ENVIRONMENTAL RISK MANAGEMENT AUTHORITY DECISION

Amended under s67A on 6 September 2007 and 30 August 2011

Date Signed: 18 October 2004

Application code:	NOC04013
Application category:	Import into Containment any New Organism under section 40(1)(a) of the Hazardous Substances and New Organisms (HSNO) Act 1996
Applicant:	Institute of Geological & Nuclear Sciences
Applicant contact:	Matthew Stott
Purpose:	To import sediments and fluids that may contain unidentified and potentially novel microorganisms from hydrothermal marine vents and adjacent areas, for the purpose of biodiversity, ecology and biotechnology studies
Date application received	23 August 2004
Consideration date:	24 September 2004
Considered by:	Committee of the Authority

1 Summary of Decision

The application 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):

> Prokaryotic microorganisms[1] present in soils/sediments and fluids taken from hydrothermal vent systems including, but not limited to, the organisms listed in Appendix 2 of this decision.

2 Legislative Criteria for Application

The application was lodged pursuant to section 40(1)(a) of the Act and 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.

[1] Primarily bacteria and archaea.

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

The application was formally received on 23 August 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 because it is unlikely that there would be any significant public interest in this application.

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 Biosecurity Authority (MAFBA) were notified and provided with an opportunity to comment on the application. Comments were included in the Evaluation and Review (E&R) Report prepared by the Agency.

The Authority, with the consent of the applicant, 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 five 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 ERMA New Zealand were:

- Application NOC04013 (form 2N);
- Scientific references cited in the application;
- Containment and Quarantine Manual for the Containment Facility for Microorganisms, Microbial Biodiversity Research Group, Institute of Geological & Nuclear Sciences, version 1(July 2004);
- 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) Standing Committee of the Authority (the Committee) appointed in accordance with section 19(2)(b) of the Act. The Committee comprised the following members: Associate Professor Marie Dziadek (Chair), Dr George Clark and Mr Neil Walter.

4 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 organisms to escape and to establish self-sustaining populations. Management techniques were considered in relation to the identified risks and those risks identified as significant were assessed (clause 12). 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.

5 Purpose of the Application

The Committee was satisfied that the purpose of the application fell under section 39(1)(h): such other purposes as the Authority thinks fit.

The purpose of the application is to obtain approval "to import sediments and fluids that may contain unidentified and potentially novel microorganisms from hydrothermal marine vents and adjacent areas, for the purpose of biodiversity, ecology and biotechnology studies."

6 Identification of the Significant Risks, Costs and Benefits of the Organism

The Committee considered the potential risks, costs and benefits relating to the application, identified in the E&R Report. In accordance with sections 5 and 6 of the Act, and clause 9 of the Methodology, the potential adverse and beneficial effects of this application were categorised and considered in terms of their area of impact on the environment, on human health and safety, and on Māori and their culture and traditions.

The Committee identified the following potential adverse effects in accordance with clauses 9 and 10 of the Methodology that reflect sections 5, 6, 8 and 44 of the Act:

Potential adverse environmental effects

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

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

- Unknown adverse effects from unidentified novel micro-organisms that are potentially present in the sediment/fluid samples.

Potential adverse effects on human health and safety

- Potential for the microorganisms to be pathogenic to humans.

Potential adverse effects on Māori and their culture and traditions

- Adverse effects to the mauri of native fauna and ecosystems and the continued role of iwi/Māori as kaitiaki.

Potential beneficial effects associated with the import into containment of the organisms

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, 10, 13, and 14 of the Methodology. The following beneficial effects were identified:

- Potential for gains in scientific knowledge in understanding the ecology of hydrothermal vent systems.

- Potential for the facilitation of scientific collaborations and increased international scientific reputation for New Zealand scientists.

7 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

(i) Containment regime

The samples collected from the hydrothermal vent systems shall be imported into a MAF registered containment facility operated to physical containment level 1 (PC1) in accordance with the MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.02 *Containment Facilities for Microorganisms* (the Standard) (controls 1.1, 1.2, 1.4). The minimum requirements for PC1 containment are those identified in the AS/NZS 2243.3:2002[2] except for the deviations specified in the Standard.

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

[2] Australian New Zealand Standard AS/NZS 2243:3 2002 Safety in Laboratories: Part 3: (*Microbiological aspects and containment facilities*).

The Committee noted the comments made by DoC and MAF regarding the physical containment level that is appropriate for potentially pathogenic microorganisms (Appendices 3 and 4 of the E&R Report). The Committee agree that potentially pathogenic microorganisms require physical containment level 2 (PC2) containment[3] however, an assessment of the risk of such organisms being present in these samples (*infra*) indicates that this risk is negligible because it is highly improbable and of minimal impact. The Committee considers that PC2 containment is only warranted where the material is likely to contain microorganisms that are normally able to cause animal, plant or human disease or have biological characteristics that make them more likely to escape from containment. The absence of these criteria in this application means that PC1 level containment is appropriate.

(ii) Biological characteristics of the organism

While some of the organisms to be imported in these samples will not have been formally identified the biological characteristics can be described as in section 4 of the E&R Report. The containment regime is considered to be adequate to contain prokaryotic microorganisms which are not independently motile and which may produce endospores.

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

The Committee has considered the potential pathways of escape of the organisms from containment (as outlined in section 6 of the E&R Report) and conclude that escape during transportation, or escape from the containment facility is highly improbable. This view is formed on the basis of the provisions of the Standard that relate to transport packaging, laboratory procedures for handling biological material, the management of the facility and contingency plans.

The Standard requires a contingency plan for escapes from containment within the facility, or to the outside, to be prepared. Section 4.9 Contingency Plans, states "action shall be immediately taken to prevent further release and where possible destroy the escaped microorganisms". The Committee further enhance this measure with controls that require the contingency plan to be implemented immediately following any breach of containment (control 3.3) and notification to MAF and ERMA New Zealand following such an occurrence (control 3.2).

ABILITY TO ESCAPE CONTAINMENT

The Committee has considered the ability of the organisms to escape from containment, the containment conditions and the potential pathways of escape. Taking all of these considerations into account it is highly improbable that the organisms would be able to escape from containment.

(iv) Ability of the organisms to establish a self-sustaining population

The Committee have considered the evidence that the microorganisms to be imported will have specific growth requirements, that there are no known natural terrestrial features in New

[3] As defined in Australian New Zealand Standard AS/NZS 2243:3 2002 Safety in Laboratories: Part 3: (*Microbiological aspects and containment facilities*).

Zealand that mimic the chemistries and physical conditions of marine hydrothermal vents, the likely quantities of microorganisms to be worked with, and inoculum sizes required for population establishment, and microbial population dynamics (sections 6.28-6.35 of the E&R Report). On the basis of this evidence the Committee considers it highly improbable that a self-sustaining population would establish in New Zealand if an escape from containment occurred. However, if such a population did establish it may be difficult to detect and to eradicate.

8 Assessment of the Potentially Significant Risks, Costs and Benefits

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. 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.

The evidence available was scientific in nature and was considered in terms of clause 25(1) of the Methodology. This evidence comprised principally that provided by the applicant and additional evidence set out in the E&R Report.

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

The evidence presented by the applicant describing the types and characteristics of the microorganisms that are typically found in hydrothermal vent systems indicates that these extremophiles have very specific growth requirements. The Committee therefore considers that even in the event of an escape from containment, it is highly improbable that the microorganisms would be able to colonise or establish on any of New Zealand's flora or fauna and cause adverse effects. The magnitude of any adverse effect should the organism escape would be minimal, therefore, the risk to New Zealand flora and fauna is considered to be negligible.

Potential for disruption of New Zealand's microflora environment

As discussed above, the Committee consider that it is highly improbable that these organisms would be able to form a self-sustaining population in the event of an escape from containment. If the organisms cannot establish self-sustaining populations then it is highly improbable that they could cause an adverse effect on New Zealand's microflora by competition and displacement of indigenous microorganisms. The magnitude of any adverse effect can be considered to be minimal and the risk to the environment is negligible.

Unknown adverse effects from unidentified novel microorganisms that are potentially present in the sediment/fluid samples

The Department of Conservation (DoC) and MAF in commenting on this application both raised the issue of the need for caution when considering applications to import unidentified organisms. The perceived risk is of unexpected effects that may be present due to the lack of characterisation of the unidentified organisms. The Committee notes that 87 species that may potentially be found in hydrothermal vents have been identified and a significant amount of information is known about the characteristics of organisms that may inhabit these extreme environments (refer to section 4 of the E&R Report). The evidence presented to the Committee indicates that microbial diversity in these environments is likely to be low and to be restricted to the biological characteristics described in section 4 of the E&R Report. Therefore the Committee concludes that the likelihood of any unanticipated adverse effects is improbable and the level of risk is negligible.

Potential for the microorganisms to be pathogenic to humans

The Committee considers that it is highly improbable that any of the microorganisms to be imported would be pathogenic to humans or animals and in the event of occupational or any other type of human exposure to the organism, the magnitude of any adverse effect would be minimal. Therefore, the overall risk to human health from this application is considered to be negligible.

The microorganisms previously isolated from hydrothermal vents have not been identified as pathogenic to humans or animals and it is anticipated that all microorganisms found in these samples will similarly be Risk Group 1[4] organisms. The Committee recognises that there is a residual uncertainty in regarding these organisms as non-pathogenic because novel species may be found that have not previously been characterised. However, this conclusion is based on the evidence that hydrothermal vents have remained relatively un-exposed to human activity and that any microorganisms present there have not had the opportunity to co-evolve with a mammalian host and therefore, will not have evolved any pathogenic traits. In addition, the selective pressures associated with the extreme conditions found in hydrothermal vent systems would favour the evolution of environmental adaptations that are different to those required to colonise a mammalian host organism. The 87 species identified from hydrothermal vents to date have been classified as belonging to Risk Group 1.

In recognition of the residual uncertainty noted above the Committee places a condition on this approval that requires the immediate transfer to PC2 containment[5] of any organism subsequently identified as capable of causing human, animal or plant disease (control 6.2). If this eventuality occurs, the facility Operator shall notify ERMA New Zealand who may then reassess that organism.

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[4] Risk Group 1 is defined in the Australian New Zealand Standard AS/NZS 2243:3 2002 Safety in Laboratories: Part 3: (Microbiological aspects and containment facilities) as a microorganism that is unlikely to cause human, plant or animal disease.

[5] Containment at physical containment level 2 as defined in the Standards listed in control 1.2.

Adverse effects to the mauri of native fauna and ecosystems and the continued role of iwi/Māori as kaitiaki.

The Committee considered the potential Māori cultural effects of this application in accordance with sections 6(d) and 8 of the HSNO Act 1996, and the assessment framework contained in the ERMA New Zealand User Guide "Working with Māori under the HSNO Act 1996".

On the basis of the above discussion, even in the event of an escape from containment, it is highly improbable that the microorganisms would be able to colonise or establish on any of New Zealand's flora or fauna and cause adverse effects. In addition, the magnitude of any adverse effect should the organism escape would be minimal due to their unique growth requirements.

Considering this information, the Committee therefore considers that the likelihood of adverse effect to the mauri of native flora, fauna and ecosystems is highly improbable and the magnitude of any adverse effect is minimal. On this basis, the application poses negligible risk to the relationship between Māori culture and their traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga.

Assessment of benefits (beneficial effects)

The Committee considered that the following benefits, which may be derived from an approval of this application, are likely to be realised, would be shared between the applicant and the greater scientific community and are likely to be of moderate value:

- Gains in scientific knowledge in understanding the ecology of hydrothermal vent systems.
- Facilitation of scientific collaborations and increased international scientific reputation for New Zealand scientists.

The Committee also noted that the long-term goal of the research is to use the scientific knowledge to develop new technologies and that this is reflected in the widely drafted scope of the purpose statement.

9 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 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 dependant upon the ability of the organisms to cause disease and that these risks are localised,

controllable and reversible. However, it is considered that in the event of the organism establishing a population it would be difficult to eradicate. Given the Committee's finding that escape from containment and population establishment is highly improbable, the extent to which these risk characteristics are present does not warrant caution additional to that required by section 7 of the Act.

10 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 and clause 26, having regard to clauses 22 and 34.

The Committee has assessed the potential risks of importing these organisms into containment including potential pathogenicity/toxicity to plants, animals and humans; potential disruption of New Zealand's microflora, potential for adverse effects to the mauri of native fauna and ecosystems and the continued role of Māori as kaitiaki; and potential unknown adverse effects from unidentified novel organisms that may be present in the samples. These risks were assessed as negligible.

The benefits (primarily gains in scientific knowledge, facilitation of collaborative research and increased international scientific reputation) are considered to be likely to be realised and would be of moderate value.

The Committee has assessed the establishment of self-sustaining populations of any of these organisms in New Zealand to be highly improbable. The proposed containment regime, based on the MAF/ERMA New Zealand Standard 154.03.02 Containment Facilities for Microorganisms at PC1 level, is considered to be adequate considering the risks posed by the organisms. Additionally, it is considered highly improbable that the organisms would be able to escape from this level of containment.

The Committee was unable to find common units of measurement with which to combine risks and costs in accordance with clause 34(a). There were no dominant sources of risk. Because the risks as a whole are negligible, 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, and did so in the context both of preventing the escape of the organisms and of effectively managing any risks. The Committee, having taken regard of 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.

11 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 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 approved organisms are outweighed by the benefits.

3. The Committee is satisfied that the proposed 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 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 33 – the risk characteristics; and
clause 34 – the aggregation and comparison of risks, costs and benefits.

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

    Prokaryotic microorganisms present in soils/sediments and fluids taken from hydrothermal vent systems including, but not limited to, the organisms listed in Appendix 2 of this decision.

_____ Date: 18 October 2004

Associate Professor Marie Dziadek

Chairperson of Decision-making Committee

Approval codes: NOC002338; NOC002295-NOC2377 inclusive; NOC000990; NOC000991; NOC001013; NOC001018; NOC001019

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

Deletion of control 6.1 requiring any person using the approval to forward to ERMA New Zealand any publication in which any unidentified organism imported under this approval is assigned a taxonomic classification.

Alteration of the wording of the control regarding what to do if at a risk group 2 organism is identified.

_____ 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 organism is subject to the following controls: [6]

1 To limit the likelihood of any accidental release of any organism or any viable genetic material[7]:

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

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

a) Ministry of Agriculture and Forestry (MAF)/ERMA New Zealand Standard 154.03.02[8]: *Containment Facilities for Microorganisms* (the Standard).

b) Australian New Zealand Standard AS/NZS 2243:3 2002[8] *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 facilities shall be approved by Ministry of Agriculture and Forestry (MAF), in accordance with section 39 of the Biosecurity Act and the Standard.

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.

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[6] 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.

[7] 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.

[8] 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 relating to the maintenance of records demonstrating compliance with the Standard, 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 Standard.

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 In the event that an organism is found to be a risk group 2 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.

Appendix 2: List of approved organisms[9]

Microbial genus and species name		Domain	Risk classification*	Optimal growth temp.	Culture collection reference	reference
Aquifex	*pyrophilus*	*Bacteria*	1	85˚C	DSM 6858	Huber *et al.,* 1992
Balnearium	*lithotrophicum*	*Bacteria*	1	70°C	DSM 16304	Takai *et al.,* 2003
Caminibacter	*hydrogeniphilus*	*Bacteria*	1	60°C	DSM 14510	Alain *et al.,* 2002
	profundus	*Bacteria*	1	55°C	DSM 15016	Miroshnichenko *et al.,* 2004
Caminicella	*sporogenes*	*Bacteria*	1	60˚C	DSM 14501	Alain *et al.,* 2002
Carboxydothermus	*restrictus*	*Bacteria*	1	65°C	DSM 7242	Svetlichnyi *et al.,* 1994
Catenococcus	*thiocyclus*	*Bacteria*	1	25°C	DSM 9165	Sorokin, 1994
Clostridium	*caminithermale*	*Bacteria*	1	42°C	DSM 15212	Brisbarre *et al.,* 2003
Deferribacter	*abyssi*	*Bacteria*	1	55°C	DSM 14873	Miroshnichenko *et al.,* 2003
	desulfuricans	*Bacteria*	1	62°C	DSM 14783	Takai *et al.,* 2003
Desulfacinum	*hydrothermale*	*Bacteria*	1	60°C	DSM 13146	Sievert and Kuever, 2000
Desulfonauticus	*submarinus*	*Bacteria*	1	45°C	DSM 15269	Audiffrin *et al.,* 2003
Desulfurobacterium	*crinifex*	*Bacteria*	1	60°C	DSM 15218	Alain *et al.,* 2003
	thermolithotrophum	*Bacteria*	1	70°C	DSM 11699	L'Haridon *et al.,* 1998
Ferroglobus	*placidus*	*Archaea*	1	85°C	DSM 10642	Hafenbradl *et al.,* 1997
Geothermobacter	*ehrlichii*	*Bacteria*	1	50-55°C	DSM 15274	Kashefi *et al.,* 2003
Halomonas	*neptunia*	*Bacteria*	1	30˚C	DSM 15720	Kaye *et al.,* 2004
	sulfidaeris	*Bacteria*	1	30˚C	DSM 15722	Kaye *et al.,* 2004
	axialensis	*Bacteria*	1	30˚C	DSM 15723	Kaye *et al.,* 2004
	hydrothermalis	*Bacteria*	1	30˚C	DSM 15725	Kaye *et al.,* 2004
Halothiobacillus	*hydrothermalis*	*Bacteria*	1	35°C	DSM 7121	Durand *et al.,* 1997
	kellyi	*Bacteria*	1	37°C	DSM 13162	Sievert *et al.,* 2000
Hyperthermus	*butylicus*	*Archaea*	1	99°C	DSM 5456	Zillig *et al.,* 1990
Idiomarina	*loihiensis*	*Bacteria*	1	30°C	DSM 15497	Donachie *et al.,* 2003
Ignicoccus	*pacificius*	*Archaea*	1	90°C	DSM 13166	Huber and Stetter, 2000

[9] The approved organisms are all prokaryotic microorganisms present in soils/sediments and fluids taken from hydrothermal vent systems including, but not limited to, those organisms on this list. For a complete updated list of identified organisms covered by this approval refer to the ERMA New Zealand Register of new organisms (http://www.ermanz.govt.nz).

Microbial genus and species name		Domain	Risk classification*	Optimal growth temp.	Culture collection reference	reference
Marinithermus	*hydrothermalis*	*Bacteria*	1	70°C	DSM 14884	Sako *et al.,* 2003
Marinitoga	*camini*	*Bacteria*	1	55°C	DSM 13578	Wery *et al.,* 2001
	piezophila	*Bacteria*	1	65°C	DSM 14283	Alain *et al.,* 2002
Methanocaldococcus	*fervens*	*Archaea*	1	85°C	DSM 4213	Jeanthon *et al.,* 1999
	infernus	*Archaea*	1	85°C	DSM 11812	Jeanthon *et al.,* 1998
	vulcanius	*Archaea*	1	80°C	DSM 12094	Jeanthon *et al.,* 1999
	indicus	*Archaea*	1	85°C	DSM 15027	L'Haridon *et al.,* 2003
	jannaschii	*Archaea*	1	80-85°C	DSM 2661	Jones *et al.,* 1984
Methanotorris	*igneus*	*Archaea*	1	85°C	DSM 5666	Burggraf *et al.,* 1990
Methanopyrus	*kandleri*	*Archaea*	1	98°C	DSM 6324	Kurr *et al.,* 1992
Methanothermococcus	*okinawensis*	*Archaea*	1	65°C	DSM 14208	Takai *et al.,* 2002
	thermolithotrophicus	*Archaea*	1	65°C	DSM 2095	Huber *et al.,* 1984
Nanoarchaeum	*equitans*	*Archaea*	1	90˚C?	-	Huber *et al.,* 2003
Oceanithermus	*profundus*	*Bacteria*	1	60°C	DSM 14977	Miroshnichenko *et al.,* 2003
Palaeococcus	*ferrophilus*	*Archaea*	1	80-83°C	DSM 13482	Takai *et al.,* 2000
Persephonella	*marina*	*Bacteria*	1	70°C	DSM 14350	Götz *et al.,* 2002
	guaymasensis	*Bacteria*	1	70°C	DSM 14351	Götz *et al.,* 2002
	hydrogeniphila	*Bacteria*	1	70°C	DSM 15103	Nakagawa *et al.,* 2003
Pyrococcus	*horikoshii*	*Archaea*	1	95°C	DSM 12428	González *et al.,* 1999
	woesei	*Archaea*	1	97-100°C	DSM 3773	Zillig, 1988
	furiosus	*Archaea*	1	97-100°C	DSM 3638	Fiala and Stetter, 1986
Pyrodictium	*brockii*	*Archaea*	1	85-105°C	DSM 2708	Stetter *et al.,* 1984
	occultum	*Archaea*	1	85-105°C	DSM 2709	Stetter *et al.,* 1984
	abyssi	*Archaea*	1	98°C	DSM 6158	Pley and Stetter, 1991
Pyrolobus	*fumarii*	*Archaea*	1	103°C	DSM 11204	Blöchl *et al.,* 1999
Rhodothermus	*marinus*	*Bacteria*	1	65°C	DSM 4253	Alfredsson *et al.,* 1995
Staphylothermus	*marinus*	*Archaea*	1	85-90°C	DSM 3639	Fiala *et* al., 1986
	hellenicus	*Archaea*	1	85°C	DSM 12710	Arab *et al.,* 2000
Stetteria	*hydrogenophila*	*Archaea*	1	93°C	DSM 11227	Jochimsen *et al.,* 1997
Tepidibacter	*thalassicus*	*Bacteria*	1	50°C	DSM 15285	Slobodkin *et al.,* 2003
	formicigenes	*Bacteria*	1	45°C	DSM 15518	Urios *et al.,* 2004
Thermaerobacter	*marianensis*	*Bacteria*	1	75°C	DSM 12885	Takai *et al.,* 1999
	nagasakiensis	*Bacteria*	1	70°C	DSM 14512	Nunoura *et al.,* 2002
Thermoanaerobacter	*siderophilus*	*Bacteria*	1	70°C	DSM 12299	Slobodkin *et al.,* 1999

Microbial genus and species name		Domain	Risk classification*	Optimal growth temp.	Culture collection reference	reference
Thermococcus	*profundus*	*Archaea*	1	80°C	DSM 9503	Kobayashi and Horikoshi, 1995
	chitonophagus	*Archaea*	1	85°C	DSM 10152	Huber and Stetter, 1996
	alcaliphilus	*Archaea*	1	85°C	DSM 10322	Keller *et al.,* 1995
	peptonophilus	*Archaea*	1	85°C	DSM 10343	González *et al.,* 1996
	guaymasensis	*Archaea*	1	88°C	DSM 11113	Canganella *et al.,* 1998
	barophilus	*Archaea*	1	85°C	DSM 11836	Marteinsson *et al.,* 1999
	aegaeus	*Archaea*	1	90°C	DSM 12767	Arab *et al.,* 2000
	stetteri	*Archaea*	1	75°C	DSM 5262	Miroshnichenko, 1990
	celer	*Archaea*	1	88°C	DSM 2476	Zillig, 1983
	litoralis	*Archaea*	1	83°C	DSM 5473	Neuner *et al.,* 2001
	pacificus	*Archaea*	1	85°C	DSM 10394	Miroshnichenko *et al.,* 1998
	gorgonarius	*Archaea*	1	85°C	DSM 10395	Miroshnichenko *et al.,* 1998
	acidaminovorans	*Archaea*	1	85°C	DSM 11906	Dirmeier *et al.,* 2001
	siculi	*Archaea*	1	85°C	DSM 12349	Grote *et al.,* 2000
	waiotapuensis	*Archaea*	1	85°C	DSM 12768	González *et al.,* 1999
	aggregans	*Archaea*	1	85°C	DSM 12819	Canganella *et al.,* 1998
	fumicolans	*Archaea*	1	85°C	DSM 12820	Godfroy and Meunier, 1996
	atlanticus	*Archaea*	1	85°C	DSM 15226	Cambon-Bonavita *et al.,* 2003
	gammatolerans	*Archaea*	1	88°C	DSM 15229	Jolivet *et al.,* 2003
Thermodesulfatator	*indicus*	*Bacteria*	1	70°C	DSM 15286	Moussard *et al.,* 2004
Thermodesulfobacterium	*hydrogeniphilum*	*Bacteria*	1	70°C	DSM 14290	Jeanthon *et al.,* 2002
Thermosipho	*japonicus*	*Bacteria*	1	70°C	DSM 13481	Takai and Horikoshi, 2000
Thermotoga	*maritima*	*Bacteria*	1	80°C	DSM 3109	Huber *et al.*, 1986
	neapolitana	*Bacteria*	1	85°C	DSM 4359	Jannasch *et al.,* 1989
Thermovibrio	*ruber*	*Bacteria*	1	80°C	DSM 14644	Huber *et al.,* 2002
	ammonificans	*Bacteria*	1	75°C	DSM 15698	Vetriani *et al.,* 2004
Thiomicrospira	*crunogena*	*Bacteria*	1	25°C	DSM 12353	Jannasch *et al.,* 1985
Vulcanithermus	*mediatlanticus*	*Bacteria*	1	65°C	DSM 14978	Miroshnichenko *et al.,* 2003