



## FORM NO1R

Application approval to

### IMPORT FOR RELEASE A NEW ORGANISM THAT IS NOT A GENETICALLY MODIFIED ORGANISM BY RAPID ASSESSMENT

**Application Title:**

**Applicant Organisation:**

ERMA Office use only	
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"/> Formally received: ___/___/___
ERMA NZ Contact:	Initial Fee Paid: \$
Application Status:	

**IMPORTANT**

1. An associated User Guide is **not** yet available for this form.
2. This application form (NO1R) covers **rapid assessment** of the adverse effects of importing a new organism that is **not** a genetically modified organism for release under **section 35** of the HSNO Act. It can be used to seek approvals for imports for release by rapid assessment of more than one new organism where the organisms are of a similar nature. **This form replaces the old Form 1 which should not now be used.** Before using this form (NO1R) you should check with an ERMA New Zealand Applications Advisor or the ERMA New Zealand web site to ensure that you are using the latest version.
3. If you are making an application to import for release or release from containment, any new organism (including a genetically modified organism) but which does **not** meet the criteria for rapid assessment under section 35 of the HSNO Act, then you should complete **Form NOR**. If you are making an application to import for release, or release from containment, **with controls**, any new organism (i.e. a conditional release) then you should complete **Form NOCR**.
4. We strongly advise you to contact 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.
5. 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.
6. 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.
7. Applicants must sign the form and enclose the correct application fee (plus GST). The (initial) application fee can be found in our recently published Fees and Charges Schedule. Please check with ERMA New Zealand staff or the ERMA New Zealand website for the latest Fees Charges Schedule effective from 1 December 2003. **We are unable to process your application without the correct application fee.**
8. **Unless otherwise indicated, all sections of this form must be completed for your application to be processed.**
9. 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 without this signed hard copy.**
10. When completing this application form please refer to the relevant sections of the HSNO Act referenced throughout the form.
11. **If your application is for a plant, it is recommended that you support this application with a reputable weed risk assessment (refer to section 6 of this form).**
12. **If your application on this form (NO1R) under section 35 of the HSNO Act fails the rapid assessment criteria, you may request ERMA New Zealand continue with your application under section 34 in which case you will need to complete Form NOR.**

This version of the application form was approved by the Chief Executive of ERMA New Zealand on 10<sup>th</sup> December 2004. If you need further information, one of our Application Advisors will be able to help you. Please contact:

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ENVIRONMENTAL RISK MANAGEMENT AUTHORITY  
NGĀ KAIWHAKATŪPATO 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 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 to be used for **rapid assessment** of importing for release a new organism, which is **not** a genetically modified organism, under **section 35** of the HSNO Act.

**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 statement is required for section 20(2)(c) of the Act. Briefly describe the organism(s) to be imported for release 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.

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**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 application to release the organism(s), including the potential use for the organism(s), so that people not directly connected with the application can understand what is proposed and the reasons for the release.

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

If the application is for release of more than one organism, information must be provided separately for each organism where there are details specific to the different organisms to be released. 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

Organisms may be specified at varying levels of taxonomic specification as indicated by the interpretation in Section 2 of the Act, but “species” is the usual level. 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 risks of the organism.

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

Please provide details of the following, to satisfy sections 34(c) and (d) of the Act:

**Latin binomial, including full taxonomic authority** (e.g. *Canis familiaris* Linnaeus, 1758) **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):

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**Other information**, (e.g. 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 released

These name(s) will be on the public register and should clearly identify the organism (e.g. *Canis familiaris* Linnaeus, 1758) as required by section 20(2)(b) of the Act.

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

Information under this heading is required to assist the identification and assessment of the effects of the organism(s) as required by section 34(2)(e) of the Act. Provide information on the biology, ecology and the main features or essential characteristics of each of the organism(s) to be released. For example, comment on pathogenicity, production of spores/seeds/pollen, conditions for growth and reproduction.

Provide information on attributes and characteristics of the family and genus the proposed organism belongs to

Provide information on the biology and lifecycle of the organism including

- climatic and ecological preferences that result in the natural distribution of the organism
- habitat requirements including factors that may limit its distribution
- basic description of the structure of the organism
- life history and life cycle information
- competitors and predators in managed and natural environments

As required by section 34(2)(f) of the Act provide information on the affinities with New Zealand organisms/biota in terms of its potential to interact, form associations or interbreed

As required by section 34(2)(g) of the Act provide information on the potential use for the organism.

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**3.5 Identify and characterise any likely inseparable organisms**

Inseparable organisms are those which are inherently associated with the main organism e.g. gut bacteria in animals. Information on this is required by section 34(2)(d) of the Act.

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## Section Four – The Proposed Release Programme

Provide details of the source of the organism for release and the proposed release programme including comments on timing and location(s) of the release(s) etc.

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## Section Five - Identification and Assessment of Adverse Effects (Risks)

Information in this category is required by section 34(2)(e) of the Act) and in accordance with the Methodology. This section should include information on the adverse effects of the type referred to in the HSNO Act. As set out in section 6 of the Act, you must take account of the physical environment, effects on human health and welfare, the relationship of Māori and their culture and traditions and New Zealand's international obligations.

In filling out this section please consider both the organism(s) and any inseparable organism.

It is expected that organisms meeting the rapid assessment requirements will not normally have any *significant* biological risks associated with them, so that a full assessment of adverse effects may not be necessary. However, sufficient information must be provided to confirm this, and also to confirm that the requirements for rapid assessment are met. These requirements are set out in Section Six of this form.

It is recommended that sections five and six of the form are filled out in parallel to ensure that sufficient information is provided, but not duplicated.

### 5.1 Identification and assessment of biological and physical adverse effects of the organism(s).

Effects in this category are those set out in sections 6(a), 6(b) and 6(c) of the Act; and repeated in other words in section 35(2)(b) of the Act. Cross reference the material in this sub-section with that in Section Six of the form.

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### 5.2 Identification and assessment of 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

Under sections 6(d) and 8 of the HSNO Act the Authority must be satisfied that the release of the organism does not raise particular issues for Maori. If your application might especially possibly have impacts on native flora and fauna, or flora and fauna which it is reasonable to think may be valued by Maori, you should address these issues here. Include details of any consultations that you have undertaken in relation to this application. If concerns were raised during the consultation process you should consider whether or how you are able to address those concerns to the satisfaction of Maori.

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### 5.3 Identification and assessment of other effects

Other effects include economic and related benefits and costs (section 6(e) of the Act and impacts on New Zealand's international obligations section 6(f) of the Act. The possibility of economic, social and cultural effects/issues should also be covered if relevant (section 5(b) of the Act).

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## Section Six – Satisfaction of the Criteria for the Rapid Assessment of Risk from Release of the New Organism(s)

This section of the application form must include information on the matters referred to in sections 35 and 36 of the HSNO Act. Because sections 35 and 36 have different thresholds (i.e. highly improbable versus significant respectively), your primary concern should be to meet the more stringent criteria. These are generally the criteria set out in section 35(2)(b). If these criteria cannot be met then your application will fail irrespective of whether the requirements of section 36 are met. If you do fail you can request ERMA New Zealand continue with your application for a full (rather than rapid) assessment in which case you will need to complete form NOR.

Please address each of the subsections below. These reflect the matters just referred to in sections 35 and 36 in the HSNO Act. Give as much detail as the subject warrants. Include a 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. The importance of showing that the organism(s) is obviously low risk is paramount.

As already indicated you will probably find it convenient to complete sections five and six of the form at the same time. To avoid duplication cross reference between the two sections.

**Note:** If your application is for a plant, it is recommended that you obtain an independent reputable (e.g. from Landcare Research) weed risk assessment. If the risk score is above zero (i.e. there is some degree of weediness) then it is more likely that your application will be declined and/or referred on for a full assessment in which case you should complete form NOR. Please incorporate the results of your weed risk assessment into the relevant headings below **and** attach a copy of the weed risk assessment.

### 6.1 Unwanted organisms

Under section 35(2)(a) of the HSNO Act the Authority must be satisfied that the new organism(s) to be released are not 'unwanted organisms' as defined in the Biosecurity Act 1993. **Note:** An 'unwanted organism' means any organism that a chief technical officer, appointed under the Biosecurity Act, believes is capable or potentially capable of causing unwanted harm to any natural and physical resource or human health. Provide information on this.

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## 6.2 Probability of the new organism forming self-sustaining populations and ease of eradication

Under section 35(2)(b)(i) of the HSNO Act the Authority must be satisfied that it is highly improbable that the organism, after release, could establish self-sustaining populations anywhere in New Zealand, taking into account the ease of eradication. Please assess the potential of the organisms to establish self-sustaining populations. Also assess how easy it would be to eradicate the organism if it was to establish and by what means would eradication be possible (e.g. mechanical, chemical, biological control, lack of reproductive or propagative potential etc.) and at what cost? For ease of reading please provide material under separate sub-headings as below.

### Formation of self-sustaining population

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### Ease of eradication

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## 6.3 Probability of the new organism displacing or reducing a valued species or causing any significant displacement of any native species within its natural habitat

Under section 35(2)(b)(ii) of the HSNO Act the Authority must be satisfied that it is highly improbable that the organism, after release, could displace or reduce a valued species. The Authority must also take into account the sustainability of all native flora and fauna and it will decline the application if displacement of any native species within its natural habitat is significant under section 36(a) of the HSNO Act. Provide an assessment of these matters. For example, how likely is it that the new organism(s) will affect the abundance or geographical distribution of a native or valued introduced species such as kauri, kiwi, ryegrass, or trout? Note: It is important to identify and address how any potential effect is likely or unlikely to occur.

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**6.4 Probability of the new organism(s) causing any significant deterioration of natural habitats**

Under section 35(2)(b)(iii) of the HSNO Act the Authority must be satisfied that it is highly improbable that the organism, after release, could cause deterioration of natural habitats. Please assess this matter. For example, how likely is it that the new organism(s) will influence the biophysical quality of, for instance, freshwater lakes and streams, or the canopy of native forests?

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**6.5 Probability of the new organism causing disease, being parasitic, or becoming a vector or reservoir for human, animal or plant disease**

Under section 35(2)(b)(iv) of the HSNO Act the Authority must be satisfied that it is highly improbable that the organism could cause disease, be parasitic, or become a vector for human, animal, or plant disease. Please assess these matters. For example, what evidence is there from other countries that the new organism(s) are hosts for plant viruses, or are carriers of bacteria pathogenic in humans?

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**6.6 Probability of the new organism having any adverse effects on human health and safety or the environment**

Under section 35(2)(b)(v) of the HSNO Act the Authority must be satisfied that it is highly improbable that the organism will have any adverse effects on human health and safety or the environment. Section 36(c) requires that the organism is unlikely to cause any significant adverse effects on human health or safety. Please assess these matters. For example, is there evidence of people displaying allergic reactions to the organism itself or pollen from the new organism(s); are the new organisms venomous?

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**6.7 Likelihood of the new organism(s) causing any significant adverse effects on New Zealand's inherent genetic diversity**

Under section 36(d) of the HSNO Act the Authority must decline the application if the organism is likely to cause any significant adverse effect to New Zealand's inherent genetic diversity. Please assess this matter. For example, how likely is it that the new organism(s) will hybridise with native or valued species or affect their current distribution?

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## Section Seven – Overall evaluation

Although not required because it is a task for the decision maker, applicants may provide their own overall evaluation of the information in Sections 5 and 6 above. In doing this the first step is to address the criteria set out in Section 6. Organisms must satisfy **all** these criteria in order to be eligible for rapid assessment. The more general risk assessments in Section 5 are intended to both support the Section 6 information and to provide information on risks which lie outside the statutory criteria for rapid assessment, but are covered by Part II of the Act.

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## Section Eight – Additional Information

### 8.1 Do any of the organism(s) need approvals under any other New Zealand legislation or are affected by international obligations?

For example, indicate whether the organism may be subject to other New Zealand legislation, e.g. the Biosecurity Act 1993; or if the organism(s) are listed in CITES, then approval is required from both the importing and exporting countries.

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### 8.2 Have any of the new organism(s) in this application previously been considered in New Zealand or elsewhere?

For example, have the organism(s) been previously considered for import (e.g. under the previous Plants or Animals Acts or under the HSNO Act)? Also include information on all occasions where the organism(s) have been considered by other countries, governments or organisations and the results of such considerations.

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### 8.3 Is there any additional information that you consider relevant to this application that has not already been included? Please provide any such information that is material to the organism(s) concerned

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

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### 8.5 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 the application is able to be read as a stand-alone document.

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## 8.6 References

Please include a list of the references cited in and supplied with this application form. Originals of the references must be supplied in full. Where the reference supplied is an extract from a book only the specific pages quoted must be supplied.

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## Section Nine– 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, the potential use of the organism, and any risks associated with their release. 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) and for members of the public who request information. **Note: 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) <sup>†</sup>	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

<sup>†</sup> The cost of the application (our fee) can be found in the “Fees and Charges Schedule” on our web site under “New Organisms” and “NO and GMO Forms and Publications”

<http://www.ermanz.govt.nz/resources/publications/pdfs/ER-FE-03-5.pdf>

**Signed:**

**Date:**