



## FORM NO3

Application for approval to

**DEVELOP WITHIN A CONTAINMENT STRUCTURE ANY  
GENETICALLY MODIFIED ORGANISM (OTHER THAN BY RAPID  
ASSESSMENT)**

**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:

## **IMPORTANT**

1. An associated User Guide is available for this form. If you need additional guidance in completing this form please contact ERMA New Zealand.
2. This application form covers the development of genetically modified organisms that **do not** meet Category A and/or B experiments as defined in the *HSNO (Low-Risk Genetic Modification) Regulations 2003*, but which shall occur within a containment structure as defined within the HSNO (Genetically Modified Organisms) Amendment Act 2002. Developments which occur either in part or as a whole **outside** of a containment structure should be applied for using an alternative application form NO3O. Please contact ERMA New Zealand for advice if any part of your development will occur outside of a containment structure.
3. If you are making an application that meets the criteria for **Category A or B genetic modifications**, as described in the *HSNO (Low-Risk Genetic Modification) Regulations 2003*, then you should complete the **rapid assessment form NO3P** instead of form NO3 (this form).
4. This form replaces all previous versions of Form NO3. Older versions should not now be used. You should check with ERMA New Zealand or on the ERMA New Zealand web site for the most up-to-date version 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 development of more than one new organism where the organisms are used in the same project, or 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.

This application form was approved by the Chief Executive of ERMA New Zealand on 7 May 2004.

## **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 >**

**Fax >**

**E-mail >**

**1.3 If the applicant is an organisation or private individual situated overseas, name and contact details of the agent authorised to transact the applicant's affairs in relation to 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 **develop** in containment a genetically modified organism (other than by rapid assessment). For development of organisms meeting the requirements of Category A or B genetic modifications of the *HSNO (Low-Risk Genetic Modifications) Regulations 2003*, the **rapid assessment** application form (NO3P) should be used. For **importation** of genetically modified organisms into containment application form NO2R or NO2G should be used.

### **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 including spaces and punctuation). What will these organisms be used for? Or why are these organisms being developed?

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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.

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### **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 developed**

If more than one type of organism is to be developed 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.

#### **3.1 Give the unequivocal identification of the host organism(s)**

Please include details on the following:

**Latin binomial, including full taxonomic authority:**

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**Common name(s), if any:**

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

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**Taxonomic family:**

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

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

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**3.2 How will the new organism(s) be developed?**

Provide details of the following:

**Vector system(s):**

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**Type and source of additional genetic material:**

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

	Yes	No
Does this application use native flora or fauna as <b>host organism(s)</b> ? <i>If Yes, provide additional details below.</i>		
Does this application use <b>genetic material</b> from native flora and fauna? <i>If Yes, provide additional details below.</i>		
If native flora and fauna are involved, are the species concerned endemic to New Zealand?		
Does this application involve <b>human</b> cell lines? <i>Answer Yes if human cell lines in any form are used, ie obtained directly from humans (either Māori or non-Māori) or from a commercial supplier etc. Please provide additional details below.</i>		
Does this application use cell lines obtained <b>directly</b> from human beings?		
Does this application involve <b>human</b> genetic material? <i>Answer Yes if human genetic material in any form is used, ie obtained directly from humans (either Māori or non-Māori), from a gene bank, synthesised, copied and so on. Please provide additional details below.</i>		
Does this application use genetic material obtained <b>directly</b> from human beings?		

**If native flora and fauna are involved, from where in New Zealand or elsewhere will this material be obtained?** Be as specific as possible as this information may be needed to decide whether Māori have been appropriately involved.

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**If genetic material or cells are derived from humans provide details of where the material is obtained from, and whether approval has been obtained from an Ethics Committee, and/or consultation with Māori has taken place.**

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**Other details of the development(s)** (such as what techniques or experimental procedures are used, if any unusual manipulations are to be carried out, and if the foreign genetic material is to be expressed):

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**3.3 Identify the category or categories of experiment(s) as described in the Schedule of the HSNO (Low-Risk Genetic Modification) Regulations 2003.**

Identify the specific class of experiment(s) (eg Schedule 1(a), 1(f) or 1(j) etc.) and explain your characterisation.

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**3.4 Characteristics of the new organism(s).**

Provide information on the main features or essential characteristics of the organism(s) to be developed. You should note characteristics of the host organism as well as any new characteristics introduced by the genetic modifications. For example, note pathogenicity, production of spores/seeds/pollen, conditions for growth and reproduction. This information should be relevant to the identification of the risks of the organism (section 5.2).

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**3.5 Provide unique name(s) for the new organism(s) that can be used on the public register.**

For example, “*Escherichia coli* DH5 $\alpha$ ; pBluescript; cholera toxin gene”

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## **Section Four – The Proposed Containment System and its Effectiveness**

### **4.1 Describe the proposed containment system (physical and operational).**

The adequacy of the containment regime is a principal consideration for the Authority so you need to provide comprehensive information on the containment system and the containment structure. A containment structure is a vehicle, room building, or other structure set aside and equipped for the development of GM organisms. Your containment structure must be registered by MAF, and you should provide documentary evidence of this.

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### **4.2 Discuss the ability of the organism to escape from the proposed containment system.**

Describe the biological features of the organism(s) which would affect its ability to escape from containment. For example, “*E. coli* DH5 $\alpha$  is genetically debilitated such that it requires nutritional supplements that make it very unlikely to survive outside of laboratory culture.” or “Plants will be grown to reproductive stage, but inflorescences will be bagged to prevent escape of pollen or seeds.”

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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 this incidence. Provide a description of where the information in the application has been sourced from, eg from in-house research, independent research, technical literature, community or other consultation. Please attach copies of all reference material cited in the application.

### **5.1 Ability of organism(s) to establish a self-sustaining population.**

Discuss the ability of the organism to establish a self-sustaining population outside of containment. You should consider the ability of the organism to survive and reproduce if it did escape from containment. Also consider whether the organism could be eradicated outside of containment.

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### **5.2 Identify all potential adverse effects of the organism(s).**

Identify potential adverse effects associated with the organism(s). Consider effects on the environment (for example ecosystems) and human health and welfare, including any ethical and cultural effects. Remember to consider adverse effects of the organism(s) both in and out of containment. It is important to think about the source of the risk, ie the way in which the risk is created (the exposure pathway), and then the consequences of exposure. Adverse effects that are potentially non-negligible should be identified for the following categories:

**(a) Potential adverse effects on the environment** (ie the sustainability of native and valued introduced flora and fauna and the intrinsic value of ecosystems)

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**(b) Potential adverse effects on public health** (including occupational exposure)

>

**(c) Potential adverse effects 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). This section is best completed after consultation with Māori.

>

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

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### **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 (ie **the risk**), and the value (in monetary or non-monetary terms) of a particular adverse effect (ie **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** (ie the sustainability of native and valued introduced flora and fauna and the intrinsic value of ecosystems)

>

**(b) Potential adverse effects on public health** (including occupational exposure)

>

**(c) Potential adverse effects 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). If consultation with Maori has been undertaken you should provide details of 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 monetary and non-monetary benefits associated with the development of the new organism(s). You should focus on the immediate benefits associated with the development. For example, “increase in scientific knowledge”, “production of pharmaceutical for clinical trials”. Ensure that any beneficial effects identified can be realistically achieved during the course of the research approval.

**(a) Potential beneficial effects on the environment** (ie the sustainability of native and valued introduced flora and fauna and the intrinsic value of ecosystems)

>

**(b) Potential beneficial effects on public health**

>

**(c) Potential beneficial effects 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). This section is best completed in consultation with Māori.

>

**(d) Other potential beneficial effects** (such as social or economic positive effects)

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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 the new organism(s) (if possible), and any uncertainties associated with this assessment. You should also indicate who will receive the benefits.

**(a) Potential beneficial effects on the environment** (ie the sustainability of native and valued introduced flora and fauna and the intrinsic value of ecosystems)

>

**(b) Potential beneficial effects on public health**

>

**(c) Potential beneficial effects 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). Please refer to any results from consultation with Māori.

>

**(d) Other potential beneficial effects** (such as social or economic positive effects)

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**5.6 Overall evaluation of risks, costs, and benefits**

Doing this overall evaluation is the main task of the Authority. However, 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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**5.7 Controls on an approval**

The Authority has the discretion to impose additional controls on approvals to develop in containment any new organism(s). Please comment on the following:

**(a) the feasibility of a restricted time limit (eg. 5 years) being placed on an approval of this development**

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**(b) the feasibility of setting additional controls to measure or monitor any adverse effects associated with the development.**

For example, a control requiring the applicant to report on any otherwise unexplained allergenicity experienced by researchers handling the new organism(s)

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**(c) controls setting out reporting requirements**

The Authority is likely to consider setting controls which require reports to be made. Please comment on whether there are any particular aspects of the work on which you think regular, occasional, or one-off reporting would be useful.

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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, the development may involve modification of whole animals, which also requires an approval under the Animal Welfare Act 1999; or if genetic material from species listed by CITES is used, 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 approved for import?**

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

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

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**6.5 List of appendices.**

Give the names of any appendices included with this application. Appendices should contain any information that is commercially sensitive, or additional material included with the application (such as details of consultations, vector diagrams, referenced articles). The main application should refer to the relevant appendices but be able to be read as a stand-alone document.

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**6.6 List of references.**

Please include a list of the references cited in and supplied with this application. Originals of the references must be supplied in full.

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## **Section Seven – Application Summary**

Summarise the application in clear, simple language that is able to be understood by the general public. Include a description of the new organism(s), the purpose for which they will be developed, how they will be developed, the proposed containment system, and any risks and benefits associated with their development or use. 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, Ministry for the Environment, Department of Conservation, Regional Councils, etc) and for members of the public who request information. Do not include any commercially sensitive information in this summary.

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

\*NA – not applicable

**Signed:**

**Date:**