



FORM NOCR

Application for approval to

**IMPORT FOR RELEASE
OR RELEASE FROM CONTAINMENT WITH CONTROLS
ANY NEW ORGANISM**

**under section 38A 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:

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IMPORTANT

1. Please refer to the associated User Guide when completing this form. If you need further guidance please contact ERMA New Zealand.
2. This application form covers import for release, or release from containment, **with controls**, of any new organism (including a genetically modified organism) under s38A of the HSNO Act and may be used to seek approvals for more than one organism where the organisms are of a similar nature.
3. If you are making an application to import for release or release from containment any new organism (i.e. full release **without controls** as opposed to conditional release) you should use Form NOR. If you are making an application for a field test in containment of any new organism you should use Form NO4.
4. You should periodically check with ERMA New Zealand or on the ERMA New Zealand web site for new versions of this and any other forms mentioned.
5. You can talk to an Applications Advisor at ERMA New Zealand who can help you scope and prepare your application. We need all relevant information early on in the application process. Quality information up front will speed up the process and help reduce costs.
6. 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 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.
11. **Note:** Applications to conditionally release new 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).

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

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Wellington, NEW ZEALAND
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ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
NGĀ KAIWHAKA ĀPĀTO WHAKARARU TAIAO



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 >

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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.

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 import for release or release from containment, **with controls**, any new organism (i.e. conditional release).

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)*

Briefly describe the organism(s) to be imported for conditional release or conditionally released from containment and the purpose(s) for which you wish to do so.

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2.2 Provide a brief 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 programme can understand why these organisms are being conditionally released.

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

If more than one type of organism is to be conditionally released, this section must be completed separately for each organism.

3.1 State the taxonomic level at which the organism(s) to be conditionally released are to be specified

If the taxonomic level is different to “species”, provide reasons for this. The reasons should take account of the need to adequately describe risk.

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3.2 Give the unequivocal identification of the organism(s) to be conditionally released

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) and genotype(s), if relevant:

Other information (including presence of any inseparable or associated organisms and information on consideration of the organism(s) by other states, countries or organisations):

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3.3 Provide unique name(s) for the new organism(s) to be conditionally released

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3.4 Characteristics of the organism(s) to be conditionally released

Provide information on the biology, ecology and the main features or essential characteristics of (each) of the organism(s) to be conditionally released. You should also indicate whether the organism is pathogenic or a potential pest or weed.

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3.5 If the organism to be conditionally released is a genetically modified organism, where applicable provide details on the development of the organism

If the organism to be conditionally released is a genetically modified organism, state whether the development of the organism was carried out under a HSNO approval. If this was the case, provide the approval number and translate the relevant details to the headings below. If the genetically modified organism is to be imported for conditional release, also provide this information to the extent possible:

Identify the category of the host organism (i.e. category 1 or 2) and genetic modification (i.e. category A or B) involved in the development of the organism with reference to the HSNO (Low-Risk Genetic Modification) Regulations 2003. Please explain your characterisation.

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

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Type and source of additional genetic material.

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

	Yes	No
Were native or valued flora or fauna used as the host organism(s) ?		
Was genetic material from native or valued flora and fauna used?		
If native flora and fauna were involved, were the species concerned indigenous to New Zealand?		
Was human genetic material involved? <i>Answer Yes if human genetic material in any form was used, i.e. obtained directly from humans (either Maori or non- Maori from a gene bank, synthesised, copied and so on).</i>		
Was genetic material obtained directly from human beings used? <i>If Yes, provide additional details below.</i>		

If the genetic modification involved DNA of human origin, provide details of from where the material was obtained (including provenance and/or informed consent), and whether approval was obtained from an Ethics Committee, and/or whether consultation with Maori has taken place.

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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).

>

Section Four – Proposed Conditional Release Programme and Controls

4.1 Proposed Conditional Release Programme

Please provide full details of your intended conditional release programme e.g. size, timing and location(s) of the conditional release etc. Specifically indicate whether or not an expiry date for any approval is expected and give reasons for this expectation.

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4.2 Proposed Course of Action if the Conditional Release Approval is Set to Expire

Indicate by marking the following table which course of action is preferred if the conditional release approval is set to expire:

Course of Action	Yes	No
<p>1. Full (unconditional) release of the organism. <i>Note: you will need to formally apply for a full (unconditional) release at or after the time of applying for a conditional release but prior to its expiry. The full release would then take effect immediately after the expiry of the conditional release approval.</i></p> <p>2. Return of the organism into containment through an existing containment approval. <i>Note: give the appropriate approval code and relevant details in the space below.</i></p> <p>3. Return of the organism into containment through a new (yet to be gained) approval. <i>Note: you will need to formally apply for a containment approval at or after the time of applying for a conditional release but prior to its expiry.</i></p> <p>4. Disposal of the organism. <i>Note: unless you have gained another approval (containment or full unconditional release) prior to the expiry of your conditional release approval you will need to provide information relevant to disposal in section 4.3.</i></p>		

Please give reasons justifying the selection of the (above) course of action and any other relevant information (e.g. the approval code and details of the appropriate existing containment approval etc.)

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4.3 Disposal of the organism(s) on the expiry of the conditional release approval

Section 38F of the HSNO Act requires the organism(s) to be disposed of if and when a conditional release approval expires, unless before expiry another approval (containment or full unconditional release) is granted under the Act. Provide information (preferably in the form of proposed controls) to explain what steps will be taken to ensure that the organism(s) can be identified and located at the expiry of the approval, and the method of disposal intended.

>

4.4 Proposed control(s)

Please outline the relevant control(s) that you recommend be imposed to deal with any risks that may be posed by the organism(s) to be conditionally released. In doing so make reference to the types of controls listed in section 38D of the HSNO Act. If you do not consider any of these controls to be appropriate explain why. Also provide information on how effective these controls are likely to be in meeting the objective(s) of the control(s).

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4.5 Monitoring of effects

Conditional releases may provide an opportunity to collect information related to the occurrence of adverse effects and to the operation or not of associated pathways. The Authority wishes to encourage applicants to take full advantage of the conditional release situation to conduct monitoring which will provide an assurance that risks are being effectively managed through the controls imposed and/or provide information which will assist in the consideration of any future conditional or full release applications. Describe any such monitoring you propose to put in place.

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Section Five – Identification of Risks, Costs and Benefits

Risk means the combination of the magnitude of an adverse effect and the probability of its occurrence. Cost means the value of a particular adverse effect expressed in monetary or non-monetary terms. Benefit means the value of a particular positive effect expressed in monetary or non-monetary terms. In this part of the form you are required to identify (in section 5.3) the risks, costs and benefits of the organism(s) in the context of the application. A very broad approach should be taken to this, so that a wide range of possibilities are canvassed. However, it is also important at the end of this exercise but still at the identification stage to identify those risks, costs and benefits which warrant more detailed assessment at a later stage (in section 6). To assist the process of identification this section also requires information to be provided on the ability of the organism(s) to establish a self-sustaining population and on the ease of eradication. Please refer to the ERMA New Zealand Technical Guides “*Identifying Risks for Applications*” and “*Risks, Costs and Benefits for Applications*” for further information. These are available from the ERMA New Zealand website or in hard copy on request.

5.1 Ability of the organism(s) to establish a self-sustaining population

Discuss the ability of the organism(s) to establish a self-sustaining population and the ease with which the organism(s) could be recovered or eradicated if an undesirable self-sustaining population established.

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5.2 Effects of any inseparable organism(s)

State whether or not there are any inseparable organisms associated with the organism that is the subject of the application. If there are any effects of inseparable organisms that might need to be considered, state this and then identify them under the relevant headings in section 5.3.

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5.3 Identify all the potential risks, costs and benefits of the organism(s) to be conditionally released

Please identify all potential risks, costs and benefits whether you consider them to be non-negligible or not. To do this effectively you should identify both the source of the risk (or hazard) and what is at risk (or area of impact). You should also identify the route (or exposure pathway) between the source and the area of impact. An indication of any non-monetary and monetary costs and benefits to be derived from the conditional release of the organism(s) and whether these are direct or indirect should be given. Please cover all of these issues under each of the following headings (areas of impact) which reflect those matters referred to in Part II of the HSNO Act:

A. Effects on the environment (in particular on ecosystems and their constituent parts)

As per sections 5(a), 6(a) and 6(b) of the Act, list the risks, costs and benefits associated with the organism(s) to be conditionally released. Also address the ways that these risks, costs and benefits might adversely effect or improve/enhance (in the case of benefits) the New Zealand environment e.g. the life

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supporting capacity of air, water, soil and ecosystems; the sustainability of 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.

Risks and costs:

>

Benefits:

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B. Effects on human health and safety (including occupational exposure)

As per section 6(c) of the Act, list any potential risks and benefits to human health that may be related to the conditional release of the organism(s) in New Zealand.

Risks and costs:

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Benefits:

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C. Potential effects on the relationship of Maori and their culture and traditions with their ancestral lands, water, sites, wahi tapu, valued flora and fauna and other taonga (taking into account the principles of the Treaty of Waitangi)

As per sections 6(d) and 8 of the Act, list any potential adverse and beneficial effects on the relationship of Maori and their culture and traditions with their ancestral lands, water, sites, wahi tapu, valued flora and fauna and other taonga (taking into account the principles of the Treaty of Waitangi). In this area it is especially important to indicate the extent to which potential effects reflect the expressed views of the Maori community. However, details on this can be dealt with under the assessment section (section 6).

Risks and costs:

>

Benefits:

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D. Economic Effects

As per section 6(e) of the Act, list the economic risks, costs and benefits that might arise to New Zealand. Also identify who will bear the risks and costs and/or who the beneficiaries are likely to be.

Risks and Costs:

>

Benefits:

>

E. Cultural, social, ethical and spiritual effects

As per section 5(b) of the Act, list any adverse and beneficial impacts on people and communities that might arise and adversely affect or maintain/enhance (in the case of beneficial impacts) their capacity to provide for their own social and cultural wellbeing both now and into the future. Also list any ethical or spiritual risks, costs and benefits that might arise as per section 68(1)(a) of the Act. Indicate what steps have been taken to assist the identification of the effects in this area, for example, was there any community involvement?

Risks and Costs:

>

Benefits:

>

F. Other effects (including New Zealand's international obligations)

List any remaining adverse and beneficial affects not already covered including any effects on New Zealand's international obligations (as per section 6(f) of the Act).

Risks and costs:

>

Benefits:

>

Section Six – Assessment of Potential Non-negligible Risks, Costs and Benefits

This section entails detailed assessment of those effects identified in section 5.3 that you consider to be non-negligible. It should also provide an estimate of the likelihood of occurrence (which may be measured as frequency or probability) and the magnitude of the outcome if the adverse effect should occur. Please state why you consider an effect to be negligible before discounting it from the assessment. You should carry out your assessment firstly in the absence of any controls then in the context of the proposed controls being in place. Evaluating the effectiveness of controls is also part of the assessment process. ERMA New Zealand uses qualitative scales for assessing effects which may be of some use to you in completing this section – please refer to the ERMA New Zealand Technical Guide “*Decision Making: techniques for identifying, assessing and evaluating risks, costs and benefits*” for further details. Any uncertainties associated with this assessment should also be discussed. Please cover all of these issues under each of the following headings (areas of impact) which reflect those matters referred to in Part II of the HSNO Act:

6.1 Effects on the environment (in particular on ecosystems and their constituent parts)

Assess the risks, costs and benefits associated with the organism(s) to be conditionally released and the ways that they might adversely affect or improve/enhance (in the case of benefits) the New Zealand environment e.g. the life supporting capacity of air, water, soil and ecosystems; the sustainability of 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.

Risks and costs:

>

Benefits:

>

6.2 Effects on human health and safety (including occupational exposure)

Assess any potential risks, costs and benefits to human health that may be related to the conditional release of the organism(s) in New Zealand.

Risks and costs:

>

Benefits:

>

6.3 Potential effects on the relationship of Maori and their culture and traditions with their ancestral lands, water, sites, wahi tapu, valued flora and fauna and other taonga (taking into account the principles of the Treaty of Waitangi)

Assess any potential adverse and beneficial effects on the relationship of Maori and their culture and traditions with their ancestral lands, water, sites, wahi tapu, valued flora and fauna and other taonga (taking into account the principles of the Treaty of Waitangi). If there are potentially non-negligible effects to consider in this area, it is expected that consultation will have occurred with Maori. Give details of this in the space provided (see the User Guide for what is required).

Risks and costs:

>

Benefits:

>

Consultation with Maori:

>

6.4 Economic effects

Assess the potential magnitude and distribution of the economic risks, costs and benefits. Effects on third parties and to New Zealand of the proposed conditional release need to be specifically evaluated. Applicants should provide a cost benefit analysis.

Risks and Costs:

>

Benefits:

>

6.5 Cultural, social, ethical and spiritual effects

Assess the magnitude and distribution of any adverse and beneficial impacts on people and communities that adversely affect or maintain/enhance (in the case of beneficial impacts) their capacity to provide for their own social and cultural wellbeing both now and into the future. Also assess any ethical or spiritual risks, costs and benefits that might arise.

Risks and Costs:

>

Benefits:

>

6.6 Other effects (including New Zealand's international obligations)

Assess any remaining adverse and beneficial effects not already covered including any effects on New Zealand's international obligations.

Risks and costs:

>

Benefits:

>

6.7 Overall evaluation of risks, costs and benefits

It is the role of the Authority to decide whether the positive effects (benefits) of the conditional release outweigh the adverse effects (risks and costs) taking into account any control(s) that may be imposed. However, if you have a view on the relative importance of the different risks, costs and benefits and how they should be brought together in the overall evaluation of your application then please state that here.

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Section Seven – Additional Information

7.1 Do any of the organism(s) to be conditionally released need approvals under any other New Zealand legislation or is the application affected by New Zealand's international obligations?

Please indicate whether any of the organism(s) to be conditionally released are subject to other New Zealand legislative requirements e.g. Biosecurity Act 1993, Welfare Act 1999. Also indicate if the organism is subject to any international obligations e.g. CITES.

>

7.2 Have any of the organism(s) to be conditionally released been previously considered in New Zealand or elsewhere?

For example, have the organism(s) been considered for import under the Plants Act? Have the organism(s) been developed as a result of a genetically modified development approval from either ERMA New Zealand or a delegated IBSC, or has it been considered by ERMA New Zealand for field testing?

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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

>

7.6 References

Please include a list of the references cited in this application form.

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Section Eight - 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 conditional release, proposed controls and any associated risks, costs and benefits. Any consultation that was undertaken should be noted. 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 – this 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 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 initial fee required with the application can be found on our web site under new organism applications. Note that we will be moving to a fixed pricing policy effective from 1 December 2003 – please ask ERMA staff for further details.

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Signed:

Date:

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