

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
 NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO



FORM NO30

Application for approval to

**DEVELOP IN CONTAINMENT
 OUTSIDE OF A CONTAINMENT STRUCTURE
 ANY
 GENETICALLY MODIFIED ORGANISM
 OR
 REGENERATION OF A NEW ORGANISM FROM
 BIOLOGICAL MATERIAL**

**under section 40 with reference to section 44A 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:

20 Customhouse Quay,
 Cnr Waring Taylor & Customhouse Quay
 PO Box 131, Wellington
 Phone: 04-916 2426 Fax: 04-914 0433
 Email: info@ermanız.govt.nz
 Website: www.ermanız.govt.nz

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
 NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO



Application for approval to develop in containment outside of a containment structure any genetically modified organism or regeneration of a new organism from biological material

ER-AF-NO30-1-12/04

FORM NO30

Page 1

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 the development in containment of any genetically modified organism or regeneration of a new organism from biological material which shall occur either in part or as a whole **outside of a containment structure**. A “containment structure” means a containment facility that is physically enclosed on all sides e.g. a vehicle, room, building, or other structure, set aside and equipped for the development of new organisms.
3. Where the organism(s) to be trialled is a specific developed GMO the **Form NO4 – Field test in containment any genetically modified organism** should be used. In this instance containment is taken to mean either inside or outside a containment structure as defined above. Comprehensive fencing arrangements are considered to be containment but not a containment structure.
4. Applications covering developments 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*, and which shall occur **within a containment structure** as defined within the HSNO (Genetically Modified Organisms) Amendment Act 2002 should be made on **Form NO3**.
5. If you are making an application for a development within a containment structure that meets **category A or B experiments**, as described in the *HSNO (Low-Risk Genetic Modification) Regulations 2003*, then you should complete the **rapid assessment Form NO3P**.
6. This form, the revised Form NO3 and Form NO3P, replace the previous versions of Form NO3. Older versions should not now be used. You should always check with ERMA New Zealand or on the ERMA New Zealand web site for the latest version of this form.
7. You can talk to an Applications Advisor at ERMA New Zealand who can help you prepare and define the scope of 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.
8. This application form may be used to seek approvals for the development of more than one new organism where the organisms are used in the same research programme, or are of a similar nature. It may also be used for the approval of organisms which are specified in generic terms i.e. so that there are boundaries on the scope of the organism, but particular conditions must be met for this to be acceptable. Please refer to the policy statement on “Generic Approvals” in the ERMA New Zealand document *Policy relating to the rapid assessment of low-risk new organisms, including medicines*.
9. 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.
10. 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.
11. 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.
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. This application form was approved by the Chief Executive of ERMA New Zealand on 23 December 2003

**Application for approval to develop in containment
outside of a containment structure any genetically
modified organism or regeneration of a new organism
from biological material**

ER-AF-NO30-1-12/04
FORM NO30

Page 2

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

ERMA New Zealand
20 Customhouse Quay
PO Box 131
Wellington
NEW ZEALAND
Telephone: 64-4-916 2426
Facsimile: 64-4-914-0433
E-mail: info@ermanız.govt.nz www.ermanız.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 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.

**Application for approval to develop in containment
outside of a containment structure any genetically
modified organism or regeneration of a new organism
from biological material**

ER-AF-NO30-1-12/04
FORM NO30

Page 4

Name >

Position >

Address >

Phone >

Fax >

E-mail >

Section Two – Confirmation of the type of application

A GMO development with an outdoor component and a field test of a GMO may have much in common from a biological and physical point of view. The definition of a development in the HSNO Act refers to the “*genetic modification of an organism: regeneration of a new organism from biological material of the organism that cannot, without human intervention, be used to reproduce the organism: but does not include field testing*”. An organism can be developed outside of a containment structure if it is necessary to do so for the maintenance of the organism.

Applications for a development using this form are not expected to assess the effect of environmental conditions upon the organism. (Please check the notes on page 1 for a description of other application routes available for organism development). Please refer to the ERMA New Zealand Protocol *Interpretations and Explanations of Key Concepts* for guidance on the boundary between a field test and development. Explain why you are applying to develop a GMO outside a containment structure.

Regeneration of a new organism (including GMOs and non-GMOs) from biological material is considered to be a development for the purposes of the HSNO Act. Please explain why this development needs to be performed outside a containment structure.

>

Section Three – Purpose of 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 including spaces and punctuation). Briefly describe the organism(s) to be developed, and the purpose(s) for which you wish to develop the organism(s).

>

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

Describe the rationale for the overall development programme so that people not directly connected with the research can understand why the development of these organisms is being undertaken. 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. Detail should also be included on the methods to be used, the general location, associated facilities and duration of the development.

>

3.3 Public interest in the application

Provide comment on whether or not there is reason to believe that there is potential for significant (see section 53(2) of the HSNO Act) 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 new organism, level or nature of the risks involved, extent to which the application sets a precedent.

>

Section Four – Information on the Organism(s) to be developed

If more than one type of genetically modified 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.

Generic descriptions may be used for the organism(s) to be developed. However a general description may be given of the vector systems proposed for use and the genetic material to be inserted. This description must be sufficiently specific so that there are quite clearly boundaries on the scope of the organisms able to be developed so that the risks (adverse effects) arising from all the organisms within the scope can be satisfactorily assessed.

Note: For regeneration of new organism(s) from biological material that are not GMOs, please complete questions 4.1, other details of development part of 4.2, 4.4 and 4.5 of section 4.

4.1 Give the unequivocal identification of the organism(s).

Please include details on the following:

Latin binomial, including full taxonomic authority:

>

Common or trade name(s), if any:

>

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

>

Taxonomic class, order and family:

>

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

>

Other information, including presence of any inseparable or associated organisms; whether a prohibited organism is involved.

>

Application for approval to develop in containment outside of a containment structure any genetically modified organism or regeneration of a new organism from biological material

4.2 How will the new organism(s) be developed?

Provide details of the following if applicable. If not applicable, state why not. It is noted that some of these questions will only be appropriate to GM developments and some only to the regeneration of a new organism from biological material.

Vector system(s):

>

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 host organism(s) ? <i>If Yes, provide additional details below.</i>		
Does this application use genetic material from native flora and fauna? <i>If Yes, provide additional details below.</i>		
Does this application involve human 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 directly from human beings?		
Does this application involve human 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 directly from human beings?		

Application for approval to develop in containment outside of a containment structure any genetically modified organism or regeneration of a new organism from biological material

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

>

If the genetic modification or regeneration of a new organism involves material of human origin, provide details of from where the material is obtained, and whether approval has been obtained from your institution's Human Ethics Committee, and/or consultation with Māori has taken place.

>

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). In the case of regeneration of an organism from tissue or other biological material, identify the nature of the tissue and where it was sourced from.

>

4.3 Identify the category or categories of experiment(s) as described in the HSNO (Low-Risk Genetic Modification) Regulations 2003 if applicable.

If not applicable, state why not. Identify specific class of experiment(s) and explain your characterisation.

>

4.4 Characteristics of the new organism(s).

Provide information on the biology, ecology and 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 6.2). If the organism is genetically specified be sure to include information which covers the whole of the scope of the organism.

>

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

An example of a host, vector and donor description is "*Escherichia coli* DH5 α ; pUC18; cholera toxin gene"
"Cloned *Ovis ammon* (Argali sheep)"

>

Section Five – Outline of the proposed development, containment and control system and its effectiveness and comments on additional controls

5.1 Outline of the proposed outdoor development site and containment system

Information on the location and duration of the outdoor development phase and associated facilities. Details of the general location, number of organisms, and experimental plan should be included. Describe how the containment facility will be inspected and monitored during the outdoor phase of the development.

>

5.2 Detail 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. 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 and/or provide other appropriate documentary evidence to support your description of the containment system and its operation. Identify if the facility is currently registered by MAF as a containment facility. If so provide registration details.

>

5.3 Clean up controls and post development monitoring of an approval.

The HSNO (Genetically Modified Organisms) Amendment Act 2002 requires that at the completion of an outside development all “heritable material” is removed or destroyed. “Heritable material” means viable biological material, including gametes and spores, arising from the organism that can, without human intervention, regenerate the organism or reproduce a new generation of the same species of the organism. “Destroyed” includes leaving genetic elements to break down or become inactive at the site of the development or field test.

Additionally there is a requirement to monitor for the transfer of any genetic elements to other organisms on or around the site.

Describe what mechanisms you propose to put in place to achieve these objectives and any associated inspection and monitoring you propose.

>

5.4 Discuss the ability of the organism(s) to escape from the proposed containment system.

Describe the biological features of the organism(s) that relate to 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.”

>

5.5 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**

>

- (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)

>

- (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.

>

Section Six- 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 1996 and the HSNO (Genetically Modified Organisms) Amendment Act 2002. 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 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.

6.1 Ability of organism(s) to establish an undesirable self-sustaining population and ease of eradication.

Discuss the ability of the organism to establish an undesirable self-sustaining population outside containment, taking into account the ease of its eradication if it did establish such a population (section 37 of the HSNO Act). You should consider the ability of the organism to survive and reproduce if it did escape from containment.

Establishment of an undesirable self-sustaining population

>

Ease of eradication

>

6.2 Identify all potential adverse effects of the organism(s). Identify potential adverse effects associated with the organism(s) and any inseparable organisms (section 6 and 44A(2) of the HSNO Act). Consider effects on the environment (especially ecosystems), human health and safety, and any ethical and cultural effects. Remember to consider adverse effects of the organism(s) both in and out of containment. (Identify also any effects resulting from the transfer of any genetic elements to other organisms in or around the site of the development or field test). At the identification stage, all that is required are short statements which identify the risk or adverse effect, and indicate whether it is sufficiently “possible” to warrant assessment. Detailed assessments should be set out in section 6.3.

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 development.** (“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 flora and fauna and other taonga** (taking into account the principles of the Treaty of Waitangi). These effects should include those identified during consultation with Māori.

>

- E. Other potential adverse effects** (such as New Zealand’s international obligations, social or economic adverse effects, ethical issues)

>

6.3 Provide an assessment of the adverse effects identified in Section 6.2.

The assessment should include the nature, likelihood or probability of occurrence and magnitude of each adverse effect (i.e. **the risk**), and the value (in monetary or non-monetary terms) of a particular adverse effect (i.e. **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. However, the impacts of not having controls or containment in place should also be considered. Adverse effects should be assessed in relationship to:

A. Potential 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. 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 development.

>

D. 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

Application for approval to develop in containment outside of a containment structure any genetically modified organism or regeneration of a new organism from biological material

account the principles of the Treaty of Waitangi). If consultation with Māori has been undertaken you should provide details of the outcome.

>

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

>

6.4 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)

>

6.5 Provide an assessment of the benefits identified in Section 6.4

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. Discuss the likelihood of any of these benefits being realised by any of the alternative methods identified in section 7.1. 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.

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)

>

6.6 Overall evaluation of risks, costs, and benefits

Application for approval to develop in containment outside of a containment structure any genetically modified organism or regeneration of a new organism from biological material

This overall evaluation is the main task of the Authority. The Authority has to decide whether the beneficial effects of the development outweigh the adverse effects, and whether the research objectives could be achieved by other methods with fewer adverse effects. The Authority must also be satisfied that the organism and any genetic elements can be safely contained and that any heritable material can be removed from the site or destroyed. 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.

>

Section Seven – Other requirements

7.1 Identify any alternative method(s) of achieving the research objective(s) that has fewer adverse effects on the environment and human health and safety than the development proposed.

>

7.2 Monitoring of effects and pathways

The Authority wishes to encourage applicants to take full advantage of the outdoor phase of the development to conduct monitoring which will provide an assurance that risks are being effectively managed and/or provide information which will assist the consideration of any future release application. Describe any monitoring you propose to put in place.

>

Section Eight – Additional Information

8.1 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.

>

8.2 Have any of the new organism(s) in this application previously been considered for import or other approval under legislation in New Zealand or elsewhere?

>

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

>

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

>

8.5 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.

>

8.6 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.

>

Section Nine – Application Summary

Summarise the application in clear, simple language that is able to be understood by the general public. Include a description of the organism(s), the purpose of the development, how the development will be conducted to achieve its

Application for approval to develop in containment outside of a containment structure any genetically modified organism or regeneration of a new organism from biological material

objectives, the proposed containment system, and any risks and benefits associated with the development. 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, Local Authorities) and for members of the public who request information. Do not include any commercially sensitive information in this summary. Please attach confidential information as a separate appendix which is clearly marked as “confidential”.

>

Application for approval to develop in containment outside of a containment structure any genetically modified organism or regeneration of a new organism from biological material

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) [†]	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 current pricing policy. The current 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: