

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
 NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO



FORM NO-04N

Application for approval to

**FIELD TEST IN CONTAINMENT AN ORGANISM
 THAT IS NOT 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:

IMPORTANT

1. This application form covers field testing in containment of any new organism that is not genetically modified.
2. An associated user guide is available to help you complete this form on the ERMA New Zealand website. If you need additional guidance, please contact ERMA New Zealand.
3. If the application is for importation of a new organism that is not genetically modified, use Form NO-02N.
4. If the application is for field testing in containment of a genetically modified organism, use Form NO-04.
5. If the application is for a conditional release approval, use Form NO-CR.
6. Please note that large scale fermentations are not now considered field tests and are instead regulated as a development. The correct form to use is in the series NO3.
7. This version of the application form is the most recently approved by the Chief Executive of ERMA New Zealand and replaces all other versions. We will not accept older versions. Check with ERMA New Zealand or on the ERMA New Zealand website, www.ermanz.govt.nz, for the current version of this form.
8. An applications advisor at ERMA New Zealand can help you scope and prepare your application as part of the free pre-application consultation. We need all relevant information early in the application process. Quality information up front will speed up the process.
9. Any extra material that does not fit in the application form must be clearly labelled, cross-referenced, and included as appendices.
10. Collate commercially sensitive information in a separate appendix. Justify why you consider the material commercially sensitive, and make sure it is clearly labelled as such.
11. Applicants must sign the form and enclose the correct application fee (plus GST). Please check with ERMA New Zealand staff or on our website for the latest schedule of fees. We are unable to process applications that do not contain the correct application fee.
12. Unless otherwise indicated, all sections of this form must be completed for the application to be progressed.
13. 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.
14. **Note:** Applications to field test non-genetically modified organisms are not required to be publicly notified by the Authority (section 53 of the Act).
15. This application form was approved by the Chief Executive of ERMA New Zealand on 27 July 2006.

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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 >

Email >

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 >

Email >

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 >

Email >

Section Two – purpose of the application

This form is to be used for an application to **field test** in containment an organism that is not genetically modified. To field test a genetically modified organism complete **Form NO-04**.

2.1 Give a short summary of the purpose if this application is 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. Discuss 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, number of the organisms involved, and duration of the field test.

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2.3 Long-term objectives of this project

Is the long-term intention of this project to apply for conditional release or release of the organism(s)? If this is the case what timeframe do you have in mind?

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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 and confidentiality is intended alternative approaches must be discussed with and agreed to by ERMA New Zealand.

3.1 Give the unequivocal identification of the new organism(s)

Please include details on the following:

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

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

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Other information, including the presence of any inseparable or associated organisms; whether a prohibited organism is involved (refer to Second Schedule of the Act); whether an unwanted organism is involved, as defined by the Biosecurity Act 2003; and information on consideration of the organism(s) by other states, countries or organisations:

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3.2 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. For example: lifecycle, 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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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 and their topography, the number of organisms to be field tested and the expected duration of the field test.

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4.2 Describe the proposed containment system (physical and operational)

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

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4.3 Inspection and monitoring of the containment system

Clause 4 of Part II of the Third Schedule of the Act states that controls imposed by an approval shall specify inspection and monitoring of the containment facilities. Describe how you will achieve any such controls.

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4.4 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.

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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 Act. Adverse effects include risks and costs, and beneficial effects are described as benefits. Describe all effects in terms of the magnitude of the effect if it should occur and the likelihood of occurrence. Consider monetary and non-monetary effects, and include a comment on the distribution of the adverse and beneficial effects across affected parties. Provide a brief account of where the information in the application has been sourced from, eg 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. Consider contingencies to recover or destroy escaped organisms.

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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 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

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(B) Potential adverse effects on human health and safety (including occupational exposure).

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(C) 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).

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

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

The assessment should include the nature, probability of occurrence and magnitude (in monetary or non-monetary terms) of each adverse effect. Also discuss the uncertainty bounds of the information contained in the assessment. 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. Assess adverse effects in relationship to:

(A) Potentially significant adverse effects on the environment, in particular ecosystems and their constituent parts

(eg 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).

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(B) Potentially significant adverse effects on human health and safety (including occupational exposure).

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(C) 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.

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(D) Other potentially significant adverse effects

(such as effects on society and community, effects on the economy and effects on New Zealand's international obligations).

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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. Identify benefits for the following categories:

(A) Potential beneficial effects on the environment, in particular on ecosystems and their constituent parts

(eg 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).

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(B) Potential beneficial effects on human health and safety

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(C) Potential beneficial effects specific to Māori

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(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)

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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. You should also indicate who would receive the benefits, and the time-course of delivery of the benefits. Assess beneficial effects in relationship to:

(A) Potentially significant beneficial effects on the environment, in particular on ecosystems and their constituent parts

(eg 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).

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(B) Potentially significant beneficial effects on human health and safety

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(C) Potentially significant beneficial effects specific to Māori

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(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).

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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.

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Section Six – Other requirements

6.1 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.

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Section Seven – Additional information

7.1 Do any of the organism(s) need approvals under any other New Zealand legislation, or are they affected by international obligations?

For example, the field test may require an approval under the Animal Welfare Act 1999; or if a species listed by CITES is used, then approval is required from both the importing and exporting countries.

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7.2 Have any of the new organism(s) in this application previously been considered in New Zealand or elsewhere?

For example, have the organism(s) been considered for import under the Plants Act? Has the organism been given any other ERMA New Zealand approval? Have any other countries' regulatory bodies assessed the organism for approval?

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

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

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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.

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7.6 References

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

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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 that 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 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 fee enclosed (incl. GST) [†]	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

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

Signed:

Date: