Environmental Protection Authority
Te Mana Rauhī Taiao

APPLICATION FORM
CONTAINMENT

Application for containment approval for new organisms

under the Hazardous Substances and New Organisms Act 1996

Send by post to: Environmental Protection Authority, Private Bag 63002, Wellington 6140 OR email to: noinfo@epa.govt.nz

Application number

APP201737

Applicant

AgResearch Ltd

Key contact

Karen Wilson

Important

This application form should be used if you intend to import, develop or field test any new organism (including genetically modified organisms (GMOs)) in containment. These terms are defined in the HSNO Act. The HSNO Act can be downloaded from: http://www.legislation.govt.nz/act/public/1996/0030/latest/DLM381222.html.

If your application is for a project approval of low-risk genetic modification, use application form EPA0062.

The HSNO (Low Risk Genetic Modification) Regulations can be downloaded from: http://www.legislation.govt.nz/regulation/public/2003/0152/latest/DLM195215.html.

Applications to field test GMOs will be publicly notified. The other application types may or may not be publicly notified.

This application form will be made publicly available so any confidential information must be collated in a separate labelled appendix.

The fee for this application can be found on our website at www.epa.govt.nz.

If you need help to complete this form, please look at our website (www.epa.govt.nz) or email us at noinfo@epa.govt.nz.

This form was approved on 1 May 2012.

1. What type of containment activity are you applying for?

Tick appropriate option:

Application type	Type of new organism
Import into containment	☐ GM
	✓ Non-GM
Develop in containment i.e. regeneration, fermentation or genetic modification	☐ GM
	☐ Non-GM
Field test in containment	☐ GM
	☐ Non-GM

2. Brief application description

Provide a short description (approximately 30 words) of what you are applying to do.

To import and hold in containment Risk Group 1 and 2 microorganisms (including bacteria, archaea, protozoa, fungi, bacteriophages, viruses) as cultures or within samples derived from animals, plants and the environment, for laboratory based research.

3. Summary of application

Provide a plain English, non-technical description of what you are applying to do and why you want to do it.

New Zealand depends on the primary sector for its economic growth. The New Zealand pastoral sector generates export revenues in excess of $18.6 billion per annum, nearly half of merchandise exports.

AgResearch is a Government-owned Crown Research Institute (CRI) focused on supporting the pastoral sector through scientific research and development.

AgResearch's purpose is to enhance the value, productivity and profitability of New Zealand's pastoral, agri-food and agri-technology sector value chains to contribute to economic growth and beneficial environmental and social outcomes for New Zealand. Microbiology is an important scientific discipline that enables AgResearch to fulfil its purpose through the provision of research and transfer or technology and knowledge in partnership with key stakeholders.

The purpose of this application is to seek permission to import and hold Risk Group 1 and 2 microorganisms, including bacteria, archaea, protozoa, fungi, bacteriophages, viruses, either as cultures (axenic or mixed) or within samples derived from animals, plants and the environment (such as soil, dung, grass, water, gastro-intestinal tract and contents, saliva, milk, diet, etc.) from which these microorganisms may be cultured in containment. This will facilitate the development and implementation of strategies for animal production systems and improve our understanding of how members of microbial communities interact with their hosts to improve overall health, well-being, productivity and greenhouse gas emissions. Some examples of the type of research we do are the Global Rumen Census (www.globalrumencensus.org.nz) and Hungate 1000 projects. These projects seek to

identify and understand the roles microbes in samples that represent ruminants and livestock present all world-wide. These projects form part of the Rumen Microbial Genomics Network, a global collaboration between livestock researchers.[1]

4. Describe the background and aims of your application

This section is intended to put the new organism(s) in perspective of the wider activities(s) that they will be used in. You may use more technical language but please make sure that any technical words used are included in a glossary.

Microbes associated with animals, forage plants and the environment play a key role in food digestion and pastoral ecosystems and therefore animal productivity and greenhouse gas formation. The purpose of this application is to seek permission to import and hold in containment Risk Group 1 and 2 microorganisms, including bacteria, archaea, protozoa, fungi, bacteriophages, viruses, either as cultures (axenic or mixed) or within samples derived from animals, plants, and the environment (such as soil, water, gastro-intestinal tract and contents, saliva, milk, diet, etc.) from which these microorganisms may be cultured for research purposes. Our research aims to facilitate the development and implementation of strategies for pasture-based animal production systems and improve our understanding of how certain members of the microbial community interact with their mammalian hosts to improve overall health and well-being. One example of this is the development of beneficial microbial preparations to improve calf health.[2] The benefits of this research programme to New Zealand include:

- Improved understanding of microbial physiology and fermentation capabilities of ruminant, macropod, camelid and livestock-associated microorganisms;
- New opportunities for agriculture-derived greenhouse gas mitigation and pastoral climate change adapatation, as well as improved animal productivity
- Development of agri-food and bio-based products and agri-technologies;
- Enhanced pasture-based animal production systems;
- Opportunity to increase scientific resources, knowledge, and expertise of researchers in microbiology

5. Information about the new organism(s)

- For non-GMOs: provide a taxonomic description of the new organism(s).
- For GMOs: provide a taxonomic description of the host organism(s) and describe the genetic modification (i.e. the experimental procedures and biological material to be used in the genetic modification and where the expression of foreign nucleic acid may occur).
- Describe the biology and main features of the organism including if it has inseparable organisms.
- Describe if the organism has affinities (e.g. close taxonomic relationships) with other organisms in New Zealand.
- Could the organism form an undesirable self-sustaining population? If not, why not?
- How easily could the new organism be recovered or eradicated if it established an undesirable self-sustaining population?

The organisms covered by this application are Risk Group 1 and 2 microorganisms, including bacteria, archaea, protozoa, fungi, bacteriophages and viruses.

Risk Group 1 microorganisms are those that are unlikely to cause human, plant or animal disease and are therefore considered to pose a low risk to individuals, the community or the environment.[3]

Risk Group 2 microorganisms are those that may cause disease in humans, animals, plants, or fungi, but are unlikely to be a serious hazard to laboratory personnel, the community, animal or the environment; and have effective treatment and preventative measure with respect to any infections that they may cause; and present a limited risk of the spread of infection. Most of the Risk Group 2 species we seek to import are commensal or commonly occur in the environment. They do not cause disease in the normal course of exposure. However, if

they gain access to other areas of the body such as open wounds they may be able to cause disease and are therefore considered Risk Group 2 organisms.[3]

The organisms will be imported as either axenic or mixed cultures, or within samples derived from animals, plants and the environment.

Cultures: Reference, enrichment and mixed cultures of microorganisms will generally be imported from either recognised culture collections or experts in the field (including laboratories). Where possible, the microorganisms will be identified to at least phylum level prior to importation. However, due to the complexity of the ruminant, macropod, camelid and livestock-associated microbial populations, cultures may require testing and examination in New Zealand to fully elucidate their taxonomic identities. For more details refer to the online NCBI taxonomy database.[4]

Such cultures will contain primarily Risk Group 1 anaerobic microorganisms so the in the event of a breach of containment, the majority would be destroyed by exposure to oxygen. It is probable, however, that some samples will include anaerobic microorganisms and higher risk microorganisms of species not found in NZ. Therefore the risks associated with these samples are considered similar to those of Risk Group 2 bacteria, and the samples will be stored and handled commensurate with those risks.

Samples derived from animals, plants and the environment: These will be provided by collaborators worldwide. They will include dung, soil, water, gastro-intestinal tract and contents, saliva, milk, non-viable forage plants and animal feed samples.

Taking into account the structure and operation of the AgResearch facilities, the training, the qualification and experience of AgResearch staff, and the proposed controls, it is highly improbable that imported microorganisms, including those associated with animal, plant and environmental samples cannot be contained within our facility. The majority of microorganisms covered by this application, including any in imported ruminant, macropod, camelid and livestock-associated samples, are undoubtedly already normally present in New Zealand and form part of “normal” ruminant, macropod, camelid and livestock-associated microbial communities, but their presence was not discovered and/or documented prior to 1996. In the unlikely event of these entering the environment and forming a self-sustaining population, it would be difficult to distinguish them from local strains of the same species. It is therefore highly improbable that they would establish an undesirable population that would significantly affect the environment, animal or human health or the economy

Risk Group 2 organisms on the Unwanted Organisms in the Ministry of Agriculture and Forestry Unwanted Organism Registry any organisms that fall within Risk Group 3 or 4 of the Australian/New Zealand classification of risk groups, contained in the AS/NZS2243.3 are excluded from this application. Samples for micro-organism culture imported under this application will be restricted to samples from apparently healthy animals, plants, and environments with no recent reports of plant or animal disease, to limit the likelihood of accidental import of Risk Group 3 and 4 microorganisms or unwanted organisms. Recently received samples will be destroyed immediately upon notification of a disease outbreak in the vicinity where they were collected.

The organism that is the subject of this application is also the subject of:

a. an innovative medicine application as defined in section 23A of the Medicines Act 1981. ☐ Yes ☒ No

b. an innovative agricultural compound application as defined in Part 6 of the Agricultural Compounds and Veterinary Medicines Act 1997. ☐ Yes ☒ No

6. For field tests: The nature and method of the field test

Describe the nature and method of the field test and the experimental procedures to be used.

Not applicable

7. Proposed containment of the new organism(s) (physical and operational)

Describe how you propose to contain the new organism(s) after taking into account its ability to escape from containment (i.e. the possible pathways for escape).

All Risk Group 1 and 2 microorganism stocks and cultures and samples (animal or environmental) will be stored and maintained, and any *in vitro,* cell or tissue culture experiments will be performed in a facility approved to MPI Zealand Standard: *Facilities for Microorganisms and Cell Cultures:* 2007a. All microbiology laboratories in the AgResearch containment facility are approved to operate at PC 2. The facility is audited every 6 months by the MPI.

Laboratory experiments involving these organisms will be conducted by trained personnel under a minimum of PC2 level containment

Appropriate controls will be in place to ensure viable microorganisms are contained and do not leave the containment facility through any outlets including exhaust system, air filters and water discharge. All open container manipulations of risk group 2 bacteria, imported unidentified mixed cultures or rumen samples will be carried out in a sealed glove box, Class II biological safety cabinet (BSC) or anaerobic hood. To minimise the chance of organisms escaping from the facility, all samples, cultures, and consumables from experiments will be autoclaved on site prior to disposal, or sent for specialist biohazard waste disposal. Records will be maintained for all imported microorganisms as required by the MPI standard and will include a reference to the original BACC and EPA approval. Culture records for microorganisms isolated from imported animal and environmental samples will also include a reference to the original BACC and EPA approval.

While some organisms or samples to be imported may cause disease in humans in extreme circumstances (young, old, immunocompromised), with the containment standards and conditions in place at AgResearch, the likelihood of these organisms escaping from containment and infecting a susceptible host is essentially nil.

8. Detail of Māori engagement (if any)

Discuss any engagement or consultation with Māori undertaken and summarise the outcomes.

AgResearch has an ongoing agreement with the local iwi (Tanenuiarangi Manawatu) that we will consult with them as part of the application process to identify any cultural issues with the proposed research. We discussed this application with Jonathan Procter of Tanenuiarangi Manawatu Inc. to identify any cultural issues. While he had some reservations about the range of material that we are proposing to import, he is satisfied that the material and organisms will be imported into containment, therefore will not pose risks to the environment.

9. Identification and assessment of beneficial (positive) and adverse effects of the new organism(s)

Adverse effects include risks and costs. Beneficial or positive effects are benefits.

- Identification involves describing the potential effects that you are aware of (what might happen and how it might happen).

- Assessment involves considering the magnitude of the effect and the likelihood or probability of the effect being realised.

Consider the adverse or positive effects in the context of this application on the environment (e.g. could the organism cause any significant displacement of any native species within its natural habitat, cause any significant deterioration of natural habitats or cause significant adverse effect to New Zealand's inherent genetic diversity, or is the organism likely to cause disease, be parasitic, or become a vector for animal or plant disease?), human health and safety, the relationship of Māori to the environment, the principles of the Treaty of Waitangi, society and the community, the market economy and New Zealand's international obligations.

Potential risks

The majority of microorganisms covered by this application, including any in imported ruminant, macropod, camelid and livestock-associated samples, are likely to be already present in New Zealand and form part of "normal" ruminant, macropod, camelid and livestock-associated microbial communities, although their presence may not have been discovered and/or documented. In the unlikely event of these entering into the environment, it is highly improbable that they would significantly affect the environment, animal or human health or the economy.

In the event of removal of a culture or sample and its deliberate release we believe the effects would be negligible and the risks of such an act of sabotage to be very small (i.e. the ability to gain entry to the building, enter lab or storage areas unobserved, locate the correct freezer and then locate the organism would invoke an extremely low probability). We believe if such an event was to happen and the effect were observed, it would be localised and transient as environmental constraints would hamper further growth of the micro-organism and force its numbers into decline. Given that most of these organisms probably already 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 highly implausible scenarios.

Benefits

Importing these microorganisms and samples into containment allows us to establish a reference collection of bacterial cultures to be used in the Hungate1000 project (http://www.hungate1000.org.nz/). This is a global initiative to produce a reference set of rumen microbial genome sequences specifically to support international efforts to develop methane mitigation and rumen adaptation technologies. The project will also enable genome-based research aimed at understanding rumen function, feed conversion efficiency, methanogenesis and plant cell wall degradation in order to find a balance between food production and greenhouse gas emissions.

10. For developments of GMOs that take place outdoors and field tests of GMOs: Alternative methods and potential effects from the transfer of genetic elements

- Discuss if there are alternative methods of achieving the research objective.
- Discuss whether there could be effects resulting from the transfer of genetic elements to other organisms in or around the site of the development or field test.

Not applicable

11. For imports of GMOs: Could your organism(s) undergo rapid assessment (s42B of the HSNO Act)?

Discuss whether the GMO(s) to be imported fulfil the following criteria:

- The host organism(s) are Category 1 or 2 host organisms as per the HSNO (Low Risk Genetic Modification) Regulations.

- The genetic modifications are Category A or B modifications as per the HSNO (Low Risk Genetic Modification) Regulations and the modifications are not listed in the Schedule of these Regulations.
- The minimum containment of the GMO(s) will be as per the HSNO (Low Risk Genetic Modification) Regulations (PC1 or PC2 as per AS/NZS2243.3:2002).

Not applicable

12. Other information

Add here any further information you wish to include in this application including if there are any ethical considerations that you are aware of in relation to your application.

13. Appendices(s) and referenced material (if any) and glossary (if applicable)

1. http://www.globalresearchalliance.org/app/uploads/2012/03/GRA-A2-Milestone-report-3_RMG_Network_Whitepaper-sanitised.pdf
2. http://www.donaghys.com/fileadmin/downloads/BAPM/ProCalf_System_Fact_Sheet.pdf
3. Australia/New Zealand Standard 2243.3:2002: Safety in Laboratories Part 3: Microbiological aspects and containment facilities, fifth edition
4. http://www.ncbi.nlm.nih.gov/Taxonomy/Browser/wwwtax.cgi?name=Eubacteria

14. Signature of applicant or person authorised to sign on behalf of applicant

☐ I request the Authority to waive any legislative information requirements (i.e. concerning the information that shall be supplied in my application) that my application does not meet (tick if applicable).

I have completed this application to the best of my ability and, as far as I am aware, the information I have provided in this application form is correct.

Signature **Date**