

**Application title:**

**Applicant organisation:**

**Considered by:**

IBSC	ERMA

**Please clearly identify any confidential information and attach as a separate appendix.**

**Please 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 references attached	Yes/NA
Application signed and dated	Yes
Electronic copy of application e-mailed to ERMA New Zealand	Yes

**Signed:**

**Date:**

Develop in containment a project of low risk genetically modified organisms by rapid assessment

1. An associated User Guide NO3P 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 or your IBSC.
2. This application form only covers the development 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 genetic modification experiments, as described in the HSNO (Low-Risk Genetic Modification) Regulations 2003, then you should complete form NO3O instead.
4. This form replaces all previous versions of Form NO3P.
5. 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.
6. 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.
7. 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.
8. Applicants must sign the form and enclose the correct application fee (plus GST) if it is submitted to ERMA New Zealand. Details of the 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.
9. Unless otherwise indicated, all sections of this form must be completed for the application to be progressed.
10. 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.

This version of the application form was approved by the Chief Executive of ERMA New Zealand on 12 November 2007.

## Section One – Applicant details

refer to page 9 of the user guide

<b>Name and details of the organisation making the application:</b>
Name: Postal Address: Physical Address: Phone: Fax: Email:
<b>Name and details of the key contact person <i>(if different from above)</i>:</b>
Name: Postal Address: Physical Address: Phone: Fax: Email:
<b>Name and details of a contact person in New Zealand, if the applicant is overseas:</b>
Name: Postal Address: Physical Address: Phone: Fax: Email:

Note: The key contact person should have sufficient knowledge of the application to respond to queries from ERMA New Zealand staff.

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## **Section Two: Lay summary and scientific project description**

*refer to page 9 of the user guide*

### **Lay summary of the application (approximately 200 words)**

Note: This summary should describe the genetically modified organism(s) being developed, the purpose of the application or what you want to do with the organisms(s). Use simple non-technical language.

### **Scientific project description (describe the project, including the background, aims and a description of the wider project)**

*refer to page 10 of the user guide*

Note: This section is intended to put the genetically modified organism(s) being developed in perspective of the wider project(s) that they will be used in. You may use more technical language but make sure that any technical words are included in the Glossary.

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**Short summary of purpose (please provide a short summary of the purpose of the application)** (255 characters or less, including spaces) *refer to page 11 of the user guide. This section will be transferred into the decision document.*

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### **Section Three –Description of the organism(s) to be developed**

*refer to page 13 of the user guide*

#### **3.1 Identification of the host organism to be modified**

Complete this section separately for **each host organism** to be modified.

<b>Latin binomial, including full taxonomic authority:</b>	
<b>Common name(s), if any:</b>	
<b>Type of organism</b> (eg bacterium, virus, fungus, plant, animal, animal cell):	
<b>Taxonomic class, order and family:</b>	
<b>Strain(s) if relevant:</b>	
<b>Other information</b> , including presence of any inseparable or associated organisms and any related animals present in New Zealand:	

### 3.2 Information on the host organism

Refer to pages 14-19 and pages 33-38 of the user guide for assistance in completing this section

Complete this section separately for **each host organism** to be modified.

		Yes	No
1	Is the organism normally capable of causing disease in humans, animals, plants or fungi?		
	<i>If yes, provide details here</i>		
2	Is the organism a human cell line?		
	<i>If yes, provide details here of where the material has been obtained from and whether approval has been obtained from an Ethics Committee (if required)</i>		
3	Is the organism native to New Zealand?		
	<i>If yes, provide details here for example, from where will this material be obtained? Be as specific as possible as this information may be needed to determine whether Māori have been consulted appropriately</i>		
4	Does the organism contain infectious agents normally able to cause disease in humans, animals, plants or fungi?		
	<i>If yes, provide details here.</i>		
5	Does the organism produce desiccation resistant structures (such as spores or cysts) that can normally be disseminated in the air?		
	<i>If yes, provide details here.</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, provide details here.</i>		
8	If the organism is a whole plant or plant tissue, do you intend to: a) Allow it to develop reproductive structures <i>If yes, please provide further information on containment in section 4</i> b) Keep it in a closed container?		
9	Is the host a Category 1 organism (as defined in the HSNO (Low-Risk Genetic Modification) Regulations 2003)?		
10	Is the host a Category 2 organism (as defined in the HSNO (Low-Risk Genetic Modification) Regulations 2003)?		

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 42A(2)(a) of the HSNO Act for the rapid assessment of projects for low-risk genetic modification.

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### 3.3 Nature and range of the proposed genetic modification(s)

Refer to pages 15-19 and pages 33-38 of the user guide for assistance in completing this section

Provide details on the following

Complete this section separately for **each host organism** to be modified only if there are significant differences in the modifications for each of the host organisms listed above.

#### Information on how the new organism(s) will be developed

<b>Vector system used, eg cloning or expression, plasmid, or viral</b>	
<b>Range of elements that the vectors may contain</b>	
<b>Type, source and function of any donor genetic material</b>	

#### Use of special genetic material

	Yes	No
Does the proposed modification use genetic material derived from organisms capable of causing disease in humans, animals, plants or fungi?		
<i>If yes, provide details here including the sequences as well as the species and strains they were derived from. If the genetic material to be introduced is characterised so that its sequence and gene function are known, please state this</i>		
Does the proposed modification use genetic material from native biota?		
<i>If yes, provide details here including where this material will be obtained from. Be as specific as possible as this information may be needed to determine whether Māori have been consulted appropriately</i>		
Does the proposed modification involve human genetic material? Answer yes if human genetic material in any form is used, ie whether it is obtained directly from humans, from a gene bank, synthesised, copied and so on.		
<i>If yes, provide details here including where the material is obtained from, and whether approval has been obtained from an Ethics Committee (if required). Also complete section 5 of this form.</i>		

**Other details of the modification**, including any unusual manipulations, if the foreign genetic material is to be expressed, where it is expected to be expressed and what techniques will be used in the modification.

### 3.4 Identify the category of experiments as described in the HSNO (Low-Risk Genetic Modification) Regulations, 2003.

Refer to pages 17-19 and pages 33-38 of the user guide for assistance in completing this section.

		Yes	No
1	Is the proposed modification to a Category 1 host organism?		
2	Is the proposed modification to a Category 2 host organism?		
3	Will the proposed modification increase the pathogenicity, virulence, or infectivity of the host organism to laboratory personnel, the community, or the environment? <i>If you answer yes to this question, please confirm with an ERMA advisor that the modification is low risk.</i>		
4	Will the proposed modification result in a genetically modified organism with a greater ability to escape from containment than the unmodified host? <i>If you answer yes to this questions, please confirm with an ERMA advisor that the modification is low risk.</i>		
5	Is the proposed modification to be carried out under a minimum of PC1 containment?		
6	Is the proposed modification to be carried out under a minimum of PC2 containment?		
7	Does the proposed modification conform to the requirements of a Category A genetic modification?		
8	Does the proposed modification conform to the requirements of a Category B genetic modification?		

**Explanation of categorisation, if necessary.** This is particularly important for work involving pathogenic microorganisms and viral vectors

## Section Four – The proposed containment system

*Refer to page 20 of the user guide for assistance in completing this section*

**Describe the containment facility and the proposed containment system (physical and operational)**

Question	Answer
Which MAF/ERMA Standard is this containment facility approved under?	
What physical containment level (AS/NZS 2243.3:2002) is this containment facility approved to operate at (where relevant)?	
What other physical measures do you propose to use to contain this organism?	
What procedural or operational measures do you propose to use to contain this organism?	
Any other information relevant to the containment of the organism.	

## Section Five – Identification and assessment of adverse effects

*Refer to page 21 of the user guide for assistance in completing this section*

This section should only be completed in detail if pathogenic microorganisms, human cells, native or valued flora and fauna were identified as host or sources of donor genetic material in section 3. It is expected that organisms meeting the low-risk regulations will not normally have any significant biological risks associated with them. 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

<b>What adverse effects could this organism have on the environment? <i>For all stages of the life cycle</i></b>
<b>What adverse effects could this organism have on human health and safety?</b>
<b>What adverse economic effects could this organism have?</b>
<b>What adverse effects could this organism have on the relationship of Māori 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)?</b>
Include details of any consultation that you have undertaken.
<b>Are there any other potential adverse effects?</b>

## Section Six – Additional information

*Refer to page 31 of the user guide for assistance in completing this section*

Additional Information	Y/N	If yes, explain
Do any of the organism(s) need approvals under any other New Zealand legislation?		
Does New Zealand have any international obligations relating to (any of) the organism(s)?		
Have any of the new organism(s) in this application previously been considered in New Zealand or elsewhere?		
Is there any additional information that you consider relevant to this application that has not already been included?		
Following the development of this organism what will the genetically modified organism be used for? <i>eg will experimental animals or plants be exposed to this organism?</i>		

**Provide a glossary of scientific and technical terms used in the application:**

**List of appendices attached:**

**List of references attached:**