

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
 NGĀ KAIWHAKATUPATO WHAKARARU TALAO



FORM NO2G

Application for approval to

**IMPORT INTO CONTAINMENT ANY NEW ORGANISM
 THAT IS GENETICALLY MODIFIED**

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

Application Title:

Applicant Organisation:

ERMA Office use only

Application Code:

Formally received: ___/___/___

ERMA NZ Contact: _____

Initial Fee Paid: \$

Application Status:

**Application for approval to import into containment
any new organism that is genetically modified,
under Section 40 of the Hazardous Substances and
New Organisms Act 1996**

ER-AN-02G 11/02
FORM 2G

Page 1

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 or your Institutional Biological Safety Committee.
 2. This application form covers importation into containment of any new organism that is genetically modified, under section 40 of the Act.
 3. If you are making application to import into containment an organism that is **not a genetically modified organism** you should complete **Form NO2N** instead of this form (Form NO2G).
 4. This form, together with form NO2N, 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 website 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 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.

ERMA New Zealand
20 Customhouse Quay
PO Box 131
Wellington
NEW ZEALAND
Telephone: 64-4-916 2426
Facsimile: 64-4-914-0433
E-mail: info@ermanız.govt.nz
www.ermanız.govt.nz

20 Customhouse Quay,
Cnr Waring Taylor & Customhouse Quay
PO Box 131, Wellington
Phone: 04-916 2426 Fax: 04-914 0433
Email: info@ermanız.govt.nz
Website: www.ermanız.govt.nz

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
NZE KAITIARAUPATO WHAKARARU TAIAU



Section One – Applicant Details

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

Name >

Postal Address >

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 >

Position >

Address >

Phone >

Fax >

E-mail >

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 genetically modified. For an application to import into containment a new organism that is **not** genetically modified, use **Form NO2N**.

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).

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

Describe the 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. This explanation is particularly important if the work involves DNA from native flora and fauna, or the use of human genes. In addition, discuss whether expression of the foreign genetic material is anticipated, and any unusual manipulative steps involved in the development.

>

2.3 Public interest in the application

Provide comment on whether there is reason to believe or not to believe that there is potential for public interest in any aspect of the application. This may be related to any novel or unusual genetic manipulation, use of species or subjects of cultural significance, intended use of the GMO, level or nature of the risks involved, extent to which the application sets a precedent.

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

If the application is for importation of more than one organism, information must be provided 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

Please provide details of the following:

Latin binomial, including full taxonomic authority:

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Common name(s), if any:

>

Type of organism (eg bacterium, virus, fungus, plant, animal, animal cell):

>

Taxonomic class, order and family:

>

Strain(s) and genotype(s), if relevant:

>

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

>

3.2 Provide unique name(s) for the new organism(s) to be imported for entering in the public register.

These name(s) should clearly identify the species and strain(s) and genetic modification(s).

For example, "*Escherichia coli* DH5a modified by pBluescript containing cholera toxin gene"

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**Application for approval to import into containment
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ER-AN-02G 11/02
FORM 2G

Page 6

3.3 How were the new organism(s) developed?

Provide details of the following:

Vector system(s):

>

Type and source of additional genetic material:

>

Use of special genetic material of significance to Maori:

Please complete this table by marking the correct box

	Yes	No
Were native flora or fauna used as host organism(s) ?		
Was genetic material from native flora and fauna used in developing these GMOs?		
If native flora and fauna were involved, are the species concerned endemic to New Zealand?		
Was human genetic material involved in developing these GMOs? <i>Answer Yes if human genetic material in any form was used, ie obtained directly from humans (either Maori or non-Maori), from a gene bank, synthesised, copied and so on.</i>		
Was genetic material obtained directly from human beings used in developing these GMOs? <i>If Yes, provide additional details below.</i>		

If native flora and fauna were involved (either as host organisms or as a source of genetic material), from where in New Zealand or elsewhere, was this material obtained? Be as specific as possible as this information may be needed to decide whether Maori have been appropriately consulted.

>

If human genetic DNA was obtained directly from human beings, please provide details.

>

Other details of the genetically modified organism(s) (such as whether the modification is stably inherited, if the foreign genetic material is to be expressed, and anticipated characteristics resulting from such expression):

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3.4 Identify the category or categories of genetic modification(s) as described in the current HSNO (Low-Risk Genetic Modification) Regulations, had the genetic modifications been carried out in New Zealand.

Identify specific class of modifications(s) as described in the Regulations and explain your characterisation.

>

3.5 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).

>

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.

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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 their 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 to survive and reproduce if it did escape from containment.

>

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, human health and safety (e.g. of workers in the containment facility), and 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)

>

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

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- C. Potential adverse effects on the relationship of Maori 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.

>

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

>

5.3 Provide an assessment of the adverse effects identified in Section 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. The assessment should consider options and proposals for managing risks identified and consider whether the identified risks can be adequately managed by the proposed containment system. 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)

>

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

>

- C. Potential adverse effects on the relationship of Maori 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 of consultation and the outcome.

>

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

>

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.

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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.

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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 inseparable organism(s). 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.

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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.

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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)?

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

>

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

>

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.

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Section Seven – Application Summary

Summarise the application in clear, simple language that can be understood by the general public. Include a description of the organism(s) to be imported into containment, and any risks and benefits associated with their importation. This summary will be used to provide information for those people and agencies who will be notified of the application (eg Ministry of Agriculture and Forestry, Department of Conservation, Crown Research Institutes) and for members of the public who request information. Do not include any commercially sensitive information in this summary.

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**Application for approval to import into containment
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ER-AN-02G 11/02
FORM 2G

Page 14

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: