

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
 NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO



FORM NO3F

Application for approval to

**DEVELOP (BY FERMENTATION) IN CONTAINMENT ANY
 NEW 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:

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

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IMPORTANT

1. Application forms are reviewed regularly. Always check with ERMA New Zealand whether you have the most up to date version of this form.
2. An associated User Guide is not yet available for this form. If you need further guidance in completing this form please contact ERMA New Zealand.
3. This application form covers development (by fermentation) in containment any new organism that is not genetically modified, under section 40 of the Hazardous Substances and New Organisms Act 1996 (“the Act”). According to the ERMA New Zealand Policy Series: Protocol 3 *Interpretations and Explanations of Key Concepts*, “**fermentation**” refers to the liquid culture or “bulking up” of microorganisms rather than strictly to the anaerobic biochemical process. For further guidance on how “fermentation” is interpreted by the Authority under the Act please refer above policy document. To obtain a copy please contact ERMA New Zealand or download one from the ERMA New Zealand web site (<http://www.ermanz.govt.nz/no/index.asp>).
4. If you are making an application to develop in containment a **genetically modified organism** (by fermentation) please contact ERMA New Zealand to obtain an application form for development of a genetically modified organism **ER-AF-NO3**.
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.
6. This application form may be used to seek approvals for development (by fermentation) in containment volumes of 10 litres or more. If you already have an approval to import your new organism into containment and you wish to culture volumes smaller than 10L in a single vessel then you do not require an additional development approval.
7. This application form may be used to seek approvals for development (by fermentation) in containment for more than one new (non-genetically modified) organism where the organisms are of a similar nature.
8. 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.
9. Commercially sensitive information must be collated in a separate appendix. You need to justify why you consider the material confidential, and make sure it is clearly labelled as such.
10. 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.
11. Unless otherwise indicated, all sections of this form must be completed for the application to be progressed.
12. Please provide an electronic version of the completed application form, as well as sending a signed hard copy. We are unable to process your application until a complete signed copy is received.

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 13 October 2004.

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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 >

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 >

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E-mail >

1.3 If the applicant is an organisation or individual situated overseas, provide 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.

Name >

Position >

Address >

Phone >

Fax >

E-mail >

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Section Two – Purpose of the Application

This form is to be used for an application to develop (by fermentation) in containment any new organism that is not genetically modified.

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). This requirement comes from sections 39(1) and 45(1) of the Hazardous Substances and New Organism Act 1996 (the Act). Briefly describe the organism(s) to be developed in containment, and the purpose(s) for which you wish to develop the organism(s).

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

Describe the purpose of the development and rationale for the overall project that these organisms are to be used in, so that people not directly connected with the research can understand why these organisms are required.

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2.3 Public interest in the application

This requirement comes from section 53(2) of the Act. Provide comments on whether or not there is reason to believe that there is potential for significant public interest in any aspects of the application. This may relate to anything particularly novel or unusual about the organism or issues of cultural significance, level or nature of risks involved, or the extent to which the application sets a precedent.

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

If the application is for development of more than one organism, 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 organism(s) to be developed

This requirement comes from section 20(2)(b) of the Act. These names will be on the public register and should uniquely identify the organisms. Please provide details of 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 class, order and family:

>

Strain(s) if relevant:

>

Other information, including the presence of any inseparable or associated organisms:

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3.2 Characteristics of the organism(s) to be developed

Provide information on the biology, ecology and the main features or essential characteristics of each organism(s) to be developed. For example, note production of spores, conditions for growth and reproduction. What chemicals or products will the microorganisms being cultured produce and are these products toxic to plants, animals or humans? Also provide information on affinities of the organism(s) with other organism(s) in New Zealand. This information should be relevant to the identification of the risks of the organism (in section 5 of this form).

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3.3 How will the new organism be developed?

Describe the fermentation process that will take place under this approval. This section will be used by the decision-maker and must include enough detail to enable a risk evaluation of all relevant details such as the techniques or experimental procedures used; volumes used; the duration of each fermentation step; is the microorganism culture deactivated at the end of the process? if so how? are there any unusual manipulations that will take place? This information should be relevant to the identification of the risks of the organism (in section 5 of this form).

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Section Four – The Proposed Containment System and other proposed controls and their Effectiveness

4.1 Describe the proposed containment system (physical and operational). This requirement comes from section 45(1)(a)(iii) of the Act. The adequacy of the containment regime is a principal consideration so you need to provide comprehensive information on the containment system. Provide information on the physical characteristics of the containment system including security features as well as the operational procedures followed in the management of the containment system including supervision, training and qualifications of named staff. Pay special attention to the containment system used to handle large volumes that will be used in the microorganism culture process and describe any contingency plans to manage any spills.

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4.2 Describe the ability of the organism(s) to escape from the proposed containment system. Identify all possible pathways of escape of the organism(s) from containment, including through lapses of security or structural failure. Describe the biological features of the organism(s) that relates to its ability to escape from containment.

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Section Five - Identification and Assessment of Risks, Costs, and Benefits

This section must include information on all beneficial and adverse effects of developing (by fermentation) the organism(s). 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 description 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.

5.1 Ability of organism(s) to establish a self-sustaining population and the ease of eradication.

This requirement comes from section 37(a) of the Act. Discuss the ability of the organism(s) to establish an undesirable self-sustaining population outside of containment, should an escape from containment occur, and the ease with which such a population could be eradicated. You should consider the large volumes involved and 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). This requirement comes from sections 5, 6, 7 and 8 of the Act. Identify potential adverse effects associated with the organism(s) and with any inseparable organisms, both within containment, and outside of containment (should an escape occur). Consider effects on the environment, and human health and safety (e.g. of workers in the containment facility), and any ethical and cultural effects. It is important to think about the source of the risk, i.e. the way in which the risk is created (the exposure pathway), and then the consequences of exposure. Identification should be kept brief. The intention is to mainly ensure that all possible risks have been considered and to draw the distinction between those that warrant detailed assessment (in section 5.3 of this form below), and those that do not. Where detail assessment is not warranted explain why.

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)

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B. Potential adverse effects on public health (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 flora and fauna and other taonga (taking into account the principles of the Treaty of Waitangi). For example, you should consider whether the organism(s) would have an effect on specific native flora or fauna if they escaped from containment. If consultation with Maori has been undertaken, provide details of the process used and the outcome.

>

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 significant adverse effects identified in Section 5.2 for a full assessment.

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. Adverse effects should be assessed in relationship to:

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 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). For example, you should consider whether the organism(s) would have an effect on specific native flora or fauna if they escaped from containment.

>

D. Other potential adverse effects (such as New Zealand's international obligations, social or economic adverse effects, ethical issues). Also include potential methods of mitigation or remedying of these adverse effects.

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5.4 Identification of beneficial effects (benefits)

This requirement comes from sections 5, 6 and 8 of the Act. Identify and describe monetary and non-monetary benefits associated with developing the organism(s) in containment. Outline and discuss the purpose(s) for the development and the potential use of the fermentation product(s). Focus on the immediate benefits, as well as longer-term benefits. For example, “increase in scientific knowledge”, “increased production of agricultural produce”. Substantiate claims by reference to sources of information. Specify whether the benefits identified are environmental, public health or economic benefits; and/or are specific benefits to Maori.

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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 developing the organism(s) in containment, and any uncertainties associated with this assessment. You should also indicate who would receive the benefits and the expected time-course of delivery of the benefits.

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5.6 Overall evaluation of risks, costs, and benefits

This overall evaluation is the main task of the Authority. The Authority has to decide whether the beneficial effects of developing the organism in containment outweigh the adverse effects of the organism and any associated inseparable organisms. The Authority must also be satisfied that the organism can be safely contained. 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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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? This requirement comes from section 6(f) of the Act. For example, indicate whether the organism is subject to other New Zealand legislation, e.g. the Biosecurity Act 1993, or Animal Welfare Act 1999; or if the organism(s) are listed in CITES, 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? This requirement comes from section 40(2) of the Act. For example, has the organism(s) been previously considered for development (e.g. under the Plants Act 1970)? If yes please provide details.

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6.3 Is there any additional information that you consider relevant to this application that has not already been included? If yes, please provide details. Attach copies of the additional information if relevant.

>

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

>

6.5 List of appendices. List any appendices included with this application. Any information that is commercially sensitive or additional material included with the application (such as details of consultations, referenced articles) should be contained in appendices clearly marked confidential. The main application should refer to the relevant appendices but be able to be read as a stand-alone document.

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Section Seven – Application Summary

Summarise the application in clear, simple language that can be understood by the general public. Include a description of the organism(s) to be developed in containment, and any risks and benefits associated with their development. This summary will be used to provide information for those people and agencies that will be notified of the application (e.g. Ministry of Agriculture and Forestry, Department of Conservation, Crown Research Institutes) and for members of the public who request information. Do not include any commercially sensitive information in this summary. Any such information should be attached as a separate appendix and clearly marked confidential”.

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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 initial fee (incl. GST) enclosed	Yes/No
If "yes", state amount:	\$.....
Direct credit made to ERMA bank account:	Yes/No
If "yes" give date of direct credit .../.../... and amount deposited:	\$.....
Application signed and dated	Yes
Electronic copy of application e-mailed to ERMA New Zealand	Yes

*NA – not applicable

Signed:

Date: