are captured under the HSNO Act definition of an organism as it is "a genetic structure, (other than a human cell) that is capable of replicating itself, whether that structure comprises all or only part of an entity, and whether it comprises all or only part of the total genetic structure of an entity". Viruses can only reproduce by entering a host cell and utilising the existing cellular machinery to replicate themselves. Bacteriophages are viruses that infect bacteria only so while pathogenic they still meet the Risk Group 1 definition.

Containment regime

7.11. The microorganisms shall be imported into and maintained within a containment facility registered under the Biosecurity Act 1993 in accordance with the MAF Biosecurity Authority/ ERMA New Zealand Standard 154.03.02: Containment Facilities for Microorganisms (Standard 154.03.02) and operated at Physical Containment level 1 (PC1) (see controls 1.1, 1.2 and 1.4 in Appendix 1 of this decision). The minimum requirements for PC1 containment are those identified in the Australian/New Zealand Standard 2243.3:2002: Safety in Laboratories Part 3: Microbiological aspects and containment facilities, fifth edition (AS/NZS 2243.3:2002) except for the deviations specified in Standard 154.03.02.

7.12. Standard 154.03.02 requires the facility to be constructed and operated in a manner to ensure that micoorganisms are securely contained and held only within the facility. Standard 154.03.02 contains adequate provisions to ensure that containment is maintained. These provisions cover access, staff training, contingency plans, waste disposal, record keeping and packaging for organisms in transit.

7.13. The containment facility will be run in accordance with the principles of AS/NZS 2243.3:2002, which contains provisions relating to good laboratory procedure (control 1.2, Appendix 1). The Committee noted that adherence to this standard requires that where there is a significant risk from the production of aerosols open container manipulations (whereby the culture is exposed to the atmosphere and includes plating and subculturing) should be conducted in a biological safety cabinet operated in accordance with the requirements of AS/NZS Standard 2243.3:2002. The Committee considered that based on the specified organism description, in particular the absence of fungi with the exception of yeasts, the production of aerial dispersed propagules is unlikely. However, to allow for the possibility proposed additional control 6.8 (Appendix 1) stipulates this requirement except where the user of the approval has assessed and documented, including test methods and results, that aerial dispersed propagules are not formed by the isolate being manipulated. Such documents are to be held by the user of the approval and be available for auditing purposes.

Potential pathways for escape of organisms from the containment facility

7.14. The Committee considered potential pathways for escape of the microorganisms. Four pathways were identified and associated mitigating controls prescribed under Standard 154.03.02 and additional controls to this approval are discussed below.

Escape from containment during transport

7.15. The Committee considered the ability of the microorganisms likely to be imported under this approval to escape containment during transport. Transport of samples are subject to the regulations set out in Standard 154.03.02 (control 1.2, Appendix 1) which details requirements such as packaging being ‘of good quality, strong enough to withstand the

shocks and loadings normally encountered during transport' and triple packaging.

7.16. The Committee noted the potential for inspection at the border to result in accidental release of the organisms. Additional control 6.9 (Appendix 1) places requirements on users of the approval to label packages with the ERMA New Zealand application code and a clearly visible direction that the package should only be opened in a registered containment facility.

Escape from the containment facilities by accidental/unintentional or deliberate removal by staff

7.17. The Committee considered the ability of the microorganisms likely to be imported under this approval to escape due to accidental/unintentional or deliberate removal by staff. Barriers to the escape of the organism by this route include the operation of the facilities in accordance with Standard 154.03.02 (control1.2, Appendix 1) which specify use of procedures to ensure that no accidental or unintended removal of organisms from the facility occurs. These procedures cover all aspects of laboratory management including operation and management of the facility, control of access, vermin control, waste disposal, and staff training. The Committee noted that a number of 'teaching laboratories' are operated under this standard so could utilise this approval.

7.18. Many of the procedures that ensure containment are susceptible to human error and rely on the training and experience of the staff involved. These procedures are potentially compromised by the high volume of students with limited experience in containment procedures that utilise teaching laboratories. For this reason additional control 6.10 (Appendix 1) prohibits the use of any organisms imported under this approval in laboratories used for teaching purposes.

7.19. To limit the potential for escape from containment to occur through unintentional removal of an inoculated host additional control 6.11 (Appendix 1) specificially prohibits the inoculation of any organisms imported under this approval into any other organisms with the exception of bacteriophages. Bacteriophages infect only bacteria and being infected by a bacteriophage does not increase the ability of bacteria to escape containment so the risk of escape is not increased and does not require additional controls.

7.20. The Committee noted that this approval allows small scale fermentation of the organisms. ERMA New Zealand Policy Series: Protocol 3, April 2005, page 39 states that fermentations over 10 L in volume require a development approval. As large scale fermentations present additional risks to escape from containment due to the large volumes involved additional control 6.12 Appendix 1 limits the fermentation of organisms held under this approval to a volume of 10 L..

Escape from containment by deliberate removal by unauthorised persons

7.21. The Committee considered the ability of the microorganisms likely to be imported under this approval to escape due to deliberate removal by unauthorised persons. As noted in section 3.2 significant adverse public interest in research likely to be done under this approval is not expected, so sabotage seems unlikely.

7.22. The Committee noted that adherence to Standard 154.03.02 (control 1.2, Appendix 1) will result in restricted access to the containment facility limiting the opportunity for unauthorised persons to aid escape from containment.

Escape from containment following natural disaster (e.g. flood, earthquake or fire)

7.23. Standard 154.03.02 (control 1.2, Appendix 1) requires a contingency plan for escapes from containment within the facility, or to the outside, to be prepared in the event of accidental release or spillage of microorganisms, fire, sabotage, theft or other emergency. The Committee noted that prior to exercising the approval users will need to develop such a contingency plan and implement it immediately in the event of a breach of containment (control 3.3, Appendix 1) and notify MAF and ERMA New Zealand of the event (control 3.2, Appendix 1).

Conclusion on the adequacy of the containment regime

7.24. The Committee considered that based on the proposed containment regime (that is physical facilities and operational procedures), the additional controls and the biology of the organism, and the additional proposed controls escape during transport, accidental or deliberate removal by staff and/or unauthorised persons and/or natural disaster is highly improbable. Taking all the above into account the Committee concludes that the organisms will be adequately contained.

8. Ability of the Organism to Establish a Self-Sustaining Population and Ease of Eradication

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

8.2. The Committee noted that should an escape from containment occur, given the wide range of organisms likely to be imported (some of which are expected to already be present in New Zealand) it is considered very likely that most of them would be able to form self-sustaining populations. The Committee noted that should a self-sustaining population establish it is likely to go undetected and would be difficult to eradicate.

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

9.1. The Committee considered the potential risks and costs relating to the application, identified and assessed in section 6 of the E&R Report. In accordance with sections 5 and 6 of the Act, and clause 9 of the Methodology, the potential adverse effects of this application were categorised and considered in terms of their area of impact on the environment, on human health and safety, the culture and traditions of Māori, the market economy and society and the community. The Committee considered that there are no significant potential adverse effects on the market economy or on society and the community associated with the importation of the microorganisms.

9.2. The potential risks and costs assessed here are those identified as significant, having regard for those matters set out in clauses 9 and 10 of the Methodology, which reflect sections 5, 6, 8 and 44 of the Act. Risks were considered in terms of the requirements of section 45(4) of the Act and clause 12 of the Methodology, including the assessment of consequences and probabilities, the impact of uncertainty and the impact of risk management. Costs were considered in terms of clause 13 of the Methodology. A "cost" is defined in clause 2 as "the value of a particular adverse effect expressed in monetary or non-monetary terms". Therefore, these have been assessed in an integrated fashion together with the risks of those adverse effects in the following assessment.

Environment

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

9.3. The Committee noted that in order for this adverse effect to be realised a series of events would be required to occur. Firstly, an organism capable of causing disease would need to be imported either as a deliberate act of non-compliance or unknowingly due to a lack of information, escape from containment of that organism in sufficiently large numbers to provide a sufficient base for a self-sustaining population to establish and location of a suitable host.

9.4. The Committee considered that the magnitude of the potential adverse effect would be minimal to minor depending on the hosts affected. Given the containment regime (including the restriction to Risk Group 1 organisms) the Committee consider it to be highly improbable that the effect would be realised. Therefore, the risk of the organisms being pathogenic to plants or animals in New Zealand is negligible

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

9.5. The Committee considered the potential for this adverse effect to occur as a result of competition for natural resources resulting in displacement or interbreeding. In order for this affect to be realised the Committee noted that a similar scenario to that discussed in section 9.3 would be required effect to be

realised except the final event would be aggressive behaviour to compete successfully for resources and/or interbreeding.

9.6. The Committee noted that it was difficult to determine the magnitude of the adverse effect due to the limited understanding of the importance of the microflora in ecosystems and the magnitude would vary depending on the importance of the microorganism affected but determined it be minimal to moderate. For the reasons already discussed in section 9.3 the Committee considered it highly improbable that such an adverse effect would be realised. Therefore, the risk of the microorganisms (excluding bacteriophages) causing disruption of microflora ecosystems is negligible.

9.7. The Committee did a separate risk assessment for bacteriophages given their ability to cause death of bacteria. The magnitude was assessed as being the same as for the other microorganisms (section 9.6), however, given their known effect on bacteria the likelihood was assessed as improbable for a minimal effect and highly improbable for a moderate effect to be realised. Therefore, the risk of bacteriophages causing disruption of microflora ecosystems is negligible.

Human Health and Safety

Potential for the microorganisms to be pathogenic to humans

9.8. The Committee noted that the scenario as discussed in section 9.3 would be required for this adverse effect to be realised. Should the scenario occur the Committee considered that the magnitude would be minimal to minor depending on the human health effect. The Committee considered it highly improbable such an effect would be realised. Therefore, the risk of microorganisms causing human disease is negligible.

Māori and their culture and traditions

Potential for the microorganisms to cause adverse effects to the mauri of native flora, fauna and ecosystems

9.9. In light of the information presented in the preceding risk assessment the Committee considered that adverse effects to the mauri of native flora, fauna and ecosystems would be minimal in magnitude and highly improbable to be realised. Therefore, the risk of microorganisms causing adverse effect to Māori and their culture and traditions is negligible.

10. Identification and assessment of potentially significant beneficial effects

10.1. The Committee considered the potential risks and costs relating to the application, identified and assessed in section 7 of the E&R Report. In accordance with sections 5 and 6(e) of the Act and clauses 9, 10, 13, and 14 of the Methodology. The potential beneficial effects identified are:

- Improved understanding of the role and relative importance of microflora ecosystems;

- Skill development by staff and post-graduate students from working with a range of microorganisms; and
- Enhanced research reputation possibly resulting in additional funding.

10.2. The Committee considered that these beneficial effects would have a moderate magnitude and that it was very likely that they would be realised. Therefore, these benefits were considered to be non-negligible.

11. Establishment of the Approach to Risk in the Light of Risk Characteristics

11.1. 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 controls will reduce most biological and physical risks to a low level.

11.2. 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 considers 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 dependent upon escape from containment of the organisms and the establishment of an undesirable self-sustaining population. Given the Committee's finding that escape from containment and establishment of an undesirable self-sustaining population is highly improbable, while acknowledging the potential for a self-sustaining population to form, but expecting that it will not 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.

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 the microorganisms into containment including the potential for pathogenicity of the microorganisms to flora, fauna or humans, potential disruption of New Zealand's microflora ecosystem and potential for adverse effects to the mauri of native flora, fauna and ecosystems and the continued role of Māori as kaitiaki. These risks were assessed as negligible.

12.3. The potential benefits associated with importing the microorganisms (including increased knowledge, skill development, enhanced research reputation and profitability) would be of moderate value and are very likely to eventuate.

12.4. It is evident to the Committee that these benefits outweigh the costs.

12.5. The Committee has evaluated the potential of the organisms to establish undesirable self-sustaining populations in the highly improbable likelihood that they escape containment. While the organisms do have the biological capacity to establish a self-sustaining population the likelihood of pathogenic organisms being imported and escaping from containment and then forming and undesirable self-sustaining population is considered to be highly improbable.

12.6. 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) of the Methodology.

12.7. The Committee considered all of the controls, set out in Appendix 1, and did so in the context of both preventing the escape of the organisms and effectively managing all 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, specifically section 39(1)(h) of the Act: "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 the following organisms are outweighed by the benefits:
Risk Group 1 species (as defined in the Australia/New Zealand Standard 2243.3:2002: Safety in Laboratories Part 3: Microbiological aspects and containment facilities, fifth edition, or any equivalent subsequent editions) belonging to the taxonomic groups currently known as bacteriophages and Bacteria, Archaea and yeasts of the Order Saccharomycetales'.

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:

Risk Group 1 species (as defined in the Australia/New Zealand Standard 2243.3:2002: Safety in Laboratories Part 3: Microbiological aspects and containment facilities, fifth edition, or any equivalent subsequent editions) belonging to the taxonomic groups currently known as bacteriophages and Bacteria, Archaea and yeasts of the Order Saccharomycetales'.

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.

Dr Max Suckling Date: 31 March 2006

Chair, New Organisms Standing Committee of the Authority

Approval codes: NOC002470

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
- 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
- Correction of cross reference to contingency plan in control 6.3

_____ Date: 6 September 2007

Dr Max Suckling
Chair, New Organisms Standing Committee

Amendment: November 2009

Changes to controls:

- Removal of controls that duplicate the requirements of the MAF/ERMA New Zealand Standard: *Facilities for Microorganisms and Cell Cultures: 2007*
- Removal of controls 6.2 and 6.5, the requirements of which are managed under the Biosecurity Act 1993
- Inclusion of two controls (new controls 1 and 2)
- Simply wording of controls and update controls to reflect current wording used in recent approvals

_____ Date: 28 June 2010

Dr Shaun Ogilvie
Chair

Amendment: January 2011
Amend decision to remove *Rhodopseudomonas palustris* determined to be not a new organism, through non-statutory advice

Dr Max Suckling **Date :** 16 February 2011
Chair of New Organisms Standing Committee

Amendment: August 2011
Deletion of control 13 - The approval user must notify ERMA New Zealand of the name and unique identifier of any organism imported under this approval within three months of importation.

Alteration of the control regarding what to do in the event that new information on the pathogenicity of the organisms becomes available.

_____ 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,* 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. The approval user (organisation using this approval) must ensure compliance with the following controls.

2. This approval is limited to the importation into containment of non-pathogenic micro-organisms (Risk Group 1) for the purpose of forming a reference collection for diagnostic and taxonomic research purposes.

3. Subject to the other controls of this approval, the organisms must be held within a containment facility in accordance with the MAF-ERMA New Zealand Standard *Facilities for Microorganisms and Cell Cultures: 2007*[3] (the microorganism standard) at Physical Containment Level 1 (PC1), as defined in AS/NZS Standard 2243.3.2002, *Safety in Laboratories Part 3: Microbiological Aspects and Containment Facilities*[1] (the AS/NZS Standard).

4. The approval user must, the first time it uses this approval at each containment facility, notify ERMA New Zealand and the MAF Inspector in writing.

5. The only fungal species that can be imported are those belonging to the order currently known as Saccharomycetales.

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

6. All packages of organisms must be clearly labelled with the HSNO Act approval code NOC002470 and the direction that the primary package[4] must not be opened outside of a containment facility. That labelling documentation must be attached to the package in such a way that the primary package does not have to be opened to access it.

7. The name and address of the institute or individual that supplied the approved organisms must be recorded in the register of culture collection (as defined in the microorganism standard).

8. All 'open container[5]' manipulations of organisms must be performed in a biological safety cabinet in accordance with the requirements of the AS/NZSStandard unless documented evidence is provided that aerial dispersed propagules are not formed by that organism.

9. The approved organisms must not be stored or used in 'teaching laboratories'[6].

10. The approved organisms must not be used to deliberately infect living organisms with the exception of endoparasites of bacteria eg bacteriophages and *Bdellovibrio*-like organisms.

11. Fermentations of approved organisms in liquid culture must not exceed 10 L in a single vessel.

12. Within 24 hours of the discovery of any breach of containment[7] the approval user must notify the MAF Inspector of the breach and details of any action taken to restore containment.

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[4] Primary package means the package that comes into direct contact with the organisms.

[5] Open container manipulations are procedures whereby the culture is exposed to the atmosphere and includes plating and subculturing.

[6] Teaching laboratories are differentiated from research laboratories as being places where the primary purpose is to give instruction, training, or lessons as opposed to the conducting of experiments for the purpose of gathering new information.

[7] A breach of containment includes: escape of organism(s), unauthorised entry to the facility, and/or the structural integrity of the facility being compromised.

13. If new information on the pathogenicity of the organism becomes available 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 one year, the organism must be destroyed.