

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY DECISION

20 July 2010

Application code:	ERMA200423
Application category:	To develop in containment genetically modified organisms under sections 40(1)(b) and 42A of the Hazardous Substances and New Organisms (HSNO) Act 1996.
Applicants:	AgResearch Limited Cawthron Institute Landcare Research New Zealand Ltd Lincoln University Massey University Museum of New Zealand - Te Papa Tongarewa National Institute of Water and Atmospheric Research (NIWA) New Zealand Institute for Plant and Food Research University of Auckland University of Otago Victoria University of Wellington University of Waikato The New Zealand Forest Research Institute (trading as Scion)
Purpose:	To develop genetically modified non-pathogenic strains of <i>Escherichia coli</i> and bacteriophage lambda to answer identification, taxonomic, population or evolutionary questions for genes and organisms from native or valued flora and fauna.
Date application received:	15 July 2010
Consideration date:	20 July 2010
Considered by:	Chief Executive, ERMA New Zealand

1 Summary of Decision

- 1.1 Application ERMA200423 to develop, as a project, genetically modified organisms (as described in Table 1 of this decision) in containment is **approved, with controls** (see Appendix 1 of this decision), having been considered in accordance with the Hazardous Substances and New Organisms (HSNO) Act 1996 (the Act), the HSNO (Low-Risk Genetic Modification) Regulations 2003 (the Low Risk Regulations), and the HSNO (Methodology) Order 1998 (the Methodology).

The organisms approved are:

- 1.2 The organisms approved for development are the genetically modified organisms (GMOs) described in Table 1:

Table 1: Organisms as recorded on ERMA New Zealand Register

Host organism	Category of host organism	Modified by:	Category of modification/containment level
<i>Escherichia coli</i> (Migula 1895) Castellani and Chalmers 1919 non pathogenic laboratory strains	1	<p>Non-conjugative plasmid cloning vectors, bacteriophage and bacteriophage plasmid vectors.</p> <p>Expression plasmid vectors are excluded from this approval.</p> <p>Vectors will include commercially available promoters and other gene regulatory elements, reporter and selectable marker genes and origins of replication.</p> <p>The native donor genetic material will be sourced from Kingdoms Animalia, Plantae, Fungi, Protista and Monera, and viruses and viroids. The sequences (derived from genomic or complementary DNA) permitted are those used in identification, phylogenetic, taxonomic or population studies. Sequences will include those of DNA marker motifs such as microsatellite regions and the coding, non-coding and regulatory regions of genes used in identification, phylogenetic, taxonomic or population studies such as the ribosomal loci. Other sequences may also be used as required to address specific scientific or technical questions.</p> <p>Libraries may also be created from native genomic or complementary DNA from the Kingdoms Animalia, Plantae, Fungi, Protista and Monera and viruses and viroids.</p> <p>The modifications will not:</p> <ul style="list-style-type: none"> • Involve any human genetic material. • Involve any genetic material from CITES listed species, unless the appropriate approval has been obtained. • Intentionally express protein. • Intentionally produce infectious particles (except for bacteriophage). • Intentionally increase the pathogenicity, virulence, or infectivity of the host organism or enhance its ability to escape containment. 	A/PC1
Bacteriophage lambda (ICTV approved name is Enterobacteria phage λ), non pathogenic laboratory strains	1	<p>Non-conjugative plasmid cloning vectors, bacteriophage and bacteriophage plasmid vectors.</p> <p>Expression plasmid vectors are excluded from this approval.</p> <p>Vectors will include commercially available promoters and other gene regulatory elements, reporter and selectable marker genes and origins of replication.</p> <p>The native donor genetic material will be sourced from Kingdoms Animalia, Plantae, Fungi, Protista and Monera, and viruses and viroids. The sequences (derived from genomic or complementary DNA) permitted are those used in identification, phylogenetic, taxonomic or population studies. Sequences will include those of DNA marker motifs such as microsatellite regions and the coding, non-coding and regulatory regions of genes used in identification, phylogenetic, taxonomic or population studies such as the ribosomal loci. Other sequences may also be used as required to address specific scientific or technical questions.</p> <p>Libraries may also be created from native genomic or complementary DNA from the Kingdoms Animalia, Plantae, Fungi, Protista and Monera and viruses and viroids.</p> <p>The modifications will not:</p> <ul style="list-style-type: none"> • Involve any human genetic material. • Involve any genetic material from CITES listed species, unless the appropriate approval has been obtained. • Intentionally express protein. • Intentionally produce infectious particles (except for bacteriophage). • Intentionally increase the pathogenicity, virulence, or infectivity of the host organism or enhance its ability to escape containment. 	A/PC1

2 Consideration

Sequence of the consideration

- 2.1 The application was formally received on 15 July 2010. The decision to formally receive was based on the information supplied by the applicant in the application form.
- 2.2 The application was considered by me (Rob Forlong, the Chief Executive of ERMA New Zealand). Relevant staff within ERMA New Zealand provided advice on the application.
- 2.3 In reaching my decision, I have considered the relevant sections of the Act, clauses of the Methodology and the Low Risk Regulations.
- 2.4 In accordance with section 42A of the Act, the approach I adopted was to identify the circumstances of the genetic modification, to evaluate these against the criteria specified in the Low Risk Regulations established under section 41 of the Act, and to consider whether there are any residual risks that require further consideration. My approach covered the following issues:
- organism description;
 - purpose of the application (section 39 of the Act);
 - assessment against the criteria of the Low Risk Regulations;
 - Part II of the Act;
 - precedents;
 - assessment of whether the applicant needs to provide progress reports on the research; and
 - containment controls.

Organism description

- 2.5 I considered that the organism description in this application falls within the bounds of a project for the development of GMOs. The description of the organisms includes the taxonomy of the host, the types of vector to be used and a detailed description of the source and function, and the nature and range of proposed genetic modifications, including the range of regulatory sequences and selectable markers (see Table 1). The application provides a sufficient description of the GMOs which will be developed to confirm that they conform to the Low Risk Regulations.

Purpose of the application

- 2.6 The purpose of this application is to develop genetically modified non-pathogenic strains of *E. coli* and bacteriophage lambda to allow for the identification of genes and organisms from native or valued flora and fauna to allow studies of a taxonomic, population and/or evolutionary nature. In order to achieve this purpose, native genetic material from the Kingdoms Animalia, Plantae, Fungi, Protista and Monera, and viruses and viroids will be collected. Either the DNA will be extracted, or the RNA will be extracted and then transcribed to complementary DNA (cDNA). DNA or cDNA sequences will then be inserted into the non-pathogenic strains of *E. coli* and bacteriophage lambda for DNA sequence analysis. This application also covers the cloning of amplified DNA, which was created by the Polymerase Chain Reaction (PCR). This application does not allow the development of a commercialised product.
- 2.7 I consider that the purpose of this application falls within the bounds of a project. This project represents a particular line of scientific inquiry and has clearly defined objectives.
- 2.8 I have determined that this application is for a valid purpose being *the development of any new organism* as provided for in section 39(1)(a) of the Act.
- 2.9 I note that prior to using this approval, each user must confirm that the proposed research meets the purpose of this approval (ie, to answer identification, taxonomic, population or evolutionary questions) and that:
- the iwi local to the site(s) where the native material will be collected and the site(s) of the containment facilities where this research will occur have been consulted;
 - if protected native species to be are collected, then a Wildlife Act Permit must be approved by the Department of Conservation (DOC);
 - if native biota is to be collected from a national park or reserve, a High Impact Research Collection Permit must be approved by DOC;
 - if species listed on the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) are to be used, appropriate approval will need to be sought from DOC;
 - the organisms will be maintained as per the containment controls placed on this approval (Appendix 1);
 - and that to the best of their knowledge the genetic modifications they intend to perform fall under the approved organism description in Table 1.

Assessment against the criteria for low-risk genetic modification

Category of host organism

- 2.10 The non-pathogenic laboratory strains of *E. coli* and bacteriophage lambda to be used by the applicant are not capable of causing disease in humans, animals, plants or fungi, do not normally infect, colonise, or establish in humans, nor do they produce desiccation-resistant structures, such as spores or cysts. As such, non-pathogenic laboratory strains of *E. coli* and bacteriophage lambda are considered Category 1 host organisms as defined in clause 7(1) of the Regulations.

Category of genetic modification

- 2.11 I note that research using known native genetic material is covered under this approval. I acknowledge that prior to collecting native genetic material, applicants will consult with the iwi local to both the collection site/s and the containment facilities where the research will occur (control 6).
- 2.12 Native genetic material is defined as RNA or DNA from a plant or animal originating naturally in New Zealand. Organisms that are *native* to New Zealand include organisms that have originated in New Zealand or were present at the time of the first human occupation. Marine organisms within the 12 nautical mile of New Zealand territorial limit and also, within the 200 mile Exclusive Economic Zone (EEZ) limit may be considered native and/or valued species.
- 2.13 Valued flora and fauna are a subset of introduced flora and fauna. Species may be valued for symbolic, spiritual and utilitarian values, and particular animals and plants maybe valued for aesthetic, symbolic, economic or historic reasons. For example, valued flora and fauna include kumara, kiore, some varieties of Māori potatoes and hue.
- 2.14 I further note that intentional protein expression (ie, expression of protein from the sequences cloned into the plasmid vector), intentional production of infectious particles (excluding bacteriophage) or modifications that intentionally increase the pathogenicity, virulence, or infectivity of the host organism or enhance its ability to escape containment are not permitted under this approval. Therefore, users of this approval must not knowingly use vector systems or donor genetic material that will produce protein or infectious particles or increase the pathogenicity, virulence, or infectivity of the host organism or enhance its ability to escape containment.

- 2.15 However, I acknowledge that in biological systems unexpected events can occur and therefore, control 7 has been imposed to cover for these eventualities.
- 2.16 Control 7 requires that in the event that a GMO developed under this approval inadvertently expresses proteins, produces infectious particles (excluding bacteriophage), or shows enhanced pathogenicity, virulence, infectivity or enhanced abilities to escape containment, ERMA New Zealand and the MAF Inspector responsible for supervision of the facility must be notified immediately and all research involving the GMO must cease. The GMO 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 GMO must be destroyed.
- 2.17 I note that the genetic material from organisms capable of causing disease in humans, animals, plants or fungi can be used provided that the organism description in the approval is met and none of the exclusions in Table 1 are triggered.
- 2.18 The genetic modifications to non-pathogenic laboratory strains of *E. coli* and bacteriophage lambda (described in Table 1) are not expected to increase the pathogenicity, virulence or infectivity of the organisms to laboratory personnel, the community, or the environment. In addition, the developments will not result in the organisms having a greater ability to escape from containment than the unmodified organisms. Therefore, the genetic modifications to non-pathogenic laboratory strains of *E. coli* and bacteriophage lambda as described in Table 1 of this decision are Category A genetic modifications as defined in clause 5(1) of the Regulations and shall be contained at a minimum of Physical Containment level 1 (PC1).
- 2.19 I am satisfied that the developments meet the criteria for low-risk genetic modification specified in the Regulations. The developments involving non-pathogenic laboratory strains of *E. coli* and bacteriophage lambda meet the requirements of Category A modifications as defined in clause 5(1) of the Regulations.

Part II of the HSNO Act

- 2.20 I have considered Part II of the Act, including the:
- purpose of the Act,
 - principles set out in section 5 of the Act;
 - precautionary approach;
 - Treaty of Waitangi; and
 - Methodology.

- 2.21 I consider that the information provided by the applicant is relevant and appropriate to the scale and significance of the risks, costs, and benefits associated with the application (as required by clause 8 of the Methodology). In accordance with clauses 9, 10 and 12 of the Methodology (which incorporate sections 5, 6, and 8 of the Act) the information supplied by the applicant has been evaluated as follows:
- 2.22 I consider that, given the biological characteristics of the organisms, the containment system and the controls attached to this approval (see Appendix 1 of this decision), there is no evidence for, nor any reason to expect, any non-negligible adverse effects of the proposed GMOs on humans, animals, plants, other organisms or the environment.
- 2.23 I have considered the potential Māori cultural effects in accordance with sections 6(d) and 8 of the Act and clauses 9(b)(i), 9(c)(iv) of the Methodology, in consultation with the General Manager, Māori. A level II national consultation was undertaken for this application which included the distribution of information nationally requesting feedback, and the convening of a Māori Reference Group to consider the issues posed by this application.
- 2.24 The issues raised are identified in detail in the application but the concerns largely relate to the protection of the integrity of native and/or valued species and the traditional knowledge and practice associated with them. This includes concerns about the potential for commercial exploitation of species, the inability of Māori to benefit from such exploitation and the subsequent loss of traditional knowledge and practice associated with the species involved. These concerns were further heightened by the fact that a claim to the Waitangi Tribunal (WAI 262) made by several iwi and individual claimants relating to native species remains unresolved.
- 2.25 However, respondents to consultation also acknowledged the value of the research to improving conservation management and for the potential revitalisation of knowledge and practice associated with native species. Reference group members reviewed existing approvals involving the sequencing of native species and acknowledged the benefits to the iwi/hapū groups in the relevant regions, and to Māori more broadly.
- 2.26 On considering the information raised I have imposed control 6 to ensure that iwi/ Māori groups local to both the collection site of samples (native and/or valued material) and the containment facilities used to investigate samples are consulted prior to collection. This measure is designed to ensure any risks or concerns are appropriately mitigated. Moreover it will encourage the development of relationships between research organisations and iwi/Māori to promote the negotiation of mutually beneficial outcomes.
- 2.27 With control 6, and with the other controls and containment measures in place, I do not consider that the application poses a significant adverse effect to the relationship of Māori to the environment.

Precedents

- 2.28 While each application is considered in its individual circumstances, I note that similar projects, with similar host organisms and genetic modifications, have been considered and approved under section 42A of the Act on previous occasions. For example, application in application GMD06033, a proposal to clone the DNA from specific plants to develop DNA markers, including microsatellites, to be used for studies in genetic variation in native and non-native plants for the purpose of addressing taxonomic and evolutionary questions was approved.

Progress reports

- 2.29 I consider that this current application raises some issues regarding the use of native flora and fauna which have been discussed in paragraphs 2.11 to 2.17. As control 7 has been imposed on this approval, I consider that, progress reports are not required for this approval.

Containment

- 2.30 The experiments proposed in this application, to develop genetically modified non-pathogenic laboratory strains of *E. coli* and bacteriophage lambda meet the requirements of Category A genetic modifications as defined in clause 5(1) of the Regulations. Category A experiments are required to be contained within a Physical Containment level 1 facility (PC1).
- 2.31 The facility to be used shall be approved as a containment facility under section 39 of the Biosecurity Act, in accordance with the MAF/ERMA New Zealand Standard: *Facilities for Microorganisms and Cell Cultures: 2007a*. This containment regime contains clear guidelines for the safe handling and disposal of cultures.

3 Decision

- 3.1 I am satisfied that this application is for one of the purposes specified in section 39(1) of the Act, being section 39(1)(a): *the development of any new organism*.
- 3.2 Based on consideration and analysis of the information provided, including having considered the characteristics of the organisms that are the subject of this approval, the modifications and the criteria for low-risk genetic modification detailed in the Regulations, I am of the view that the organisms meet the criteria for rapid assessment under section 42A of the Act and I have identified no significant adverse effects.

- 3.3 I have considered all the matters to be addressed by the containment controls for Importing, Developing or Field testing of Genetically Modified Organisms detailed in the Third Schedule Part I, of the Act, and in accordance with section 42A(3)(b), this approval is subject to the controls specified in Appendix 1.
- 3.4 Pursuant to section 42A(3)(a) of the Act, and acting under delegation from the Authority provided for in section 19 of the Act, I have **approved** this project application for genetically modified non-pathogenic laboratory strains of *E. coli* and bacteriophage lambda described in Table 1 of this decision, subject to the controls specified in Appendix 1 of this decision.

Mr Rob Forlong

Date

Chief Executive, ERMA New Zealand

Approval codes (BCH numbers): GMD100298 - 299

**Approval numbers and BCH numbers for Organisms in Application
ERMA200423**

Approval Code	Organism	BCH number*
GMD100298	<i>Escherichia coli</i> (Migula 1895) Castellani & Chalmers 1919 (ERMA200423)	
GMD100299	Bacteriophage lambda (ERMA200423)	

*As of 15 September 2009, new BCH numbers cannot be provided. Please use the appropriate Approval number in lieu of the BCH number.

Appendix 1: Controls required by this approval

In order to provide for the matters detailed in Part I of the Third Schedule of the Act, *Containment Controls for Importation, Development and Field Testing of Genetically Modified Organisms*, and other matters in order to give effect to the purpose of the Act, the approved organisms are subject to the following controls:

The controls imposed on the approval

1	The approval holder (AgResearch Limited, Cawthron Institute, Landcare Research New Zealand Ltd, Lincoln University, Massey University, Museum of New Zealand - Te Papa Tongarewa, National Institute of Water and Atmospheric Research (NIWA), New Zealand Institute for Plant and Food Research, University of Auckland, University of Otago, Victoria University of Wellington, University of Waikato and the New Zealand Forest Research Institute (trading as Scion)) must ensure compliance with the following controls.
2	This approval is limited to the development of the organisms described in Table 1 , for the purpose of developing genetically modified non-pathogenic strains of <i>Escherichia coli</i> and bacteriophage lambda to answer identification, taxonomic, population or evolutionary questions for genes and organisms from native or valued flora and fauna. This approval does not allow the development of a commercialised product.
3	Unless otherwise specified by the following controls, the approval holder must ensure that the location and nature of the development, and the disposal of the approved organisms are in accordance with the activities and proposed controls described in the application.
4	The approved organism must be developed and maintained within a containment facility in accordance with following MAF/ERMA New Zealand Standard and the additional controls (as follows): <ul style="list-style-type: none"> • MAF/ERMA New Zealand Standard: <i>Facilities for Microorganisms and Cell Cultures: 2007a</i>¹; • Australian/New Zealand Standard AS/NZS 2243.3:2002 Safety in laboratories: Part 3: Microbiological aspects and containment facilities¹; and • Physical Containment level 1 (PC1) requirements of the above Standards (at minimum).
5	The approval user must ensure that within 24 hours of the discovery of any breach of containment ² the MAF Inspector responsible for supervision of the facility, has received notification of the breach, and the details of any action taken by the facility since the breach occurred.
6	All users of this approval shall consult with iwi/Māori groups local to both the site of sample collection and the containment facility used to investigate the native and/or valued species prior to collection to provide information about the proposed research and discuss any issues or concerns that might arise. Where issues or concerns are evident, all efforts shall be taken to work with the group/s to develop measures or processes that might serve to mitigate such risks. Full records of these interactions must be kept on file, and available for audit by MAF BNZ.

¹ Any reference to MAF/ERMA New Zealand or AS/NZS Standards in these controls refers to any subsequent version approved or endorsed by ERMA New Zealand.

² Breach of containment includes: the escape of an organism(s), unauthorised entry to the containment facility, or a failure in the structural integrity of physical containment mechanisms.

7	<p>In the event that a genetically modified organism developed under this approval inadvertently expresses proteins, produces infectious particles (excluding bacteriophage), or shows enhanced pathogenicity, virulence, infectivity or enhanced abilities to escape containment, ERMA New Zealand and the MAF Inspector responsible for supervision of the facility must be notified immediately and all research involving the genetically modified organism must cease. The genetically modified 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 genetically modified organism must be destroyed.</p>
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