

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY  
 NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO



## **FORM NO-04**

**Application for approval to**

### **FIELD TEST IN CONTAINMENT ANY GENETICALLY MODIFIED ORGANISM**

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

**Application Title:**

**Applicant Organisation:**

|                       | IBSC | ERMA NZ |
|-----------------------|------|---------|
| <b>Considered by:</b> |      |         |

#### **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 on the ERMA New Zealand website. If you need additional guidance in completing this form please contact ERMA New Zealand.
2. This application form covers field testing in containment of any genetically modified organism and may be used to seek approvals for field testing in containment of more than one genetically modified organism where the organisms are of a similar nature.
3. If the application does not involve a defined organism and involves ongoing genetic manipulation this is not the correct form. Instead such applications covering **development of genetically modified organisms outside a containment structure** as defined within the Act 1996 should be made on **Form NO30**, instead of this form (Form NO-04).
4. This version of the application form is the most recently approved by the Chief Executive of ERMA New Zealand and replaces all other versions. Older versions will not be accepted. You should check with ERMA New Zealand or on the ERMA New Zealand web site for the current version of this form.
5. You should 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.
6. 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.
7. 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.
8. 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.
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. Until we receive the signed hard copy we will not be able to process your application.
11. **Note:** Applications to field test genetically modified organisms shall be publicly notified by the Authority (s 53(1)(d) of the HSNO Act) and may go to a hearing (s 60 of the HSNO Act).
12. This application form was approved by the Chief Executive of ERMA New Zealand on 28<sup>th</sup> June 2005.

**You can get more information by contacting us. One of our staff members will be able to help you.**

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[www.ermanz.govt.nz](http://www.ermanz.govt.nz)

## 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 the 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 the name and contact details of the agent in New Zealand 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 **field test** in containment any genetically modified organism. For applications for **development of genetically modified organisms outside of a containment structure** as defined within the HSNO Act 1996, use **Form NO3O**. For applications for development of genetically modified organisms meeting the requirements of the *HSNO (Low-Risk Genetic Modifications) Regulations 2003*, the **rapid assessment** application form (**NO3P**) 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.*

Briefly describe the organism(s) to be field tested, and the purpose(s) for which you wish to field test the organism(s).

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

Describe **in less than one page** the rationale for the overall project these organisms are to be used in so that people not directly connected with the research and with a limited knowledge of science can understand why these organisms are being field tested in containment. This explanation is particularly important if the field test involves DNA from human genes or native and valued introduced flora and fauna. In addition, discuss whether expression of the foreign genetic material is anticipated, and whether any unusual procedures will be involved in the field testing. Detail should also be included on the methods to be used, the general location, associated facilities and duration of the field test.

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### Section Three – Information on the organism(s) to be field tested

If more than one type of organism is to be field tested 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 to by ERMA New Zealand.

#### 3.1 Provide unique name(s) for the new organism(s) to be tested

These name(s) will be on the public register and should clearly identify each new organism. This must describe both the host organism as well as how it has been modified.

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#### 3.2 Give the unequivocal identification of the host organism(s)

Please include details on the following:

**Latin binomial, including full taxonomic authority:** (e.g. ---- Linnaeus 1753) **class, order and family:**

>

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

>

**Type of organism** (e.g. bacterium, virus, fungus, plant, animal, animal cell):

>

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

>

**Other information**, including presence of any inseparable or associated organisms; whether a prohibited organism is involved; and information on consideration of the organism(s) by other states, countries or organisations:

>

**3.3 Provide details on the genetic modifications and processes involved in the development of each of the organism(s) to be tested**

Experimental data and information obtained from the development phase of each genetically modified organism should be attached to this application as an Appendix to assist in risk evaluation.

**Identify the category or categories of the genetic modification(s) involved in the development as described in the HSNO Low-Risk Genetic Modification Regulations 2003.**

>

**Vector system(s) used in development of the genetically modified organisms.**

>

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

>

**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> ?  |     |    |
| Does this application use <b>genetic material</b> from native or valued introduced flora and fauna?                                     |     |    |
| If native flora and fauna are involved, are the species concerned endemic to New Zealand?   |     |    |
| Was human DNA or cell lines used that are of known Māori origin?  |     |    |
| Does this application use genetic material obtained <b>directly</b> from human beings? <i>If Yes, provide additional details below.</i> |     |    |

**If native flora and fauna are involved, from where in New Zealand or elsewhere has this material been obtained? What consultation with Māori has taken place and specifically with whom? What were the outcomes of this consultation e.g. what were the key issues raised, were options discussed to address/mitigate concerns?**

Be as specific as possible as this information may be needed to decide whether Māori have been appropriately involved.

>

**If the genetic modification involves DNA of human origin, provide details of where the material was obtained (including provenance and/or informed consent), and whether approval was obtained from an Ethics Committee, and what consultation with Māori has taken place.** Consultation with Māori will be required when human DNA or cell lines are used. In recording consultation, ensure you append any relevant information to the application including consultation feedback, minutes of meetings or other correspondence.

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**Other relevant details** (such as what techniques or experimental procedures were used, whether any unusual manipulations were carried out, and how the foreign genetic material is expressed).

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### **3.4 Characteristics of the organism(s) to be field tested**

Provide information on the main features or essential characteristics of the organism(s) to be field tested. Specify in what way the organism to be tested differs phenotypically from the unmodified organism from which it is derived. 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).

>

## Section Four – Outline of the proposed field test, containment and control system and its effectiveness

### 4.1 Describe the field test design

Include details of the location and layout of the field test and associated facilities, the number of sites involved, the number of organisms to be field tested and the duration of the field test.

>

### 4.2 Describe the proposed containment system (physical and operational)

A full account is required of how the organisms will be contained securely. Describe the physical characteristics of the containment system, including security features. Outline procedures followed in the operation and management of the containment system, and the supervision, training and qualifications of staff. Refer to relevant containment or other manuals as appropriate. Identify if the facility is currently registered by MAF as a containment facility. If so provide registration details.

>

### 4.3 Inspection of the site *before* field testing commences

Clause 6A(b) of Part 1 of the Third Schedule of the HSNO Act *may* require inspection of a site *before* field testing commences. Please provide reasons as to whether you think this clause 6A(b) should apply to your field test and describe how you would achieve this.

>

**4.4 Inspection and monitoring of containment facilities *during* the field test**

Clause 6A(a)(i) of Part 1 of the Third Schedule of the HSNO Act requires inspection and monitoring of containment facilities *during* the field test. Describe how this would be done.

>

**4.5 Clean up controls and *post* field test monitoring and inspection**

Section 45A(2)(a) and (b) of the HSNO Act requires that at the completion of a field test the organism and any heritable material from the organism (along with some or all of the remaining genetic elements) be removed or destroyed. Clause 6A(a)(ii) of Part 1 of the Third Schedule of the same Act also requires inspection and monitoring to ensure that this has taken place. Describe how you would achieve these objectives.

>

**4.6 Discuss the ability of the organism(s) to escape from the proposed containment system**

Describe the biological features of the organism(s) that would affect its ability to escape from the containment system. For example, "Plants will be grown to reproductive stage, but inflorescences will be bagged to prevent escape of pollen or seeds." "The double fencing system will be high and wide enough to prevent escape of the animals by jumping.

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## Section Five – Identification and Assessment of adverse and beneficial effects (risks, costs, and benefits)

This section must include information on the adverse and beneficial effects referred to in the HSNO Act. Adverse effects include risks and costs, and beneficial effects are described as benefits. All effects should be described in terms of the magnitude of the effect if it should occur and the likelihood of occurrence. Monetary and non-monetary effects should be considered, and a comment should be included on the distribution of the adverse and beneficial effects across affected parties. When identifying and assessing the risks of the genetically modified organism it is important to consider the increase in risk that it poses when compared to the unmodified parent organism from which it has been derived. Provide a brief account 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. Comment on the significance of uncertainty in the information and thus in the assessment of effects.

### 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, taking into account the ease of its eradication. You should consider the ability of the organism to survive and reproduce if it did escape from containment.

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### 5.2 Identify all potential adverse effects of the organism(s) (risks and costs)

Identify potential adverse effects associated with the organism(s). Consider effects on the environment (for example ecosystems), human health and safety, and any ethical and cultural effects. Remember to consider adverse effects of the organism(s) both within and out of containment should the organism escape. Identification is primarily concerned with setting out all the effects that might occur, and deciding which of them warrant more detailed assessment. The detail of assessment should be in section 5.3. 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 human health and safety** (including occupational exposure).

>

**C. Potential effects resulting from the transfer of any genetic elements to other organisms in or around the site of the field test**

("Genetic element", in relation to a new organism, means- (a) heritable material; and (b) any genes, nucleic acids, or other molecules from the organism that can, without human intervention, replicate in a biological system and transfer a character or trait to another organism or to subsequent generations of the organism).

>

**D. Potential adverse effects on the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued introduced flora and fauna and other taonga** (taking into account the principles of the Treaty of Waitangi).

>

**E. Other potential adverse effects** (such as effects on society and community, effects on the market economy and effects on New Zealand's international obligations).

>

**5.3 Provide an assessment of the potentially significant adverse effects identified in Section 5.2.**

The assessment should include the nature, likelihood or probability of occurrence and magnitude (in monetary or non-monetary terms) of each adverse effect. The uncertainty bounds of the information contained in the assessment should also be discussed. The assessment should consider options and proposals for managing identified adverse effects and consider whether they can be adequately managed by the proposed containment system. Adverse effects should be assessed in relationship to:

**A. Potentially significant adverse effects on the environment, in particular 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. Potentially significant adverse effects on human health and safety** (including occupational exposure).

>

**C. Potentially significant effects resulting from the transfer of any genetic elements to other organisms in or around the site of the development or field test.**

>

**D. Potentially significant adverse effects on the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued introduced flora and fauna and other taonga** (taking into account the principles of the Treaty of Waitangi). If consultation with Māori has been undertaken you should provide details of the outcome, including options and proposals for managing risks identified.

>

**E. Other potentially significant adverse effects** (such as effects on society and community, effects on the economy and effects on New Zealand's international obligations).

>

**5.4 Identify all potential beneficial effects of the organism(s) (benefits)**

Identify monetary and non-monetary benefits associated with the organism(s) being field tested. Focus on immediate as well as long-term benefits and specify whether these are likely to be direct or indirect benefits. Substantiate claims by reference to sources of information. Benefits should be identified for the following categories:

**A. Potential beneficial effects on the environment, in particular on ecosystems and their constituent parts** (e.g. beneficial 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 beneficial effects on human health and safety.**

>

**C. Potential beneficial effects specific to Māori.**

>

**D. Other potential beneficial effects** ((such as effects on society and community, effects on the market economy and effects on New Zealand's international obligations).

>

**5.5 Provide an assessment of the potentially significant beneficial effects identified in Section 5.4.**

Estimate the likelihood that the benefits will be realised, the magnitude of benefits associated with the new organism(s) and any uncertainties associated with this assessment. Be as specific as possible, and, where appropriate, provide documentation to support your assessment. Discuss the likelihood of any of these benefits being realised by any of the alternative methods identified in section 6.1. You should also indicate who would receive the benefits, and the time-course of delivery of the benefits. Beneficial effects should be assessed in relationship to:

**A. Potentially significant beneficial effects on the environment, in particular on ecosystems and their constituent parts** (e.g. beneficial 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. Potentially significant beneficial effects on human health and safety.**

>

**C. Potentially significant beneficial effects specific to Māori.**

>

**D. Other potentially significant beneficial effects** (such as effects on society and community, effects on the market economy and effects on New Zealand's international obligations).

>

**5.6 Overall evaluation of adverse and beneficial effects (risks, costs, and benefits)**

This overall evaluation is the main task of the Authority. The Authority has to decide whether the beneficial effects of the field trial outweigh the adverse effects. The Authority must also be satisfied that the organisms can be safely contained. You may wish to express a view on the relative importance of the different adverse and beneficial effects and how they should be brought together in making a decision.

>

## Section Six – Other requirements

**6.1 Identify any alternative method(s) of achieving the research objective(s).**

Assess each alternative method and compare the adverse effects on the environment and human health and safety with this field test. Indicate how practical the alternative method is.

>

**6.2 Monitoring of effects**

Field tests may often provide an opportunity to collect information related to the occurrence of adverse effects. The Authority wishes to encourage applicants to take full advantage of the field test to conduct monitoring which will provide an assurance that risks are being effectively managed and/or provide information which will assist in the consideration of any future release application. Describe any such monitoring you propose to put in place.

>

## Section Seven – Additional Information

**7.1 Do any of the organism(s) need approvals under any other New Zealand legislation or are affected by international obligations?** For example, the field test may require 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.

>

**7.2 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 considered for import under the Plants Act? Has the organism been developed as a result of a genetically modified development approval from either ERMA New Zealand or a delegated IBSC? Have any other countries' regulatory bodies assessed the organism for approval?

>

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

>

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

>

**7.5 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.

>

**7.6 References.** Please include a list of the references cited in and supplied with this application form. Originals of the references must be supplied in full. Where the reference supplied is an extract from a book only the specific pages quoted must be supplied, along with the cover page of the book.

>

## **Section Eight – Application Summary**

Summarise the application in clear, simple language that can be understood by the general public. Include a description of the organism(s), the purpose of the field test, how the field test will be conducted to achieve its objectives, the proposed containment system, and any risks and benefits associated with the field test. This summary will be used to provide information for those people and agencies who will be notified of the application (e.g. 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.

>

## 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 enclosed (incl. GST) <sup>†</sup>    | Yes/No   |
| If “yes”, state amount:                                     | \$.....  |
| Fee direct credited to ERMA bank account:                   | Yes/No   |
| If “yes” give date of DC .../.../... and amount:            | \$.....  |
| Application signed and dated                                | Yes      |
| Electronic copy of application e-mailed to ERMA New Zealand | Yes      |

\*NA – not applicable

<sup>†</sup> The cost of processing the application will be charged to you in accordance with our pricing policy. A fees and charges schedule, including the initial fee required with the application can be found on our web site under new organism applications.

**Signed:**

**Date:**