ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO

FORM 2

Application for approval to

IMPORT INTO CONTAINMENT ANY NEW ORGANISM

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

ERMA Application number GMC00012

Office use only ☐☐☐☐☐☐☐☐

Fees $_____ Date received ___/___/___ Verified date ___/___/___ _____Job manager

Application for approval to import into containment any new organism under Section 40 of the Hazardous Substances and New Organisms Act 1996

IMPORTANT

Before you fill in this application form please talk to ERMA New Zealand. We can help you scope and prepare your application. The scale of information we need should match the potential significance of the application. For example, applications which may pose a significant risk to the environment or to human health need to be supported with more substantial information than applications which clearly pose a more minor risk.

We need all relevant information early on in the application process. Quality information up front will speed up the process.

Any extra material that does not fit in the application form must be clearly labelled and cross-referenced in the application form. Commercially sensitive information should be collated in a separate document.

All applicants must sign at the end of the form and enclose the correct application fee. Please check ERMA New Zealand's current pricing policy, we are unable to process applications that do not contain the correct fee.

All references to regulations in this form, unless otherwise noted, refer to the Hazardous Substances and New Organisms (New Organisms Forms and Information Requirements) Regulations 1998.

Copies of all our application forms will soon also be available on our website: www.ermanz.govt.nz, and also in electronic form (MS Word format).

If you have any suggestions for improvements to this form, please contact our operations staff at the address below.

You can get more information at any time by telephoning, writing to, or calling in at our Wellington office. One of our staff members will be able to help you.

List of application forms for new organisms:

These are all our application forms related to new organisms. Please check you have the right one.

Form 1	Application for approval under section 34 of the Act to import for release, or release from containment, any new organism — including rapid assessment.
Form 2	application for approval under section (40)(1)(a) of the Act to import into containment any new organism **(this form)**.
Form 3	application for approval under section 40(1)(b) of the Act to develop in containment any genetically modified organism – including rapid assessment.
Form 4	application for approval under section 40(1)(c) to field test (including large scale fermentation) in containment any genetically modified organism.
Form 5	application for approval under section 47 to use a new organism in an emergency.
Form 6	application for approval under section 62 for grounds for reassessment of a new organism in containment.

20 Customhouse Quay,
Cnr Waring Taylor & Customhouse Quay
PO Box 131, Wellington
Phone: 04-473 8426 Fax: 04-473 8433
Email: enquiries@ermanz.govt.nz
Website: www.ermanz.govt.nz

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO

Applicant details

1. Name and address in New Zealand of the applicant:

This should be the organisation or person formally responsible for this application.

Name: Horticulture and Food Research Institute of New Zealand

Address: Private Bag 92 169, Auckland

Phone: 09 815 4200

2. The applicant's address for service in New Zealand (if different from above):

Address: same as above

3. Name of the contact person for the application (if different from applicant): This person should have sufficient knowledge to respond to queries and have the authority to make decisions on behalf of the applicant that relate to processing the application.

Name: Dr Erik Rikkerink

Position: Biological Safety Officer, Mount Albert Research Centre, HortResearch

Phone: 09 815 8768

Fax: 09 815 4201 **Email:** ERikkerink@hort.cri.nz

4. Summary

Provide a summary of the information contained in this application relating to the identification of the organism.

The information should include summaries of:

- the identity of the organism;
- if it is a genetically modified organism, the source of the donor nucleic acid material and the purpose of the modification;
- what the organism will be used for and why it has been selected.

Provide a summary of the information contained in this application relating to the assessment of the effects of the organism.

The information should include summaries of:

- the risks, costs and benefits and the assessment of these;
- the containment system proposed.

This summary will be used to provide information to people and agencies who may request it. Applications to import any new organism into containment will not be publicly notified. However, as the information in this section may be released upon request, applicants should ensure that this summary does not contain any commercially sensitive information.

[No] further information

The organism is Escherichia coli strain K12 or strain B that has been genetically modified to contain DNA from other organisms. It is genetically crippled and has been shown to be unable to establish self-sustaining populations outside the laboratory environment. The donor material is from the invertebrates,

plants, fungi and microorganisms listed in Appendix 8. It has been cloned into standard DNA cloning vectors that are not transmissible to other bacteria (also listed in Appendix 8). The organism was selected because it cannot survive in the natural environment in the event of accidental release from containment and because it is the standard host for cloning and analysis of DNA. The organism will be used as a source of cloned DNA fragments for a variety of research purposes involving the analysis of gene structure, expression and function. The benefit of the organism is that it will advance scientific knowledge and understanding. The cost of not importing the organism would be a reduction in New Zealand's ability to carry out innovative research that has the long term aim of enhancing the country's economy and public well being. The host organism is an approved Schedule 2 host in the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations, and the proposed modifications meet the conditions for Category A and Category B experiments. The proposed containment system is physical containment level 1 (PC1) as defined in the Australia New Zealand Standard for Microorganisms 2243.3:1995 and as registered by MAF to meet the MAF/ERMA Standard 154.03.02 Containment Facilities for Microorganisms.

Organism details

5. The identification of the organism:

This should include all information necessary to identify the organism and should include:

- the taxonomic classification and name of the organism;
- the essential characteristics that identify the organism and its behaviour in the environment;
- sufficient information to enable the Authority to uniquely identify the organism in the register as required by section 20(2)(b) of the Act.

(This section may also include the name by which the organism is generally known.)

The information in this section would include, for example, information on the habitat range and climatic sensitivity of the organism. References to the scientific literature supporting this information should be given here if appropriate.

In the separate box below the applicant should provide the name of the organism suitable for inclusion in the Authority's public register.

Information that is commercially sensitive should be clearly identified. If supplied separately, a cross-reference to it should be included.

Taxonomic Name: Genetically crippled derivatives of Escherichia coli K-12 and strain B

Classification:Bacteria; Proteobacteria; gamma subdivision; Enterobacteriaceae

Characteristics: Non-pathogenic Gram negative rod-shaped bacterium; originally derived from non-pathogenic bacteria inhabiting the gut of mammals; carries mutations that would prevent it from establishing a self-sustaining population outside the laboratory; has been shown to be unable to colonise humans.

References:

1. Bachmann, B. (1996) Derivatives and genotypes of some mutant derivatives of Escherichia coli K-12. In:ÊEscherichia coli and Salmonella: molecular and cellular biology. F. Neidhardt, Ed. ASM Press, Washington, USA.

2. Smith, H.W. (1975) Survival of orally administered E. coli K12 in alimentary tract of man. Nature 255:500-502.

[No] further information

[No] commercially sensitive information

Name of the organism that may be used for the Authority's public register:

Escherichia coli K-12 or B derivatives as modified by DNA cloned from donor organisms into non-conjugative plasmid or phage vectors.

6. If the organism is a genetically modified organism, information on the details of the genetic modifications:

This information shall include full details of the genetic constructs and modifications and the source and characteristics of the foreign nucleic acid.

This information should clearly identify the source of the donor genetic material and the characteristics. The desired characteristic (eg, herbicide resistance) and any other significant characteristics that may be expressed by the donor genetic material in the organism should be described.

Information on the stability and homogeneity of the construct should be given, if known. If this information is not known then this should be explicitly stated. References to the scientific literature supporting this information should be given here if appropriate.

Information that is commercially sensitive should be clearly identified. If supplied separately a cross-reference to it should be included.

[No] further information

[No] commercially sensitive information

The sources of the foreign nucleic acids are the organisms listed in Appendix 8. The DNA (genomic and copy DNA) is cloned into the vectors (also described in Appendix 8). These vectors are approved for use with Escherichia coli K12 or E.coli B derivatives under Schedule 2 of the Hazardous Substances and New Organisms (Low Risk Genetic Modification) Regulations 1998. The desired characteristic is that the donor DNA is stably replicated in cells of E. coli. The donor DNA is well characterised stable homogeneous clones of DNA or libraries of DNA clones. This application is restricted to non-conjugative host/vector systems as defined in Schedule 2 of the Hazardous Substances and New Organisms (Low Risk Genetic Modification) Regulations 1998 that fall within Category A or B of Schedule 1 of the same regulations; organisms that, due to the nature of the donor nucleic acid, fall within Category C of these Regulations are specifically excluded. Animals, fish and plants that are native to New Zealand are explicitly excluded from the list of donor organisms. No attempt will be made to clone a whole donor organism from donor nucleic acid or genetic material contained in strains of *E. coli* to be imported under this application.

The desired characteristics that are expressed by these vectors include a number of selectable markers and gene reporter systems that are useful in animal, plant and micro-organism research and development. Genes that produce compounds that are toxic or pathogenic to vertebrates are not used. In addition these vectors will usually contain DNA from the source organisms detailed in Appendix 8. There will sometimes be expression of the genes from these organisms. In most cases the level of this expression will be low since the vectors do not contain the right promoters for expression in *E. coli*. In a few selected vectors where the aim is efficient expression in *E. coli* this may not be the case. The vectors will contain promoters designed to express genes in other host organisms. Separate approvals will be required if other hosts are modified by the vectors described in Appendix 8.

7. The reason why an application is necessary for the organism:

Refer to the definitions set out in Section 2 of the Act, to the prohibited organisms in the Second Schedule of the Act, and for genetically modified organisms, to the exemptions in the HSNO (Organisms Not Genetically Modified) Regulations 1998.

An application is necessary because this importation involves a genetically modified organism that falls into Category A and B of Schedule 1 of the Hazardous Substances and New Organisms (Low Risk Genetic

Modifications) Regulations 1998. The imported organisms are not prohibited organisms listed in the Second Schedule to the Hazardous Substances and New Organisms Act (1996).

8. The purposes for which an approval is sought:

Reference should be made to the purposes specified in section 39(1) of the Act and the information should also provide sufficient details on the purpose of the application to enable the Authority to provide the information required in the register (under section 20(2)(c) of the Act).

The information in this section should be as expansive as possible. While the applicant may have only one potential use in mind, an approval would enable other uses as well. To enable the Authority to have access to all relevant information all the potential uses of the organism should be provided. The information on how well the organism performs these uses is necessary to enable the Authority to determine the performance characteristics of the organism.

Information that is commercially sensitive should be clearly identified. If it is supplied separately a cross-reference to it should be included.

[No] further information [No] commercially sensitive information

This application falls under section 39(1)(h) of the Hazardous Substances and New Organisms Act 1996, "importation of a new organism for such other purposes as the Authority thinks fit". The imported organism will be used for the following research purposes: as a source of DNA libraries to be screened for clones; as a source of cloned DNA for sub-cloning into other vectors; as a source of cloned DNA for sequencing, for mutagenesis experiments and as probes in hybridization experiments; as a source of vectors for DNA cloning experiments; and for the expression of cloned genes to enable functional analysis of gene products.

Provide in this box a statement describing the purpose for making the application. This statement may be included in the Authority's public register (please use a maximum of 255 characters):

The purpose of this application is to importable range of Escherichia coli K12 and B bacteria containing fragments of DNA from a range of species for contained laboratory research.

9. Information on any likely inseparable organisms:

Information should be provided on any organism which is unable to be separated from any new organism at the time of making the application. Examples may include foot and mouth and scrapie causing organisms in animals and viruses in plants.

[No] further information

These will be pure cultures and will not contain any inseparable organisms.

Assessment of Effects

The information to be provided in these sections should cover the assessment of effects (both adverse and positive) of the organism. Where appropriate these sections may be combined in section 13 below.

Effects should be clearly assessed where relevant, including details as to how the risks will be controlled by the proposed containment system. **Where these adverse effects are identified, in the first instance by the applicant, as being minor then these do not require in-depth assessment.**

10. Information on all the possible adverse effects of the organism on the environment:

This should include information on the effects of the organism on ecosystems, public health, and Maori culture and taonga. It should also include information relevant to the matters in sections 4, 5, 6, 7, 8, and 37 of the Act and any regulations made under section 41 of the Act. The assessment should identify and assess risks, costs and benefits.

The information should give particular regard to:

Environmental and ecosystem effects (section 6(a) and (b) of the Act)

- assessment of the known and possible adverse effects throughout the life cycle of the organism on the sustainability of native and valued introduced flora and fauna and on the intrinsic value of ecosystems. *[Include an assessment of the ability of the organism to establish an undesirable self-sustaining population and the ease with which the organism could be eradicated if it was established.]*

Public health effects (section 6(c) of the Act)

- assessment of the known and possible adverse effects throughout the life cycle of the organism on public health. *[Assessment should take account of aspects of public health and safety including, where appropriate, effects from occupational exposure and effects from environmental exposure to the organism.]*

Relationship of Maori with taonga (section 6(d) of the Act)

- assessment of the known and possible adverse effects throughout the life cycle of the organism on the relationship of Maori and their culture and traditions with their ancestral lands, water, sites, wahi tapu, valued flora and fauna, and other taonga. [Include details of consultation (if any) carried out.]

The ability of the organism to escape from containment.

Environment and ecosystem effects. All the strains of bacteria to be used are derived from E. coli K-12 or the closely related E. coli strain B. Strain K-12 was originally isolated from the stool of a person in 1922. There is no evidence that the original isolate was associated with disease. By the 1950's, after 30 years of being subcultured, it was found that the strain had a greatly reduced ability to produce the surface antigens that are characteristic of wild-type strains. It was shown in 1975 that laboratory strains of E. coli K-12 are unable to colonise the alimentary tract of a human host and do not cause any symptoms of disease. Strain B is closely related to strain K-12 and has also been subcultured in research laboratories for over 30 years so that conclusions reached with strain K-12 can be extended to strain B. In addition to the above characteristics, strains of E. coli in current use have requirements for growth factors such as amino acids and vitamins further reducing the possibility of their survival outside the laboratory. These data show that the organism would not be able to establish a self-sustaining population even if it were to escape from containment. The vectors included will not include those that are able to transfer themselves by conjugation or contain generalised transducing phages. Thus there is no ability of the manipulated DNA in these organisms to transfer by itself.

References:

1. Bachmann, B. (1996) Derivatives and genotypes of some mutant derivatives of Escherichia coli K-12. In:Escherichia coli and Salmonella: molecular and cellular biology. F. Neidhardt, Ed. ASM Press, Washington, USA.
2. Smith, H.W. (1975) Survival of orally administered E. coli K12 in alimentary tract of man. Nature 255:500-502.

Public Health Effects. The organism will be held in approved containment facilities. For reasons described above the organism would not pose any threat to public health even if it were to escape from containment.

Relationship with Maori and taonga. The organism will be held in containment so that no effect on the relationship of Maori with taonga is envisaged. The applicants acknowledge that if nucleic acids modifying the *E. coli* have been sourced from flora and fauna that is valued to Maori, there may a be risk to the relationship of Maori and their culture and traditions with their taonga. We have therefore excluded New Zealand native macroflora and macrofauna (including fungi that fall into the macrofauna class) as sources of DNA and because of this exclusion no risks to the relationship of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga are likely.

Where organisms that are native to other countries and which may be also valued by Maori and/or native to New Zealand are included on the list then the genetic material will only be sourced from countries other than New Zealand to minimise the effect on Tangata Whenua.

Use of Human Genes. This application is not for the development of GMOs but for the import of international developed material. In so far that the importation of vectors may include inserted nucleic acids sourced from humans this material will be sourced from human gene libraries and therefore should not require any additional ethical approval. Any ethical approvals required for the use and further development of imported genetically modified *E. coli* will be covered by the institutions' ethical guidelines and Institutional Biological Safety Committee (IBSC) delegation requirements. No additional issues with regard to the use of human genes are raised by the expansion of the vector and DNA donor list in Appendix 8 since these vectors and their inserted DNA are for use in plant biotechnology applications.

The ability of the organism to escape from containment. The organism will be unable to escape from containment unless accidental release occurs. Even if this were to occur, the organism would be unable to establish a self-sustaining population for reasons outlined above. The organisms will be imported into and maintained in physical containment level 1 (PC1) in compliance with the Australian/New Zealand Standard AS/NZS 2243.3: 1995 *Safety in Laboratories*. Part 3: *Microbiology*. The facilities are registered with the MAF Regulatory Authority/ERMA New Zealand Standard 154.03.02: *Containment Facilities for Microorganisms* under the Biosecurity Act 1993 and will operate in accordance with any additional controls imposed by the authorities decision. The importing facilities at Palmerston North, Mt Albert and Ruakura (all HortResearch facilities) operate in accordance with an internal containment manual, as required by the Standard *Containment Facilities for Microorganisms.*

The facilities also comply with the requirements of the MAF Regulatory Authority Standard 154.02.17 *Transitional Facilities for Biological Products* at Physical Containment Level 1 (PC1) as defined in the Australian/New Zealand Standards 2243.3:1995.

The authorities own decision on application NOC99007 which is similar in scope to this application states:
"E. coli strain K12 has been subcultured in research laboratories since 1922 and the closely related strain B has been subcultured for over 30 years. They are not known to colonise the alimentary tract of a human host or cause

any symptoms of disease. The strains are genetically crippled and therefore cannot survive without certain growth factors. As the laboratory-based strains of *E. coli* will be maintained in approved containment and are unable to survive outside of controlled conditions the Committee considered the escape and establishment of self-sustaining populations, which might cause adverse effects, as extremely unlikely.

The ease with which the organisms could be eradicated if an undesirable population was established was not considered important due to the characteristics of the organisms and their inability to survive outside of the laboratory [*section 37(a)* and *(b)*]."

This application extends the range of vectors and organisms that can be imported beyond those specified in NOC99007 the additional vectors and DNA sources included (see Appendix 8) do not pose any extra risks with regard to ability to escape or ease of eradication. The list of vectors in application NOC99007 already contains vectors that are very similar to the vectors that will be covered by this new application. The difference being that the vectors in this new application are described in a more general way. The new vector definitions and hosts have been checked and comply with the stipulations in the decision form in so far that they exclude conjugative plasmids or contain generalised transducing phages. Any further modification of the imported *E. coli* strains K12 and B derivatives and the imported vectors will be done in physical containment level 1 (PC1) laboratories (AS/NZS 2234.3:1995) and the appropriate prior approval for these modifications will be obtained from the relevant IBSC with delegated decision making authority, or from ERMA New Zealand.

Ability of genetically modified *Escherichia coli* strains K12 and B to transfer nucleic acids to other bacteria. The applicants recognise that there can be potential for horizontal gene transfer to occur should the *E. coli* strains or plasmids be conjugative, in that they are able to transfer their DNA to another cell or in the case of plasmids able to mobilise themselves from one bacterium to another.

In recognition of this the applicants will limit the organisms in this application to those that conform to the approved host/vector systems list: Schedule 2 of the HSNO (Low-Risk Genetic Modification) Regulations. Schedule 2 identifies that only non-conjugative K12 and B strains of *E. coli* and non-conjugative plasmids can be assigned PC1 containment in a development decision. Combinations of strains K12 and B and vectors that reconstitute conjugative activity will not be used for any of the importations.

11. In the identification and assessment of risks, costs and benefits and other impacts, which may occur should the organism escape, include those matters set out below.

The information should comprise of the risks identified and include:

- the nature of the adverse effects of the organism.
- the probability of occurrence and the magnitude of each adverse effect.
- the risk assessed as a combination of the magnitude of the adverse effect and the probability of its occurrence.
- the options and proposals for managing the risks identified.
- the uncertainty bounds on the information contained in the assessment, expressed quantitatively where possible but otherwise through narrative statements.

The identification and assessment of costs and benefits required in each application must include.

- the nature of the costs and benefits associated with the proposed new organism and whether they are monetary or non-monetary;
- the magnitude or expected value of the costs and benefits and the uncertainty bounds on the expected value.

Relevant costs and benefits will be those which pertain to the New Zealand economy, society and environment and which would not arise if the application was not approved (ie the opportunity cost to New Zealand). They shall include the long term as well as short term, and consequential as well as direct costs and benefits.

The information on risks, costs and benefits shall include the distributional effects over time, space and groups in the community. It shall also include the uncertainty intervals associated with these estimates.

Costs and benefits of the organism. There is no foreseeable risk associated with importation of the organism. This is because it will be held in containment; even if it were to escape from containment, it would be unable to establish a self-sustaining population; and the organism has been very widely used in research laboratories world wide for over 20 years with no evidence of adverse effects. Importation of the organism is a non-monetary benefit that will advance scientific knowledge and understanding. The costs of not importing the organism include a major reduction in New Zealand's ability to carry out innovative research (and its resultant downstream products and revenue for the country), reduced ability to access the products of biotechnology capabilities that reside overseas and would be hard and or time consuming to replicate in New Zealand, reduced opportunities to train new researchers in molecular biology and biotechnology and a reduced ability for New Zealand researchers to be part of the international scientific research community. There are no costs associated with importation of the organism.

The ability to import low-risk genetically modified *Escherichia coli* is essential for enabling New Zealand researchers to carry out a large number of innovative research projects that will enhance scientific knowledge and understanding. In particular the benefits of this modification will include the ability to import new and improved vectors and hosts that are required to maintain New Zealand's competitive research and technical position.

The magnitude or expected value of the costs and benefits and the uncertainty bounds on the expected value. Since there is very little chance of any adverse effects the magnitude of the costs of adverse effects to the community is likely to be small. The magnitude of the benefits is more difficult to predict. Biotechnology products could potentially become a major earner of export dollars for the New Zealand economy within the next 20 years. The opportunities in biotechnology have been well articulated by Dr William Rolleston who stated that " New Zealand has the opportunity to take advantage of the biology revolution and develop a biology based science research industry which can compare with Tourism for economic opportunity" [http://www.lifesciencenz.com/repository/speeches_submissions/economic_impact_biotech.htm]. The Tourism industry earns $5 billion p.a. in overseas exchange for New Zealand. Already the biotechnology research industry constitutes a component of the local economy of the order of tens of millions of dollars per year. If the underpinning nature of the research is taken into account, then it is envisaged that the uncertainty bounds of the benefits are between tens and hundreds of millions of dollars. In addition, if the entire world moves to a biotechnology based agricultural mode of operation, then the New Zealand economy is likely to suffer a large decline if it is not able to utilise the latest tools and technological advances. Such a decline could potentially be measured in billions of dollars given the importance of the agricultural sector to New Zealand's economy. Vital components of these new tools are included in this modified importation application.

Since the biotechnology industry is in a state of continual improvement, the additional importation approvals sought in this application over and above those specified in application NOC99007 are envisaged to add a component to

the magnitude of the beneficial effects, the exact nature of this component is difficult to predict. The proposed modifications pose no new or additional risk and therefore are unlikely to have any increased adverse effects.

12. Information on the positive effects of the organism:

The organism will be essential in enabling New Zealand researchers to carry out a very large number of innovative research projects in the general areas of health and biotechnology, thereby enhancing scientific knowledge and understanding.

13. Assessment of effects

If the assessment of effects is combined into this section, applicants should clearly indicate how the information requirements in sections 10, 11 and 12 of this form are addressed.

[No] further information

[No] commercially sensitive information

These effects are covered in the preceding sections (10-12).

20 Customhouse Quay,
Cnr Waring Taylor & Customhouse Quay
PO Box 131, Wellington
Phone: 04-473 8426 Fax: 04-473 8433
Email: enquiries@ermanz.govt.nz
Website: www.ermanz.govt.nz

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO

Containment System

14. Information about proposed containment system:

Provide information on how it is proposed that the organism be adequately contained including how the proposed containment system conforms to the requirements of the Parts I and II of the Third Schedule of the Act as appropriate.

This may include reference to, and outlines of, appropriate standards and codes of practice.

[No] further information

As the host organism and vectors listed under Schedule 2 of the Hazardous Substances and New Organisms (Low Risk Genetic Modification) Regulations 1998, this organism falls into Categories A and B of the Regulations. Therefore the containment level for the organism is PC1 of AS/NZS 2243.3. The organism will be imported into transitional facilities approved and registered by the Ministry of Agriculture and Fisheries pursuant to the Biosecurity Act 1993 and in accordance with MAF Regulatory Authority Standard 154.02.17, *Transitional Facilities for Biological Products* and MAF Standard 154.03.02: *Containment Facilities for Microorganisms*. A copy of Quarantine Manual for the Containment Facility at HortResearch is attached.

International and related matters

15. Information on all occasions where the organism has been considered by the government of any prescribed State or country or by any prescribed organisation and the results of such consideration: Where no countries or organisations are prescribed by regulations made under section 140(1)9k) of the Act, this section can be omitted.

If the applicant is aware that the organism has previously been considered by, for example, any OECD or APEC country, information on the nature of that consideration, including the result, should be provided if known.

[No] further information

The organism is exempt from the National Institute of Health (USA) Guidelines for Recombinant DNA Research because it does not present a significant risk to health or the environment.
Reference: National Institute of Health Guidelines for Research Involving Recombinant DNA Molecules. (http://www.nih.gov/od/orda/toc.htm).

This organism is exempt from the Genetic Manipulation Advisory Committee (GMAC) (Australia) guidelines if the foreign nucleic acids is not derived from a microorgansim able to cause disease in humans, plants or animals. If the foreign nucleic acid is a pathogenic determinant; uncharacterised DNA from microorganisms able to cause disease in humans, animals or plants; or an oncogene then it requires approval by the Institutional Biosafety Committee and Notification to GMAC. In addition the new proposed Australian legislation also classifies these organisms as exempt.

Reference: Genetic Manipulation Advisory Committee Guidelines for Small Scale Genetic Manipulation Work. April 1995. GMAC Secretariat, GPO Box 2183, Canberra, ACT 2601, Australia.

16. Information on New Zealand's international obligations that may be relevant to the application:

Where the applicant is aware that New Zealand's international obligations may be relevant to the application, indicate the nature of the obligation and the effect this may have on the application.

If the applicant is aware of obligations such as the WTO Agreements, the Convention on International Trade in Endangered Species (CITES), Trans Tasman Mutual Recognition Agreement and the like that may be relevant to the application, then information on these obligations should be provided, if known.

[No] further information

This is unlikely to apply to most of the importations envisaged under this application. However the applicants are aware that the Department of Conservation should be contacted prior to the import of genetic material from CITES listed species to ensure the requirements of CITES are met. In addition we undertake to ensure the correct documentation from the exporting country is gained, to import genetic material of species listed under CITES.

Previous considerations

17. If the application relates to an organism that has been previously considered by the Advisory Committee on Novel Genetic Techniques or the Minister for the Environment on the recommendation of the Interim Assessment Group, details of the consideration and its results:

[No] further information

ERMA has recently approved an application for importation (NOC99007) which has a similar scope to the present application. This application seeks to expand the nature of the organisms which can be imported by using the more generic descriptor terms now permitted by ERMA. The development of E. coli strains K12 and B modified by DNA from many of the donor organisms listed in Appendix 8 was approved by the Advisory Committee on Novel Genetic Techniques. Reference: New Zealand Gazette Issue 101 (for example item 112 pages 2379 – 2382). In addition a number of applications to IBSCs involving research with similar low-risk E . coli strains under PC1 or PC2 containment have been approved under the new (HSNO) legislation (for example GMD99125, GMD99127, GMD99131 and GMD99137).

Other relevant legislation

18. Information on other legislation relevant to the organism and its use throughout its life cycle.

If the organism is also subject to other legislation (eg. an Import Health Standard under the Biosecurity Act 1993, or resource consent under the Resource Management Act 1991), details should be provided.

[No] further information

The applicants are aware that each importation of the organism requires a Ministry of Agriculture and Fisheries permit under the Biosecurity Act 1993.

Glossary

19. A glossary of scientific and technical terms used in the application.

This may be appended to the application on a separate form if desired.

[No] further information

DNA library: a set of clones each containing a different DNA fragment derived from a common source.
Genetically crippled: organisms that lack genes essential for their survival outside containment.
Hybridisation: the formation of double-stranded nucleic acid molecules where each strand is from a different source.
Mutagenesis: treatment of DNA in order to introduce heritable changes to the nucleotide sequence.
Non-conjugative: a plasmid that cannot transfer itself from one bacterial cell to another.
Phytoplasma: A cell-wall less bacterial-like obligate non-culturable parasite (distantly related to mycoplasma) that causes disease in plants.

Other relevant information

20. Provide here any other information required by the Act or regulations not included under any other section of this form.

[No] further information

[No] commercially sensitive information

No further information is required by the Act.

Summary of Application Contents

(Please check the application is complete and identify attachments)

[Yes] Fees enclosed

[Yes] Assessment of effects included

[No] Confidential information supplied

[Yes] Signed and dated

[Yes] Appendices attached and cross-referenced (list below)

Quarantine Manuals for Containment facility HortResearch and its 7 Appendices
Appendix 8 Description of organisms, cloning vectors and DNA source organisms.

Signature of applicant or person authorised on behalf of applicant _____ **Date:**