

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY  
NGĀ KAIWHAKATŪPATO WHAKARARU TATAO



# FORM NOE-1

## Application for approval to

### IMPORT, RELEASE FROM CONTAINMENT, OR USE, ANY NEW ORGANISM IN AN EMERGENCY

under section 47 of the  
Hazardous Substances and New Organisms Act  
1996

Name of New Organism(s):

Applicant:

<b>Office use only</b>	
Application Code: <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Date
received: ___/___/___	
ERMA NZ Contact: _____	Initial Fees Paid: \$
Application Version No: _____	

## IMPORTANT

1. An associated User Guide is not yet available for this form. If you need guidance in completing this form please contact ERMA New Zealand.
2. This application form covers import or release from containment ,or use and new organism in an emergency under section 47 of the HSNO Act. This form is for use in anticipation of an emergency
3. If you are making an application for rapid assessment and approval of an agricultural compound or medicine that contains a new organism in a special emergency (i.e. an adverse event declared by a Minister to be a special emergency under section 49B of the HSNO Act), you should use form SER-1.
4. If you are making an application for circumstances other than emergency to import for release, or release from containment, a **genetically modified organism** you should complete **Form NO1G**. For **importation of new organisms into containment** use **Form NO2N** or **NO2G (for genetically modified organisms)**. ).
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. This application form may be used to seek approvals for importing more than one new organism where the organisms are of a similar nature.
7. 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.
8. 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.
9. 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.
10. Unless otherwise indicated, all sections of this form must be completed for the application to be progressed.
11. Please provide an electronic version of the completed application form, as well as sending a signed hard copy.

You can get more information at any time 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: 64-4-473 8426  
Facsimile: 64-4-473 8433  
E-mail: [info@ermanz.govt.nz](mailto:info@ermanz.govt.nz)  
Web-site: [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**

This form is only to be used for an application to import, release from containment, or use, a new organism in an emergency. If you are making an application for circumstances other than emergency to import for release, or release from containment, a genetically modified organism you should complete Form NO1G. For importation of new organisms into containment use Form NO2N or NO2G (for genetically modified organisms). If you are making an application for import, use or release in a Special Emergency of an agricultural compound or medicine use Form SER-1.

### **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 marks).**

Briefly describe the organism(s) to be imported for release or release from containment and the purpose(s) for which you wish to release the organism(s). (An organism is ‘released’ when it is not required to be held in a containment facility registered by the Ministry of Agriculture and Forestry).

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

Describe 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 application can understand the reasons for the release. (An organism is ‘released’ when it is not required to be held in a containment facility registered by the Ministry of Agriculture and Forestry).

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### **2.3 Give details why the new organism(s) is/are necessary to deal with the emergency.**

Please note that if “necessity” cannot be reasonably established, the Authority may decline the application. Conversely if need can be established then this meets an important criterion for approving

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**2.4 If this organism needs an approval under any other legislation, has an application for this approval been made?**

Name of Approval	Application made
Agricultural Compounds and Veterinary Medicines Act 1997	Yes/No/NA
Food Act 1981	Yes/No/NA
Medicines Act 1981	Yes/No/NA
Chemical Weapons (Prohibition) Act 1996	Yes/No/NA
Radiation Protection Act 1965	Yes/No/NA
Biosecurity Act 1993	Yes/No/NA
Resource Management Act 1991	Yes/No/NA
Other (please specify):	Yes/No
	Yes/No

### **Section Three – Information on the Organism(s) to be released**

If the application is for release of more than one organism, information must be provided separately for each organism. Include any inseparable organisms. If there are commercial reasons for not providing full information here alternative approaches must be discussed with and agreed by ERMA New Zealand. A full explanation of information required is found in the applicable user guide.

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

Please provide details of the following:

##### **Taxonomic level at which approval is sought:**

ERMA New Zealand considers approvals at the most appropriate taxonomic level for risk assessment. If the taxonomic level at which approval is sought is different from the level of species, give reasons, and justify in terms of risk (refer to section 27A of the HSNO Act).

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##### **Taxonomic identification including full taxonomic authority (e.g. ---- Linnaeus 1753) class, order and family:**

- Please provide history of any name changes and synonyms if applicable

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##### **Common name(s), if any:**

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

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

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#### **3.2 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.

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### **3.3 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. 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 (section 5.4 of this form ).

It would be appropriate to provide comment on:

- General information on attributes and characteristics of the family and genus the proposed organism belongs to.
- Information on the biology and lifecycle of the organism including:
  - climatic and ecological preferences that result in the natural distribution of the organism,
  - basic description of the structure of the organism,
  - life history and life cycle information,
  - affinities with New Zealand biota in terms of its potential to interact, form associations or interbreed,
- competitors and predators in managed and natural environments,
- potential uses.

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### **3.4 Genetic Modification**

If the organism is genetically modified, provide information on the details of the genetic modifications:

This information shall include full details of the genetic constructs and modifications and the source and characteristics of the foreign nucleic acid.

This information should clearly identify the source of the donor genetic material and the characteristics. The desired characteristic (eg, herbicide resistance) and any other significant characteristics that may be expressed by the donor genetic material in the organism should be described.

Information on the stability and homogeneity of the construct should be given, if known.

If this information is not known then this should be explicitly stated. References to the scientific literature supporting this information should be given here if appropriate.

Information that is commercially sensitive should be clearly identified. If supplied separately a cross-reference to it should be included.

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### **3.5 Inseparable Organisms**

Identify and describe (characterise) any inseparable organism(s) such as gut bacteria which cannot be separated from the organism. Associated organism (which can be removed e.g. external parasites) do not need to be considered.

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## **Section Four –Proposed plan use of the organism in an Emergency**

Provide a proposed plan for dealing with the use of the organism in an emergency. This plan will be a critical element of the consideration of the application, and of any approval. It should include:

- measures that must be taken to avoid, remedy or mitigate any actual or potential adverse effects from the use of the organisms. The effects considered should be those assessed under Section Six below, and not be able to be concluded to be negligible.

- requirements for the eradication or controls of any new organism  
Note that the Authority may decline an application if the proposed plan does not adequately control the adverse effects of the organism

The full plan may be attached to the application.

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## **Section Five - Ability of organism(s) to establish an undesirable self-sustaining population and ease of eradication**

Describe and assess the ability of the organism to establish an undesirable self-sustaining population, and the ease with which such a population could be eradicated . [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)].

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## **Section Six - Identification and Assessment of Risks, Costs, and Benefits**

In order to judge the appropriateness of the management plan described in Section 4, the risks (adverse effects) associated with the release of the organism must be identified and assessed. Costs and benefits with respect to both non-monetary and monetary terms should be described and the distribution of this discussed. 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. Identification and assessment of risks should include any inseparable organisms (see section 3.5 above).

Consider effects on the environment (for example ecosystems) and human health and welfare, including 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. 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:

### **6.1 Potential adverse effects on the environment, in particular on ecosystems and their constituent parts**

With reference to HSNO section 6(a)&(b) list the 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 incorporate assessment of the effects of any inseparable organism(s).

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### **6.2 Potential adverse effects on human health and safety** with reference to section 6(c) of HSNO list any effects including occupational exposure

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### **6.3 Potential adverse effects on the relationship of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga** With reference to section 6(d) of HSNO

and taking into account the principles of the Treaty of Waitangi list effects. If consultation with Maori has been undertaken, provide details of the outcome.

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**6.4 Other potential adverse effects** as described in section 6(e)&(f) of the HSNO Act such as New Zealand's international obligations, social or economic adverse effects, ethical issues

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## Section Seven – Additional and Attached Information

**7.1 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.

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

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

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

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**7.5 List of appendices.** 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

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**7.6 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.

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## **Section Eight – Application Summary**

Summarise the application in clear, simple language that can be understood by the general public. Include a description of the organism(s) to be released, and any risks and benefits associated with their release. 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, Crown Research Institutes) and for members of the public who request information. Do not include any commercially sensitive information in this summary.

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## Checklist

Please check and complete the following before submitting your application:

All sections completed	Yes
Appendices enclosed	Yes/ NA*
Confidential information identified and enclosed separately	Yes/NA
Copies of additional references attached	Yes/NA
Cheque for 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

**Signed:**

**Date:**