ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO

FORM NO2N

Application for approval to

IMPORT INTO CONTAINMENT ANY NEW ORGANISM THAT IS NOT GENETICALLY MODIFIED

under section 40 of the Hazardous Substances and New Organisms Act 1996

Application Title: Importation into containment of non-pathogenic microorganisms to form a reference collection

Applicant Organisation: University of Auckland

ERMA Office use only

Application Code: ☐☐☐☐☐☐☐☐ Formally received:____/____/____

ERMA NZ Contact: _____ Initial Fee Paid: $

Application Status:

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ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
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Application for approval to import into containment any new organism that is not genetically modified, under Section 40 of the Hazardous Substances and New Organisms Act 1996

IMPORTANT

1. An associated User Guide is available for this form. You should read the User Guide before completing this form. If you need further guidance in completing this form please contact ERMA New Zealand.
2. This application form covers importation into containment of any new organism that is not genetically modified, under section 40 of the Act.
3. If you are making an application to import into containment a **genetically modified organism** you should complete **Form NO2G,** instead of this form (Form NO2N).
4. This form, together with form NO2G, replaces all previous versions of Form 2. Older versions should not now be used. You should periodically check with ERMA New Zealand or on the ERMA New Zealand web site for new versions of this form.
5. You can talk to an Applications Advisor at ERMA New Zealand who can help you scope and prepare your application. We need all relevant information early on in the application process. Quality information up front will speed up the process and help reduce costs.
6. This application form may be used to seek approvals for importing more than one new (non-genetically modified) organism into containment where the organisms are of a similar nature.
7. Any extra material that does not fit in the application form must be clearly labelled, cross-referenced, and included as appendices to the application form.
8. Commercially sensitive information must be collated in a separate appendix. You need to justify why you consider the material commercially sensitive, and make sure it is clearly labelled as such.
9. Applicants must sign the form and enclose the correct application fee (plus GST). The initial application fee can be found in our published Schedule of Fees and Charges. Please check with ERMA New Zealand staff or the ERMA New Zealand website for the latest schedule of fees. We are unable to process applications that do not contain the correct initial application fee.
10. Unless otherwise indicated, all sections of this form must be completed for the application to be progressed.
11. Please provide an electronic version of the completed application form, as well as sending a signed hard copy.

You can get more information by contacting us. One of our staff members will be able to help you.

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Application for approval to import into containment any new organism that is not genetically modified, under Section 40 of the Hazardous Substances and New Organisms Act 1996

Section One – Applicant Details

1.1 Name and postal address in New Zealand of the organisation or individual making the application:

Name >
University of Auckland

Postal Address >
PO Box 92019,
Auckland

Physical Address >

Phone >

Fax >

E-mail >

1.2 If application is made by an organisation, provide name and contact details of a key contact person at that organisation

This person should have sufficient knowledge to respond to queries and have the authority to make decisions that relate to processing of the application.

Name >
David Jenkins

Position >
Hazards and Containment Manager,
University of Auckland

Address >

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1.3 If the applicant is an organisation or individual situated overseas, provide name and contact details of the agent authorised to transact the applicant's affairs in relation to the application

This person should have sufficient knowledge to respond to queries and have the authority to make decisions that relate to processing of the application.

Name >

Position >

Address >

Phone >

Fax >

E-mail >

Section Two – Purpose of the Application

This form is to be used for an application to import into containment any new organism that is not genetically modified. For an application to import into containment **a genetically modified organism**, use **Form NO2G**.

2.1 Give a short summary statement of the purpose of this application to be used on ERMA New Zealand's public register. (Maximum of 255 characters).

Briefly describe the organism(s) to be imported into containment, and the purpose(s) for which you wish to import the organism(s).

The importation for research purposes including taxonomy, ecology, biodiversity and biotechnology studies of bacteriophages and non-pathogenic Bacteria, Archaea and yeasts of the Order Saccharomycetales

2.2 Provide a short description of the background and aims of the project suitable for lay readers.

Describe the purpose of the importation and rationale for the overall project these organisms are to be used in so that people not directly connected with the research can understand why these organisms are required.

Microbiological research undertaken in the School of Biological Sciences is focussed on three areas:

- A. Environmental microbiology. This includes identification and partial characterisation of archaea, bacteria and viruses that are present in New Zealand water, sludges and soils. These studies include determining mechanisms of biofilm formation, activation of sludges, and understanding recycling of nutrients and nucleic acids between members of microbial community (microbial loops). Understanding the interaction between bacterial members of these communities and their interaction with other members (such as bacteriophage) is crucial to understanding how these communities survive and are self sustaining. This research may also hold clues as to how these communities limit the growth of each member and the conditions that precede displacement of certain members. These studies will also allow development of more efficient and more accurate tests of water quality, waste water, sewerage and sludge treatment in New Zealand by identifying accurate bio-indicators. It may ultimately lead to the development of NZ-specific bioremediation strategies.
- B. Wine microbiology This includes identification of yeasts present on grapes, wine musts and wine starter cultures in New Zealand that are responsible for flavours and aromatic qualities of wines.
- C. Understanding micro-organism communities in soil rhizospheres. This study seeks to understand the role of bacteria in health and nutrition of plants as well as the process of organic matter cycling.

All of these research areas involve identification of micro-organisms isolated from samples taken in New Zealand. Definitive identification relies on comparison with reference strains which are usually available in accredited overseas repositories such as the American Tissue Culture Collection (ATCC).

In addition to identification, reference strains are a useful for basic research such as provision of nucleic acid samples as well as their use as positive controls in a variety of analytical techniques involving analysis of reference strain genome and proteome. These analyses are often part of, or serve as useful adjuncts, to the identification process.

Importation of reference cultures requires HSNO approval because of their perceived 'new organism' status. While the reference cultures will be used to confirm the identity of micro-organisms isolated from the New Zealand environment a statement on status will not be able to be definitively made at the time of import . An alternative strategy would be to gain a statutory declaration that these organisms are present in New Zealand. This is difficult as unambiguous identification is also hampered by lack of reference strain.

To clear this impasse, we seek to import reference cultures of non-pathogenic micro-organisms (Archaea, Bacteria, Phage and Yeast) into containment. We propose to hold the micro-organisms at physical containment level 1 on the basis that these organisms meet the definition of Risk Group 1 as described in the Australian/New Zealand Standard Safety in laboratories Part 3: Microbiological Aspects and Containment Facilities, 2002. being 'a micro organism that is unlikely to cause human, plant or animal disease. The application, therefore, explicitly excludes micro-organisms with a risk classification of Risk Group 2 or higher (according to the Australian/New Zealand Standard Safety in Laboratories Part 3: Microbiological Aspects and Containment Facilities 2002) as well as excluding micro-organisms listed on the MAF Unwanted Organism Registers. MAF Unwanted Organism registers are tailored to New Zealand requirements and can be amended increase any future information regarding microbial threats to New Zealand's biosecurity.

The ability to unambiguously identify and research micro-organisms isolated in New Zealand will support efforts to improve understanding of New Zealand's biota and an understanding of the microbial diversity that exists in New Zealand.

Section Three – Information on the Organism(s) to be imported

If the application is for importation of more than one organism, this section must be completed separately for each organism. If there are commercial reasons for not providing full information here, alternative approaches must be discussed with and agreed by ERMA New Zealand.

3.1 Give the unequivocal identification of the organism(s) to be imported

These names will be on the public register and should clearly identify the organisms. Please provide details of the following:

Latin binomial, including full taxonomic authority:

see below

Common name(s), if any:

see below

Type of organism (e.g. bacterium, virus, fungus, plant, animal, animal cell):

Non-pathogenic Bacteria, Archaea, Bacteriophage, and unicellular fungi belonging to Order Saccharomycetales (Yeast)

Excluding micro-organisms that:

a. possess a classification of Risk Group 2 or higher in the Australian/New Zealand Standard Safety in Laboratories Part 3: Microbiological Aspects and Containment Facilities 2002
b. are registered as 'Unwanted Organisms' in New Zealand Ministry of Agriculture and Forestry Unwanted Organisms Registry.

Taxonomic class, order and family:

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Strain(s) if relevant:

Other information, including presence of any inseparable or associated organisms:

It is noted that reference cultures are mono-cultures and will not contain any associated or inseparable organisms.

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3.2 Characteristics of the organism(s) to be imported

Provide information on the biology, ecology and the main features or essential characteristics of each organism(s) to be imported. For example, note production of spores/seeds/pollen, conditions for growth and reproduction. Also provide information on affinities of the organism(s) with other organism(s) in New Zealand. This information should be relevant to the identification of the risks of the organism (section 5).

The proposal is for the importation of reference cultures of bacteria, Archaea, yeast and phage into containment to allow definitive identification of low risk micro-organisms already isolated from samples taken in New Zealand. The organisms that are the subject of this application are undoubtedly already present in New Zealand, but their presence has not been discovered and/or documented.

The term 'low risk' in this application is described by exclusion – i.e. those organisms are not notified either on New Zealand MAF registers as 'unwanted' or as having being registered in the Australian/New Zealand Standard Safety in Laboratories Part 3: Microbiological Aspects and Containment Facilities 2002 as having a Risk Classification of Risk Group 2 or higher. It should be noted that the above Australian/New Zealand Standard risk classification is essentially the same as those classifications used in US National Institute of Health (NIH) and Centre for Disease Control (CDC), European Union, and the Canadian LED jurisdictions.

Unwanted organisms are those organisms that have been determined unwanted by Chief Technical Officers of government departments and local territorial authorities with biosecurity interests. The Unwanted Organisms register is a requirement of the Biosecurity Act 1993 and is subject to constant revision and amendment. The register also contains organisms declined importation by the Environmental Risk Management Authority (ERMA NZ), as well as those organisms listed in the second schedule of the Hazardous Substances and New Organisms Act 1996

The following highlights the main features of Archaea, yeasts and phages.
Insert similar paragraph for bacteria and any information on biological characteristics that enhance or create issues for containment (eg aerial spores, growth in sulphuric acid) as discussed on the phone.

Archaea

The domain or superkingdom Archaea was proposed by Woese and Fox to differentiate this group of prokaryotic organisms that were distinct from Bacteria. Archaea are similar to other prokaryotes in most aspects of cell structure and metabolism. However, their genetic transcription and translation - the two central processes in molecular biology - do not show the typical bacterial features, but are similar to those of eukaryotes (e.g. their transcription involves TATA-binding proteins as in eukaryotes). No member of Archaea, at this time, are known to cause disease of humans, plants or animals. This reflects their extreme habitat in which they do not come into contact with 'normal' living organisms so that there has not been any

opportunity for the natural selection of pathogenic traits. It is noted that some extremophiles have adapted through natural selection to the anerobic and acidic conditions of animal digestive system, though they are not disease causing. The vast majority of Archaea are recalcitrant to culture and those which have been cultured are generally described as 'fastidious' in terms of their culture requirements**.**

Bacteria

A major group of prokaryotes which are the most abundant of all organisms. One estimate of the combined membership of Archaea and Bacterial Domains exceed 10 million different taxa, of which it is estimated that less than 20% have been described.

The great antiquity of the bacteria has enabled them to evolve a huge genetic diversity - for instance, the genetic distance between *E. coli* and *Thermus aquaticus* is greater than the distance between humans and oak trees. In line with this huge genetic diversity, bacteria show a wide variety of different metabolisms. The ability of bacteria to degrade a variety of organic compounds is remarkable. Highly specialized groups of microorganisms play important roles in the turnover of organic compounds. For example, the decomposition of cellulose, which is one of the most abundant constituents of plant tissues, is mainly brought about by aerobic bacteria that belong to the genus *Cytophaga.* Bacteria also display a diverse response to presence of oxygen – some can grow only in the presence of oxygen; others can grow only in the absence of oxygen and some are able to exploit both aerobic and anaerobic environments.

Some bacteria are pathogenic on animals and plants. The degree of pathogenicity of a bacterial species is determined by the ability of these pathogenic bacteria to displace normal microflora, penetrate host defences, and evade detection by the host immune system. The number of pathogenic bacteria are vastly overshadowed by the numbers of species ubiquitously present in soils, water or as symbionts on other organisms - one estimate puts the diversity of organisms at three to five thousand different bacteria per gram of soil.

In soil, microorganisms help in the transformation of nitrogen to ammonia with enzymes secreted by these microbes, which reside in the rhizosphere (a zone that includes the root surface and the soil that adheres to the root after gentle shaking). Some bacteria are able to use molecular nitrogen as their source of nitrogen, converting it to nitrogenous compounds, a process known as nitrogen fixation. Many other bacteria are found as symbionts in other organisms, where in some cases their presence is crucial. The presence of the bacteria in the gut of ungulates is essential for them to breakdown cellulose and the case of humans, gut flora in the large intestine is critical in the prevention of growth of potentially harmful microbes.

Bacteriophage

Bacteriophage are viruses that infect only bacteria. Viruses can only reproduce in a host organism. The genetic material (either in the form of DNA or RNA) within the protein coat enters

a hosts either actively by infection or passively by entry points such as wounds (explaining why many viruses are transmitted by insect vectors). Specific host cells are infected by active inclusion of the virus particle or naked nucleic acid into the cell. Once inside in the cell the virus manipulates the host's genetic machinery to replicate itself. Eventually the new virus particles are released by the action of the virus itself or external factors, going on to infect hew hosts.

Like viruses that infect eukaryotes (plants, animals and fungi), bacteriophages consist of an outer protein hull and the enclosed genetic material (which consists of double-stranded DNA in 95% of the phages known) of 5 to 650 kbp (kilo base pairs) with a length of 24 to 200 nm. The vast majority of bacteriophage (95%) have a tail to let them inject their genetic material into the host. Bacteriophage are omnipresent, with millions in just one drop of ordinary water.

Bacteriophages are a specific type of virus that infect prokaryotic cell types including the Bacteria and Archea only.. There is probably a phage for every species of bacterium. Some phages are virulent, meaning that upon infecting a cell they immediately begin reproducing, and within a short time lyse (destroy) the cell, releasing new phages. (A famous quote from the microbiologist Mark Müller says: *Bacteria don't die, they just phage away.*) Some phages (so-called *temperate phages*) can instead enter a relatively harmless state, either integrating their genetic material into the chromosomal DNA of the host bacterium or establishing themselves as plasmids. These endogenous phages, referred to as prophages, are then copied with every cell division together with the DNA of the host cell. They do not kill the cell, but monitor (*via* some proteins they code for) the status of their host. When the host cell shows signs of stress (meaning it might be about to die soon), the endogenous phages become active again and start their reproductive cycle, resulting in the lysis of the host cell. An example is phage λ of E. coli.

Bacteriophages may infect a single type or closely related group prokartyotes.. Viruses which normally infect humans, plants or animals are, by definition, not included in the bacteriophage group. Bacteriophages meet the Risk Group 1 criteria because, although they are viruses, they are not infectious to humans, animals or plants.

Fungi belonging to Order Saccharomycetales (Yeast)

Yeasts constitute a group of single-celled (unicellular) fungi, all of which are eukaryotes belonging to the phylum Ascomycota. The class Hemiascomycetes of the phylum Ascomycota includes the yeasts and yeast-like fungi. These are morphologically simple fungi; no ascoma is formed, and the asci are produced free on the host or substrate. Asexual reproduction occurs by the formation of blastospores (budding) or, less frequently, by fission arthrospores. Two main orders are recognized, the Saccharomycetales and the Taphrinales. Order Taphrinales have been excluded from this application as many members are pathogenic on plants.

Only a very few yeasts in the order Saccharomycetales, such as *Candida albicans*, can cause infection in humans. The vast majority are not pathogenic. More than one thousand species of

yeasts have been described and the most commonly used, and arguably the most economically important, are the *Saccharomyces sensu stricto* complex. This complex comprises *S. cerevisiae* and its close relatives which are used in alcoholic fermentation and baking applications.

Yeasts inhabit a wide range of habitats and may have either obligately aerobic or facultatively anaerobic physiology. In the presence of high sugar concentrations, fermentative yeasts produce their energy by converting sugars into carbon dioxide and ethanol (alcohol). Yeast may exist as diploids and also go through sexual reproduction. The *Saccharomyces sensu stricto* complex are among the best molecularly characterised organisms on the planet – *S. cerevisiae* was the first eukaryote whose genome was entirely sequenced. Due to their amenable laboratory traits (quick and easy growth, ease of genetic manipulation, molecularly well characterised), yeasts also serve as a very popular model experimental organism.

Section Four – The Proposed Containment System and its Effectiveness

4.1 Describe the proposed containment system (physical and operational) and the ability of the organism(s) to escape from this system. The adequacy of the containment regime is a principal consideration so you need to provide comprehensive information on the containment system. Containment facilities must be registered by MAF, and you should provide documentary evidence of this. Refer to relevant containment manuals as appropriate. Please also ensure that ERMA New Zealand has an up-to-date copy of the containment manual relating to this facility. Identify possible pathways of escape of the organism(s) from containment, including through lapses of security or sabotage. Describe the biological features of the organism(s) that might affect its ability to escape from containment.

It is proposed that the reference cultures that are the subject of this application be imported into one of four microbiology laboratories on the 3rd floor of the School of Biological Sciences Containment and Transitional Facility (SBS Containment Facility). A copy of the Containment Manual for the SBS Containment Facility is held on file at ERMA New Zealand.

The SBS Containment Facility is registered and approved to five MAF standards – 154.03.02 being the most relevant.

Laboratories within the School of Biological Sciences and work practices within those laboratories meet the requirements of PC1 (and in some cases PC2) as per Australian/New Zealand Standard Safety in Laboratories Part 3: Microbiological Aspects and Containment Facilities 2002.

Waste material from these laboratories is autoclaved before disposal as medical waste by incineration at Mangere Airport. Collection and transport is undertaken via a registered contractor. Autoclaves are situated on 3rd and 4th floors of the facility.

All staff and postgraduate students who use Containment laboratories undergo Containment and Transitional Facility Training in addition to local rules specific to the School of Biological Sciences Containment facility.

Access to each floor is independently controlled by access card providing access only to authorised persons. If a determined person was able to gain entry to the 3rd floor, they would then have to locate and gain access to the correct locked freezer in which these samples are located. We believe this is an unlikely scenario for escape.

Section Five - Identification and Assessment of Risks, Costs, and Benefits

This section must include information on the beneficial and adverse effects referred to in the HSNO Act. It is easier to regard risks and costs as being adverse (or negative) and benefits as being positive. You should consider costs and benefits with respect to both non-monetary and monetary (dollar) terms and also consider the distribution of this incidence. Provide a brief description of where the information in the application has been sourced from, e.g. from in-house research, independent research, technical literature, community or other consultation.

5.1 Ability of organism(s) to establish a self-sustaining population.

Discuss the ability of the organism(s) to establish an undesirable self-sustaining population, should an escape from containment occur, and the ease with which such a population could be eradicated. You should consider the ability of the organism(s) to survive and reproduce if it did escape from containment.

The proposal is for the importation of reference strains into containment to allow definitive identification of low risk micro-organisms already isolated from samples taken in New Zealand.

Therefore, the reference cultures that are the subject of this application are organisms that have already established in New Zealand. However, reference samples that are able to form undesirable populations (by virtue of being declared 'unwanted' under the Biosecurity Act or having a Risk Group 2 or higher classification) have been deliberately excluded from this application to import into containment.

The ability of these reference cultures from low risk micro-organisms to give rise to spread and displace other micro-organisms is addressed in Section 5.2 and 5.3

5.2 Identify all potential adverse effects of the organism(s).

Identify potential adverse effects associated with the organism(s) and with any inseparable organisms, both within containment, and outside of containment (should an escape occur). Consider effects on the environment, and human health and safety (e.g. of workers in the containment facility), and any ethical and cultural effects. It is important to think about the source of the risk, i.e. the way in which the risk is created (the exposure pathway), and then the consequences of exposure. Adverse effects should be identified for the following categories:

A. Potential adverse effects on the environment, in particular on ecosystems and their constituent parts (e.g. adverse effects on: life supporting capacity of air, water, soil and ecosystems; native and valued introduced flora and fauna; natural habitats and the intrinsic value of ecosystems; New Zealand's inherent genetic diversity; animal or plant health)

The potential adverse effects on the environment that must be considered for any micro-organism held in containment are its potential impact on the environment should it escape containment. The potential adverse effects could be grouped under the following headings:

- Displacement of native microbes
- Cause animal and plant diease
- Ecosystem disruption
- Interbreeding with native microflora

Because these organisms are low risk and are already present in NZ we believe that for reasons stated in 5.3 that all of the above are highly unlikely and the effects of their escape from containment would be negligible.

NB: The ability of micro-organisms to cause plant and animal disease has been discounted from the analysis because the application specifically excludes micro-organisms having a Risk Classification of Risk Group 2 and above and also specifically excludes micro-organisms deemed by MAF to be 'unwanted organisms'

B. Potential adverse effects on public health (including occupational exposure)

Organisms that are known to have adverse effect on human health or to the personnel in the Containment facility (i.e. by virtue of been given a Risk Classification of Risk Group 2 or higher) are specifically excluded from this application.

C. Potential adverse effects on the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga (taking into account the principles of the Treaty of Waitangi). For example, you should consider whether the organism(s) would have an effect on specific native flora or fauna if they escaped from containment.

Any micro-organism that escapes containment could also potentially cause damage to taonga and ecosystems which impacts of mauri and kaitiakitanga

Because these organisms are low risk and are already present in NZ we believe that for reasons stated in 5.3A and C that these effects are negligible.

D. Other potential adverse effects (such as New Zealand's international obligations, social or economic adverse effects, ethical issues)

We do not anticipate any other potential adverse effects because it is highly likely that these organisms already exist in New Zealand. Please see response to Q 5.1 and 5.2A

5.3 Provide an assessment of the adverse effects identified in Sections 5.2.

The assessment should include the nature, likelihood or probability of occurrence, and magnitude of each adverse effect (i.e. **the risk**), and the value (in monetary or non-monetary terms) of a particular adverse effect (i.e. **the cost**). The uncertainty bounds of the information contained in the assessment should also be discussed.
Adverse effects should be assessed in relationship to:

A. Potential adverse effects on the environment, in particular on ecosystems and their constituent parts (e.g. adverse effects on: life supporting capacity of air, water, soil and ecosystems; native and valued introduced flora and fauna; natural habitats and the intrinsic value of ecosystems; New Zealand's inherent genetic diversity; animal or plant health)

The micro-organisms that are subject of this application are already present in New Zealand as part of micro-communities that are normally present in soil, water, biofilms and sludges. The micro-organisms are low risk - risk and unwanted micro-organisms having been specifically excluded from the application.

In the event of removal of a culture and its deliberate release we believe the effects would be negligible and the risks of such an act of sabotage to be very small (ie the ability to gain entry to lab areas, locate the correct freezer, find the correct key and then locate the organism would invoke an extremely low probability).

We believe if such an event was to happen the effect were observed would be localised and transient as environmental constraints would hamper further growth of the micro-organism and force its numbers into decline. Given that these organisms exist in New Zealand, many are fastidious in their growth requirements or require specific hosts potential effects such as displacement of native microbes, ecosystem disruption or interbreeding with native microflora are not plausible scenarios.

In support of our contention that the effect of the intentional release of these micro-organisms would be negligible we note the following:

The survival of any micro-organisms relies on the particular habitat, the availability of nutrients and also on other members of the community (similar to eukaryotic communities and ecological systems). Their outgrowth (population explosion) is constrained by availability of nutrients, environmental factors (e.g. pH) and other members of these communities (i.e. phages).

The micro-organisms that are the subject of this application possess features that will allow their growth to be constrained by availability of nutrients, their microhabitat or by other members of the community.

In any micro-community, (whether this community is in the human gut, on a plant, in soil or in water) there are micro-organisms that possess features that allow them to exploit a

particular micro-habitat more fully (to the detriment of the habitat or displace other members of that community) or have features that allow them to evade community constraint. Such micro-organisms are given descriptors such as pathogenic or unwanted by virtue of their ability to outgrow their micro-environment or micro-community. These micro-organisms are NOT the subject of this application.

In the highly unlikely event that the reference cultures of organisms that are the subject of this application were to escape containment (as a result of deliberate theft and release), we believe their numbers would be constrained by their environment. If they were to be released in higher concentrations (e.g. deliberate theft of a stock culture), these constraints would come into play and their numbers would drop to their normal levels in that environment. We therefore believe the results of intentional release would range from negligible to un-noticeable.

There is no evidence to date that the bacteria, archaea, phage or yeasts that are the subject of this application are responsible for ecosystem disruption or displacement. In fact the reverse is quite likely, ie because they are isolated from NZ environmental samples, they are likely to be normal constituents of these micro-habitats and responsible for maintaining these habitats.

Should information become available in the future that indicates a low risk organism is responsible for adverse effects on humans, plants or animals or the environment in New Zealand, the most likely result would be that it would be added to MAF Unwanted Organism Register and be automatically excluded from importation under this application.

In the highly unlikely event that these organisms were to escape the consequences we believe would range from negligible to un-noticeable. We believe that the risks of such an occurrence are low. The costs would therefore be negligible.

B. Potential adverse effects on public health (including occupational exposure)

Organisms that are known to have risks of adverse effect on human health or to the workers in the Containment facility (i.e. by virtue of been given a Risk Classification of Risk Group 2 or higher by the US National Institute of Health) are specifically excluded from this application.

C. Potential adverse effects on the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga (taking into account the principles of the Treaty of Waitangi). For example, you should consider whether the organism(s) would have an effect on specific native flora or fauna if they escaped from containment. If consultation with Maori has been undertaken, provide details of the process used and the outcome.

In the highly unlikely event that these organisms should escape from containment, we do not anticipate any adverse effects on the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and

other taonga. The reasons for this assessment are the same as given for adverse effects on the environment.

D. Other potential adverse effects (such as New Zealand's international obligations, social or economic adverse effects, ethical issues)

Not applicable.
Refer to response to 5.3 A

5.4 Identification of beneficial effects (benefits)

Identify and describe monetary and non-monetary benefits associated with importing the organism(s) into containment. Outline and discuss the purpose(s) for the importation and the potential use of the organism(s). Focus on the immediate benefits, as well as longer-term benefits. For example, "increase in scientific knowledge", "increased production of agricultural produce". Substantiate claims by reference to sources of information. Specify whether the benefits identified are environmental, public health or economic benefits; and/or are specific benefits to Maori.

The potential beneficial effects are as follows:

1. Identification of New Zealand microfauna.
2. Adding to the sum of scientific knowledge about the relative importance of these micro-organisms in the NZ environment which will enhance reputation of New Zealand scientific community.
3. Aiding education by allowing post-graduate students to undertake projects that involve isolation and identification of micro-organisms from samples taken in NZ.

5.5 Provide an assessment of the benefits identified in Section 5.4.

Estimate the likelihood that the benefits will be realised, the magnitude of benefits associated with importing the organism(s) into containment, and any uncertainties associated with this assessment. You should also indicate who would receive the benefits and the expected time-course of delivery of the benefits.

Unambiguous identification of micro-organisms in samples taken from New Zealand has the immediate and tangible benefit of adding to sum of knowledge about the biodiversity within New Zealand.

In addition to this immediate benefit, the sum of knowledge about New Zealand microflora and the relative importance of these micro-organisms in the NZ environment will be a direct consequence of their identification. This in turn will enhance reputation of such projects and attract more funding to allow investigation of novel methods of assessing soil and water quality, wine making, efficacies of soil treatment on rhizospheres, sludge and water treatments and biotechnologies involved in isolation of novel enzymes.

Post graduate students are important members of research laboratories and are given focussed research projects which are part of the above research objectives. The

availability of reference strains would facilitate post-graduate studies involving the isolation and identification of novel micro-organisms in New Zealand.

Given the expertise of the researchers involved and the projects planned it is highly likely that these benefits will be realised and therefore they are significant.

The ability to isolate and study NZ microfauna would then allow the possibility of their use as a potential source of wealth for all New Zealanders. While the ability to attract funding is tangible and would be almost impossible if reference samples are not available, the ability of funding to generate the potentially huge benefits associated with a biotechnological application is more difficult to quantify because the immediate application of this knowledge is contingent on other discoveries.

5.6 Overall evaluation of risks, costs, and benefits

This overall evaluation is the main task of the Authority. The Authority has to decide whether the beneficial effects of having the organism in containment outweigh the adverse effects of the organism and any associated inseparable organisms. The Authority must also be satisfied that the organism can be safely contained. You may wish to express a view on the relative importance of the different risks, costs and benefits and how they should be brought together in making a decision.

We believe the benefits of being able to import reference cultures of low risk micro-organisms into containment outweigh any potential costs associated with the proposed importation, for the following reasons:

- These cultures will contain no inseperable or associated organisms This application is for importation of Low Risk reference cultures from accredited overseas repositories. As reference cultures they will contain a monoculture of an identified and known micro-organism.

- The range of micro-organisms specifically excludes pathogenic and unwanted micro-organisms.

- The application is for a low risk micro-organisms which can easily be contained under PC1 containment.

- Containment Facilities provided can adequate contain the reference cultures and prevent intentional theft. It is therefore highly improbable these reference will escape.

- The environmental impact would be negligible in case of deliberate sabotage. These micro-organisms are probably already present and possess features which makes them low risk (i.e. that they are constrained by their environment). We therefore believe that potential impacts of ecosystem through displacement would be minimal and the risk very low.

- Negligible environmental impacts? also indicate the potential adverse effect of Maori would also be negligible.

For the above reasons we believe that this proposal has an overall negligible risk. While there is always some uncertainty associated with current knowledge about the impacts of an organisms, we would note the ability of MAF to amend 'Unwanted Organisms ' databases will allow them to respond quickly should information about a particular micro-organisms become available.

The following benefits would accrue to this proposal:

- An immediate and tangible benefit of being able to unambiguously identify micro-organisms in New Zealand and increasing the sum of knowledge about New Zealand Biodiversity.

- An assessment can be made of the relative importance of these micro-organisms in the NZ environment which will be a direct consequence of their identification.

Given the expertise of the researchers involved and the projects planned it is highly likely that these benefits will be realised and therefore they are significant.

Section Six – Additional Information

6.1 Do any of the organism(s) need approvals under any other New Zealand legislation or are affected by international obligations? For example, indicate whether the organism is subject to other New Zealand legislation, e.g. the Biosecurity Act 1993, or Animal Welfare Act 1999; or if the organism(s) are listed in CITES, then approval is required from both the importing and exporting countries.

Importation of reference cultures will additionally require a Permit to Import issued by the Ministry of Agriculture and Forestry pursuant to the Biosecurity Act.

Note that although this application is broad, the use of exclusions will allow MAF Import Management and MAF border staff to independently verify that each imported culture is not a risk organism or an MAF 'unwanted' organism at the time of entry into New Zealand.

6.2 Have any of the new organism(s) in this application previously been considered in New Zealand or elsewhere? For example, has the organism(s) been previously considered for import (e.g. under the Plants Act)?

We are aware of two other similar applications to import low risk micro-organisms into containment.

University of Victoria and Landcare Research have separately been given approval to import soil, water and timber samples from Antarctica for the purposes of isolating micro-organisms into PC1 and PC2 containment respectively (NOC00002 and NOC04016 respectively).

This application differs however in that the cultures involved in this application are pure reference cultures and the organisms identity is known prior to importation. Plant and animal pathogens as well as unwanted organisms are specifically excluded from this application.

There has been at least one application to import reference cultures of Risk Group 2 or higher micro-organisms into containment have been granted to Ministry of Agriculture and Forestry – National Plant Pest Reference Laboratory (NOC 01004). That approval differs from the current application in that the reference cultures were of known plant pathogens.

6.3 Is there any additional information that you consider relevant to this application that has not already been included?

Not applicable

6.4 Provide a glossary of scientific and technical terms used in the application.

Not applicable

6.5 List of appendices.

List any appendices included with this application. Any information that is commercially sensitive, or additional material included with the application (such as details of consultations, referenced articles) should be contained in appendices. The main application should refer to the relevant appendices but be able to be read as a stand-alone document.

Appendix 1: Risk Group 2 3 and 4 Micro-organisms from Australian/New Zealand Standard 2243.3 - Safety in Laboratories Part 3: Microbiological Aspects and Containment Facilities 2002.

Appendix 2: NIH Risk Classification (for comparison with AS/NZS 2243.3)

Appendix 3 :Unwanted Organisms Register: Bacteria, Virus and Fungii

Section Seven – Application Summary

The application seeks to allow the importation of low risk micro-organism reference cultures into containment for the purposes of definitive identification of, and basic research involving micro-organisms in samples of soil, water, sludges, and fermentations collected in New Zealand. In the past importation of these reference cultures has not be permitted due their status as 'new organisms' because their presence has not been specifically documented.

To clear this impasse, we seek to import reference strains of low risk micro-organisms into containment. We are applying for importation into PC1 containment on the basis that these organisms are non-pathogenic. This application explicitly excludes micro-organisms with a risk classification of Risk Group 2 or higher (using A/NZ Starndard) as well as excluding micro-organisms present in MAF Unwanted Organism Registers. MAF Unwanted organism registers are tailored to New Zealand requirements and can be amended to take any future information about micro-organism threat to NZ Biosecurity. Additionally, reference cultures are mono-cultures and will not contain adventitious organisms, which further reduces any uncertainty surrounding that application.

We believe any risks contingent on import of reference cultures of non-pathogenic micro-organisms can easily be contained in a PC1 laboratory within the specified Containment Facility. In the highly unlikely event of deliberate theft and release the effect would range from negligible to unnoticeable. The ability of these micro-organisms to displace other micro-organisms and/or establish undesirable populations is readily constrained by their environment, other members of the micro-communities in which they exist or in many cases their fastidious growth requirements.

In contrast to the low costs associated with the very low risk of escape from containment, there is an immediate and tangible benefit of being able to identify micro-organisms that have hitherto been undocumented using reference strains from reputable overseas repositories. This will increase the sum of knowledge about New Zealand Biodiversity.

Once the micro-organism is identified, an assessment can be made of the relative importance of these micro-organisms in the NZ environment and their practical use in a number of biotechnologies such as bio-indicators of water and soil quality, or as potential source of novel enzymes can be assessed.

Checklist

Please check and complete the following before submitting your application:

All sections completed	Yes
Appendices enclosed	Yes/ NA*
Confidential information identified and enclosed separately	Yes/NA
Copies of additional references attached	Yes/NA
Cheque for initial fee (incl. GST) enclosed	Yes/No
If "yes", state amount:	$…….
Direct credit made to ERMA bank account:	Yes/No
If "yes" give date of direct credit …/…/… and amount deposited:	$…….
Application signed and dated	Yes
Electronic copy of application e-mailed to ERMA New Zealand	Yes

*NA – not applicable

Signed: **Date:**

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ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO