

**FORM NO2R****Application for approval to****IMPORT INTO CONTAINMENT
LOW RISK GENETICALLY MODIFIED ORGANISMS
BY RAPID ASSESSMENT****under sections 40 and 42B of the
Hazardous Substances and New Organisms Act 1996****Application Title:****Applicant Organisation:**

	IBSC	ERMA NZ
Considered by:		

ERMA Office use onlyApplication Code:

Formally received: ___/___/___

ERMA NZ Contact: _____

Initial Fee Paid: \$

Application Status:

IMPORTANT

1. An associated User Guide NO2R is available for this form and we strongly advise that you read this User Guide before filling out this application form. If you need guidance in completing this form please contact ERMA New Zealand.
2. This application form only covers the import of low-risk genetically modified organisms that meet Category A and/or B experiments as defined in the *HSNO (Low-Risk Genetic Modification) Regulations 2003*.
3. If you are making an application that includes not low-risk (formerly Category C) organisms, as described in the *HSNO (Low Risk Genetic Modification) Regulations 2003*, then you should complete form NO2G instead of form NO2R (this form).
4. You should periodically check with ERMA New Zealand or on the ERMA New Zealand web site for new versions of this form and only use the most recent version.
5. You can also 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 more than one new organism where the organisms are used in the same project, or have a similar risk profile.
7. Any supporting 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 but referenced in the application. You need to justify why you consider the material commercially sensitive, and make sure it is clearly labelled as such. Confidentiality of material is subject to the provisions of the Official Information Act 1982 and the basis of which is that information should be publicly available unless there is good reason to protect it. Please make yourself familiar with the Official Information Act and with ERMA New Zealand Sheet Number 12 on our website.
9. Applicants must sign the form and enclose the correct application fee (plus GST) if it is submitted to ERMA New Zealand. 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 your Institutional Biological Safety Committee or ERMA New Zealand. One of our staff members will be able to help you.

This version of the application form was approved by the Chief Executive of ERMA New Zealand on 28 October 2003.

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ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
NGĀ KAIWHAKAUPĀTO WHĀKARARU TAIAKŪ



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Section One – Applicant Details

1.1 Name and postal address in New Zealand of the organisation or private 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 >

20 Customhouse Quay,
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NGĀ KAIWHAKAUPATO WHAKARARU TAIAU



Fax >

E-mail >

Section Two – Lay Summary of the Application

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

In this summary, 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 to be imported. This explanation is particularly important if the organisms to be imported contain DNA from New Zealand native flora and fauna, or human genes. 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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Section Three –Description of Organism(s) to be Imported

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

3.1 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). What are the organisms to be imported and what will these organisms be used for? Or why are these organisms being imported?

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3.2 Give the unequivocal identification of the host organism(s) to be imported.

Please include details (if applicable) on the following:

Latin binomial or appropriate taxonomic classification to uniquely identify the organism, 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 categories such as family, order, class and division (if applicable):

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

>

Other information, including presence of any inseparable or associated organisms, and whether a prohibited organism¹ is involved:

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¹ For prohibited organisms, please refer to the Second Schedule of the HSNO Act.

3.3 Information on the host organism(s)

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

Please complete the following table.

	Yes	No
1. Is the organism normally capable of causing disease in humans, animals, plants or fungi? <i>If yes, you must give the details below and complete sections 4 & 5.1 of this form.</i>		
2. Is the organism a human cell line? <i>If yes, you must complete section 5.2 of this form and provide details below.</i>		
3. Is the organism considered to be native biota? <i>If yes, you must complete section 5.2 of this form and provide details below.</i>		
4. Does the organism contain infectious agents normally able to cause disease in humans, animals, plants, or fungi²? <i>If yes, you must give the details below and complete sections 4 & 5.1 of this form.</i>		
5. Does the organism produce dessication-resistant structures, such as spores or cysts, that can normally be disseminated in the air? <i>If yes, you must give the details below and complete sections 4 & 5.1 of this form.</i>		
6. Is the organism characterised to the extent that its main biological characteristics are known?		
7. Does the organism normally infect, colonise or establish in humans? <i>If yes, you must give the details below and complete sections 4 & 5.1 of this form.</i>		
8. If the organism is a whole plant or plant tissue³, is it: a. allowed to develop reproductive structures? <i>If yes, please provide further information on containment in section 4 of this form.</i> b. kept in a closed container?		
9. Is it a category 1 host organism⁴?		
10. Is it a category 2 host organism⁵?		

Note: If the genetic modification does not involve a category 1 or 2 host organism then the proposed project does not meet the criteria in section 42B(2) of the HSNO Act for the rapid assessment of adverse effects for importation of genetically modified organisms into containment.

² For example, mammalian cell lines containing active viruses or infectious agents normally able to cause disease in humans.

³ For a whole plant or plant tissue to be considered a Category 1 host organism, it must not be allowed to develop reproductive structures **and** must be kept in a closed container.

⁴ Refer to section 7(1) of the HSNO (Low-Risk Genetic Modification Regulations) 2003.

⁵ Refer to section 7(2) of the HSNO (Low-Risk Genetic Modification Regulations) 2003.

Other details of the host characteristics (including its ability to form a self-sustaining population) if it is a pathogenic microorganism

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If host was sourced from humans provide details of where the material was obtained from, and whether approval was obtained from an Ethics Committee (if applicable). Be as specific as possible as this information may be needed to decide whether Maori have been appropriately consulted.

>

If native biota were used as host organism, 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.

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3.4 How were the new organism(s) developed?

Provide details of the following:

Vector system(s) used:

>

Type and source of additional genetic material (i.e. donor DNA):

>

Use of special genetic material: please complete this table by marking the correct box

	Yes	No
Was genetic material derived from organisms capable of causing disease in humans, animals or plants used in developing these GMOs? <i>If Yes, you must provide full details in this section and complete sections 4 & 5.1 of this form.</i>		
Was genetic material from native biota used in developing these GMOs? <i>If yes, provide details below and complete section 5.2.</i>		
Was human genetic material used in developing these GMOs? <i>Answer Yes if human genetic material in any form was used, ie obtained directly from humans, from a gene bank, synthesised, copied and so on. Please provide details below and complete section 5.2.</i>		

If nucleic acids from pathogenic microorganisms were involved, please specify exactly which sequences and species and strain they were derived from. Be as specific as possible as this information will be needed to decide whether this application involves a low-risk genetic modification or is “not low-risk”. Include risk group classification (e.g. 1, 2, 3 or 4) if relevant. If the nucleic acid introduced was characterised so that its sequence and gene function are known, please state this and provide verifiable evidence. Please attach maps of genetic constructs if possible.

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If native biota were involved, 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 informed and/or involved.

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If material was sourced from humans provide details of where the material was obtained from, and whether approval was obtained from an Ethics Committee (if applicable). Be as specific as possible as this information may be needed to decide whether Maori have been appropriately informed and/or involved.

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Other details of the development(s) (such as what techniques or experimental procedures were used during the modification of the organism(s), if any unusual manipulations were carried out) **including if the foreign genetic material is expressed and where it is expressed:**

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3.5 Identify the category or categories of genetic modification(s) as described in the HSNO (Low-Risk Genetic Modification) Regulations 2003, had the genetic modifications been carried out in New Zealand. Identify the category of host organism (e.g. 1 or 2), category of genetic modification (e.g. A or B) and explain your characterisation if necessary. This is particularly important for work involving pathogenic microorganisms and viral vectors.

Please complete the table below as it will guide you in your classification of the organism(s) in accordance with the Regulations.

	Yes	No
1. Does this application involve a category 1 host organism? <i>Copy from question 9 of table 3.3.</i>		
2. Does this application involve a category 2 host organism? <i>Copy from question 10 of table 3.3.</i>		
3. Does the modification increase the pathogenicity, virulence, or infectivity of the host organism to laboratory personnel, the community, or the environment? <i>An answer of yes to this question may indicate that the development is not low-risk⁶. Please check with your ERMA applications advisor.</i>		
4. Does the modification result in the genetically modified organism having a greater ability to escape from containment than the unmodified		

⁶ Modifications of category 1 host organisms that result in a host organism that is more pathogenic, virulent or infectious to laboratory personnel, the community, or the environment may be considered low-risk (i.e. Category B) if the increase in pathogenicity or virulence is not considered to be of a higher level than that of a category 2 host organism.

host organism? <i>An answer of yes to this question may indicate that the development is not low-risk. Please check with your ERMA applications advisor.</i>		
5. Is the organism to be maintained under a minimum of PC1 ⁷ containment?		
6. Is the organism to be maintained under a minimum of PC2 ⁸ containment?		
7. Does the organism conform to the requirements of a Category A genetic modification? ⁹		
8. Does the organism conform to the requirements of a Category B genetic modification? ¹⁰		

Explanation of characterisation:

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3.6 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* DH5α modified by pBluescript containing cholera toxin gene"

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^{7, 8} If the answers to both questions 5 and 6 are no, then this application is not considered low-risk and must be submitted to ERMA New Zealand.

^{9, 10} If the answers to both questions 7 and 8 are no, then this application is not considered low-risk and does not meet the requirements of section 42B(2) of the HSNO Act for rapid assessment of adverse effects for importation of genetically modified organisms into containment.

3.7 Characteristics of the organism(s) to be imported

Provide information on the known phenotypic characteristics of each organism(s) to be imported. For example, note novel traits conferred by the genetic modification. This information should be relevant to the identification of the risks of the organism (section 5).

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Section Four – The Proposed Containment System and its Effectiveness

Describe the proposed containment system (physical and operational)

A brief description stating the containment level i.e. PC1 or PC2 and referencing the relevant MAF/ERMA New Zealand containment standard will be sufficient for most projects except those involving work identified for further information in Section 3.3 such as pathogenic microorganisms or organisms that produce desiccation-resistant structures normally disseminated by air. For plants, state whether they will be allowed to develop reproductive structures or not and methods to contain them if applicable. For those types of developments identified in section 3.3 and 3.4 please provide further information about the containment system and the ability of the organism(s) to escape from this system and form self-sustaining populations.

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Section Five - Identification and Assessment of Adverse Effects and Risks

This section should be completed if use of pathogenic microorganisms, human cells, native or valued flora or fauna as host or donor nucleic acid sources were identified in section 3. It is expected that organisms meeting the low risk requirements will not normally have any *significant* biological risks associated with them, so that an assessment of adverse effects will not normally be required. However, there may still be some adverse effects that need to be identified and assessed. This might include economic, social and cultural adverse effects and other risks not addressed by the *HSNO (Low-Risk Genetic Modification) Regulations 2003*.

5.1 Identification and assessment of non-cultural adverse effects of the organism(s). This section should be filled out for those types of developments identified in section 3.3 and 3.4 that warrant further assessment. Consider and identify the adverse effects of the organism(s) both in and out of containment. Assessment of adverse effects should take account of the containment system in place. If you consider that there are significant residual adverse effects a rapid assessment could be inappropriate. In that event, talk to your IBSC or to ERMA New Zealand. Complete the following sections, but state if they are not relevant to your application.

A. Effects on the environment:

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B. Effects on human health and safety:

>

C. Economic effects:

>

D. Other Effects:

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5.2 Identification and assessment of 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 If your application involves genetic material from humans, native flora and fauna, or from flora and fauna which it is reasonable to think may be valued by Maori, you should address these issues here. Include details of any consultations with Maori that you have undertaken in relation to this application. If concerns were raised during the consultation process you should consider whether or how you are able to address those concerns. If Maori have residual concerns over the application then it should be referred to ERMA New Zealand and not dealt with by the IBSC.

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Section Six – Additional Information

6.1 Do any of the organism(s) need approvals under any other legislation or are affected by international obligations? For example, the Animal Welfare Act, or the Convention on International Trade in Endangered Species.

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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, have they been previously considered for development? If yes, please provide details or the relevant approvals.

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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. Give the names of any appendices included with this application.

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CHECKLIST

Please check 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
Application signed and dated	Yes
If application submitted to ERMA New Zealand:	
Initial fee enclosed (incl. GST)	Yes
Electronic copy of application e-mailed to ERMA New Zealand	Yes

*NA – not applicable

Signed:

Date: