

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY  
 NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO



## FORM NOR

Application for approval to

**IMPORT FOR RELEASE  
 OR RELEASE FROM CONTAINMENT  
 ANY NEW ORGANISM INCLUDING A GENETICALLY MODIFIED  
 ORGANISM BUT EXCLUDING CONDITIONAL RELEASE AND RAPID  
 ASSESSMENT**

*[Short title is: New Organism Unconditional Release]*

**under section 34 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. An associated User Guide is available for this form. You should read the User Guide before completing the form. If you need further guidance in completing this form please contact ERMA New Zealand.
2. This application form covers importation for release or release from containment of any new organism (i.e. full or unconditional release) **including** genetically modified organisms but **excluding** conditional release and rapid assessment, under section 34 of the HSNO Act 1996.

If you are making an application to import for release or release from containment any new organism **with controls** (i.e. conditional release) use Form **NOCR**. If you are making an application to import for release a new organism that is not a genetically modified organism by rapid assessment use Form **NO1R**. If you are making an application to field test a genetically modified organism use Form **NO-04**.

3. The form replaces all previous versions of Form NOR. Old versions should not now be used. You should always check with ERMA New Zealand or on the ERMA New Zealand website for the most up-to-date versions of this form.
4. 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.
5. This application form may be used to seek approvals for importing or releasing more than one new organism where the organisms are of a similar nature.
6. Any extra material that does not fit in the application form must be clearly labelled, cross-referenced, and included as appendices to the application form.
7. Commercially sensitive information must be collated in a separate Appendix. You need to justify why you consider the material commercially sensitive, and make sure it is clearly labelled as such.
8. Applicants must sign the form and enclose the correct application fee (plus GST). The initial application fee can be found in our published Schedule of Fees and Charges. Please check with ERMA New Zealand staff or the ERMA New Zealand website for the latest schedule of fees. We are unable to process applications that do not contain the correct initial application fee.
9. Unless otherwise indicated, all sections of this form must be completed for the application to be progressed.
10. Please provide an electronic version of the completed application form, as well as sending a signed hard copy. Until a signed hard copy of the application is received, ERMA New Zealand will not be able to process your application.
11. **Note:** Applications for full (unconditional) releases (**this form**) shall be publicly notified by the Authority under section 53(1)(b) and may go to a hearing pursuant to section 60 of the Act.

**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 20 September 2005.

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

---

## **Section One – Applicant Details**

### **1.1 Name and postal address in New Zealand of the organisation or individual making the application:**

**Name >**

**Postal Address >**

**Physical Address >**

**Phone >**

**Fax >**

**E-mail >**

**1.2 If application is made by an organisation, provide 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 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 >**

## **Section Two – Purpose of the Application and Reasons for Requesting a Full (Unconditional) Release**

This form is to be used for a standard (publicly notified) application (i.e. other than by rapid assessment), to import for release, or release from containment, any new organism (including a genetically modified organism). It is not intended to cover conditional releases.

### **2.1 Give a short summary statement of the purpose of this application to be used on ERMA New Zealand's public register – *Maximum 255 characters (including spaces and punctuation)***

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

**Note:** An organism is 'released' when it is not required to be held in a containment facility registered by the Ministry of Agriculture and Forestry. Once released it is no longer considered a new organism.

>

### **2.2 Provide a short description of the background and aims of the proposal suitable for lay readers**

Describe in **less than one page** the rationale for the proposal to release these organisms, including the potential use for the organism(s), so that people not directly connected with the research can understand the reasons for the release.

>

### **2.3 Set out the reasons for this application being for a full (unconditional) release rather than for a conditional release**

Set out the reasons for this application being for full (unconditional) release rather than for conditional release. Under section 38B of the HSNO Act the Authority may consider an application for full (unconditional) release as if it were for conditional release (i.e. conditions can be set), with the agreement of the applicant. You should provide sufficient information to enable the Authority to decide whether or not it should approach you about obtaining agreement to switch from full (unconditional) to conditional release.

>

### **Section Three – Information on the Organism(s) to be Released and any Inseparable Organisms**

If the application is for release of more than one organism, information must be provided 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 State the taxonomic level at which the organism(s) to be released are to be specified**

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

>

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

Please provide details of 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 genotypes(s), if relevant:**

>

**Other information, (e.g. information on consideration of the organism(s) by other states, countries or organisations):**

>

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

These name(s) will be on the public register and should clearly identify the organism.

>

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

Provide information on the biology, ecology and the main features or essential characteristics of each organism(s) to be released. Provide information on affinities of the organism(s) with other organism(s) in New Zealand. You should also indicate whether the organism(s) is pathogenic or a potential pest or weed. This information should be relevant to the identification of the risks of the organism(s) (section 6 of this form).

>

**3.5 Identify and characterise any inseparable organisms**

Inseparable organisms are those which are inherently associated with each main organism e.g. gut bacteria in an animal.

>

**3.6 If the organism to be released is a genetically modified organism, provide details on the development of the organism**

If the organism to be 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 release, also provide this information on its development to the extent possible under the following headings:

**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.**

>

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

>

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

>

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

	Yes	No
Were(was) native flora or fauna used as <b>host organism(s)</b> ?		
Was <b>genetic material</b> from native or valued introduced flora and fauna used?		
If native flora and fauna were involved, were the species concerned endemic to New Zealand?		
Was human DNA or cell lines used that are of known Māori origin?		
Was genetic material obtained <b>directly</b> from human beings? <i>If Yes, provide additional details below.</i>		

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

>

**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).

>

**3.7 Does the organism have any other HSNO containment approvals not covered in 3.6 (e.g. import into containment, field test, or conditional release approval)?**

State whether the organism(s) to be released has any other HSNO containment approvals. If this is the case, provide the approval number(s) and give brief details of those approvals.

## **Section Four – Establishment and Eradication of a Self-Sustaining Population**

Information under this and the next heading is required so that the Authority can take account the matters set out in section 37 of the Act.

### **4.1 Ability of organism(s) to establish a self-sustaining population**

Describe any ability of the organism to establish a self-sustaining population. This may include, but not be restricted to, information on the time taken for the organism(s) to become established, the likely geographical spread of the organism(s), and effects of variations in climate and altitude on the establishment, distribution, abundance and biology of the organism(s). Explain any situations where the establishment of this(these) organism(s) as a self-sustaining population would not be undesirable, along with the likelihood of each possibility. For a full (unconditional) release the issue of (un)desirability is crucial, because in many cases the establishment of a self-sustaining population will be expected (e.g. a bio-control release).

>

### **4.2 Ease of eradication of a self-sustaining population**

Information under this heading must be provided although ERMA New Zealand understands this application seeks approval to import an organism for release or release from containment. Describe the ease of eradication of the population, including the methods to be used, likely costs, and the likelihood of total eradication of the population.

>

---

**Section Five – The Proposed Release Programme (and Monitoring)**

Provide full details of your intended release programme e.g. information on the breeding and culture, and the life-stage and number of the organisms to be released; timing and location(s) of release etc. Also provide information on any post-release monitoring you intend to carry out, and why.

>

## **Section Six - Identification of adverse and beneficial effects (risks, costs, and benefits)**

This section must include information on the adverse and beneficial effects referred to in the HSNO Act. Adverse effects include risks and costs, and beneficial effects are described as benefits. For convenience adverse effects are at times referred to simply as risks. All effects should be described in terms of the magnitude of the effect if it should occur and the likelihood of occurrence. Monetary and non-monetary effects should be considered, and a comment should be included on the distribution of the adverse and beneficial effects across affected parties.

In this part of the form you are required to **identify** the potential adverse and beneficial effects (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 is canvassed. In the first instance you are required to identify **all** potential adverse and beneficial effects (risks, costs and benefits) whether you consider them to be non-negligible or not. This should be carried out for inseparable organisms as well as for the principal organism. To do this effectively you should consider both the **source** of the risk (or hazard) and **what** is at risk (or area of impact). You should also consider the **route** (or exposure pathway) between the source and the area of impact.

Essentially what you should end up with is a very brief description of the potential adverse and beneficial effects (e.g. *the potential for the pathogenic micro-organism (hazard) to have adverse effects on human health (area of impact) from consumption of the organism (exposure pathway)*). A more detailed assessment of these and other matters will be required in the next section (section 7).

Once you have considered **all** possibilities then you should clearly identify those potential adverse and beneficial effects (risks, costs and benefits) that are considered to be potentially significant and warrant further more detailed assessment (in section 7). If you consider that the effects identified do not warrant detailed assessment, explain why.

You can refer to the ERMA New Zealand Technical Guides “*Identifying Risks for Applications*” and “*Risks, Costs and Benefits for Applications*” for further information and guidance on completing this section. These are available from the ERMA New Zealand website or in hard copy on request. Please undertake your identification of risks, costs and benefits under each of the following headings (areas of impact) which reflect those matters referred to in Part II of the HSNO Act:

### **6.1 Identification of potential effects on the environment (in particular on ecosystems and their constituent parts)**

Taking particular account of sections 5(a), 6(a) and 6(b) of the Act, list the environmental risks, costs and benefits associated with the organism(s) to be released, and any inseparable organisms. Risks, costs and benefits in this category include those relating to the life-supporting capacity of air, water, soil and ecosystems; the sustainability of native and valued introduced flora and fauna; the maintenance of natural habitats; the intrinsic value of ecosystems; New Zealand’s inherent genetic diversity; and animal or plant health.

List potential adverse and beneficial effects, separately. If you decide that some of them are not potentially significant and do not require further assessment, indicate why you have reached this conclusion.

#### ***Risks and costs:***

>

*Benefits:*

>

**6.2 Identification of potential effects on human health and safety (including occupational exposure)**

Taking particular account of section 6(c) of the Act, list any potential risks, costs and benefits to human health that may be related to the release of the organism(s) in New Zealand. Consider the impact on people associated with the release programme as well as the wider community.

List potential adverse and beneficial effects separately. If you decide that some of them are not potentially significant and do not require further assessment, indicate why you have reached this conclusion.

*Risks:*

>

*Benefits:*

>

**6.3 Identification of potential 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)**

Taking account of sections 6(d) and 8 of the Act, list any potential adverse and beneficial 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). In this area it is especially important to indicate the extent to which the effects reflect expressed views of the Māori community during your consultations with them. However, details on these views and how they were obtained should be dealt with under the assessment section (section 7).

List risks, costs, and benefits, separately. If you decide that some of them are not potentially significant and do not require further assessment, indicate why you have reached this conclusion.

*Risks:*

>

*Benefits:*

>

**6.4 Identification of potential effects on the market economy**

Taking particular account of section 6(e) of the Act, list the economic risks, costs and benefits that might arise to New Zealand. Include related effects (e.g. scientific knowledge), which are likely to have economic or related value.

List potential adverse and beneficial effects separately. If you decide that some of them are not potentially significant and do not require further assessment, indicate why you have reached this conclusion.

***Risks:***

>

***Benefits:***

>

**6.5 Identification of potential effects on society and communities**

Taking particular account of section 5(b) and the full definition of “Environment” in section 2 of the Act, list any adverse and beneficial impacts on people and communities that might arise and relate to their capacity to provide for their own social and cultural wellbeing both now and into the future. Also list any ethical or spiritual issues or considerations 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, or consultation? However, details on this should be dealt with under the assessment section (section 7).

List potential adverse and beneficial effects separately. If you decide that some of them are not potentially significant and do not require further assessment, indicate why you have reached this conclusion.

***Risks:***

>

***Benefits:***

>

***Ethical issues and considerations:***

>

**6.6 Identification of other potential effects (including effects on New Zealand's international obligations)**

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

List potential adverse and beneficial effects, separately. If you decide that some of them are not potentially significant and do not require further assessment, indicate why you have reached this conclusion.

***Risks:***

>

***Benefits:***

>

## **Section Seven – Assessment of potentially significant adverse and beneficial effects (risks, costs and benefits)**

This section entails detailed **assessment** of those effects identified in section 6 that you consider to be **potentially significant**. The assessment should describe the nature of the effects, and should discuss in more detail, than in section 6, the source of the effects and the pathways leading to them. Assessment also entails providing an estimate of the **magnitude** of the outcome if the effect should occur, and the **likelihood of occurrence** (which may be measured as frequency or probability). The degree of uncertainty associated with the assessment should also be analysed. The factors set out in clause 33 of the HSNO (Methodology) Order 1998 which outlines various risk characteristics that will influence the decision-makers approach to risk should be referred to. These include characteristics such as *the risk will persist over time* or *the potential adverse effects are irreversible*. In such instances the Authority will be more cautious and risk averse when considering such matters.

You should also carry out your assessment taking into account the matters regarding undesirable self-sustaining populations set out in section 37 of the Act (and addressed in section 4 of this form).

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. Please cover all of these issues under each of the following headings (areas of impact) that reflect those matters referred to in Part II of the HSNO Act:

### **7.1 Assessment of potentially significant effects on the environment (in particular on ecosystems and their constituent parts)**

Assess the potentially significant adverse and beneficial effects associated with the organism(s) to be 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.

Assess adverse and beneficial effects (risks and benefits), separately. Where benefits and risks are linked, state this (e.g. a biological control agent which has an impact on both the target organism (benefit) and non-target organisms (risk)).

***Risks:***

>

***Benefits:***

>

**7.2 Assessment of potentially significant effects on human health and safety (including occupational exposure)**

Assess any potentially significant adverse and beneficial effects on human health that may be related to the release of the organism(s) in New Zealand. If effects in this area are likely to be significant a full health assessment as set out in the relevant ERMA New Zealand technical guide may be warranted.

Assess potentially significant adverse and beneficial effects, separately.

***Risks:***

>

***Benefits:***

>

**7.3 Assessment of potentially significant 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)**

Assess the potentially significant adverse and 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). If there are potentially non-negligible effects to consider in this area, it is expected that consultation will have occurred with Māori, and any information obtained from this consultation should be appended to the application. Give details of this in the space provided (see the User Guide for what is required).

Assess potentially significant adverse and beneficial effects, separately.

***Consultation with Māori:***

>

***Risks:***

>

***Benefits:***

>

**7.4 Assessment of potentially significant effects on the market economy**

Assess the potentially significant adverse and beneficial effects on the market economy. Effects on third parties and to New Zealand of the proposed release need to be specifically evaluated. If economic effects are significant applicants should provide a cost benefit analysis. Guidance on the requirements for cost benefit analyses are set out in the ERMA New Zealand Technical Guide on Economic risks.

In this case it is still helpful to assess risks and costs, and benefits, separately but if possible these assessments may be drawn together into an overall cost benefit analysis. As a part of this, estimate net benefits.

***Risks:***

>

***Benefits:***

>

***Overall cost benefit analysis:***

>

**7.5 Assessment of potentially significant effects on society and communities**

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 well-being both now and into the future. Also discuss any ethical or spiritual issues or considerations that might arise. If social effects in particular (although it may apply to other effects also) are likely to be significant, a full impact assessment may need to be carried out. Refer to the relevant ERMA New Zealand Technical Guides for assistance. If community consultation has been carried out to assist the assessment, provide information on how this was done and the results.

Assess potentially significant adverse and beneficial effects, separately.

***Community Consultation:***

>

***Risks:***

>

***Benefits:***

>

***Ethical issues and considerations:***

>

**7.6 Assessment of other potentially significant effects (including New Zealand's international obligations)**

Assess any remaining potentially significant adverse and beneficial effects not already covered including any effects on New Zealand's international obligations. Specify any relevant international agreements.

Assess potentially significant adverse and beneficial effects, separately.

***Risks:***

>

***Benefits:***

>

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

It is the role of the Authority to decide whether the beneficial effects (benefits) of the release outweigh the adverse effects (risks and costs). 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.

>

## **Section Eight – Satisfaction of the Section 36 Minimum Standards**

Satisfaction of the minimum standards in section 36 of the Act is a requirement for approval and will always be considered prior to the overall assessment and weighing of risks to, costs and benefits. Provide a statement in each subsection below on satisfaction of the minimum standards. Cross reference as appropriate (i.e. no need to repeat) to the detailed identification and assessments of risks set out in sections 6 and 7 above.

### **8.1 Displacement of native species**

State (with reasons) whether the new organism(s) is likely to cause any significant displacement of any native species within its natural habitat.

>

### **8.2 Deterioration of natural habitats**

State (with reasons) whether the new organism(s) is likely to cause any significant deterioration of natural habitats.

>

### **8.3 Adverse effects on human health and safety**

State (with reasons) whether the new organism(s) is likely to cause any significant adverse effects on human health and safety.

>

### **8.4 Adverse effect to New Zealand's inherent genetic diversity**

State (with reasons) whether the new organism is likely to cause any significant adverse effect to New Zealand's inherent genetic diversity.

>

### **8.5 Causing disease, being parasitic, or becoming a vector for disease**

State (with reasons) whether the new organism(s) is likely to cause disease, be parasitic, or become a vector for human, animal, or plant disease. If, however, the purpose of the importation or release is to import or release an organism to cause disease, be a parasite, or a vector for disease all you need to do is state that.

>

## **Section Nine – Additional Information**

**9.1 Do any of the organism(s) need approvals under any other New Zealand legislation or are affected by international obligations?** For example, indicate whether the organism may be 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.

>

**9.2 Have any of the new organism(s) in this application previously been considered for any form of approval in New Zealand or elsewhere?** For example, has the organism(s) been previously considered for import (e.g. under the Plants Act)?

>

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

>

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

>

**9.5 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. The main application should refer to the relevant appendices but be able to be read as a stand-alone document along with the cover page of the book.

>

**9.6 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 Ten – 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 released, and any risks, costs and benefits associated with their release. 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, Department of Conservation, Ministry for the Environment 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”.

>

## 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:	\$.....
Direct credit made 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 the application (our fee) can be found on our web site under new organism applications.

**Signed:**

**Date:**