



## **FORM NO1Q**

**Application for approval to**

**RELEASE A QUALIFYING ORGANISM(S)  
BY RAPID ASSESSMENT**

**under section 38I of the  
Hazardous Substances and New Organisms Act 1996**

**Application Title:**

**Applicant Organisation:**

ERMA Office use only

Application Code: **Error! Objects cannot be created from editing field codes.** Formally  
received: \_\_\_\_/\_\_\_\_/\_\_\_\_

ERMA NZ Contact:

Initial Fee Paid: \$

Application Status:

## **IMPORTANT**

1. An associated User Guide is available for this form on the ERMA website. If you need further guidance in completing this form please contact ERMA New Zealand.
2. This application form only covers applications for approval by rapid assessment to import for release or to release from containment qualifying organisms. A qualifying organism is a new organism (including a genetically modified organism) that is contained in a medicine or veterinary medicine.
3. This form replaces all previous versions of Form NO1Q. Older versions will not be accepted. You should check with ERMA New Zealand or the ERMA New Zealand website for the most up-to-date version of this form.
4. You can talk to either 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 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**. We cannot begin processing your application until we have received payment of the application fee and a signed hard copy of the application form.
11. You can get more information by contacting ERMA New Zealand, the Ministry of Health or MAF Agricultural Compounds and Veterinary Medicines Group (ACVM). 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 2 June 2004.

If you need further information, one of our Application Advisors will be able to help you. Please contact:

ERMA New Zealand  
20 Customhouse Quay  
PO Box 131  
Wellington  
New Zealand  
Telephone: 64-4-916-2426  
Facsimile: 64-4-914-0433

20 Customhouse Quay,  
Cnr Waring Taylor & Customhouse Quay  
PO Box 131, Wellington  
Phone: 04-916 2426 Fax: 04-914 0433  
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Website: [www.ermanız.govt.nz](http://www.ermanız.govt.nz)

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY  
NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO



E-mail: [info@ermanız.govt.nz](mailto:info@ermanız.govt.nz), [www.ermanız.govt.nz](http://www.ermanız.govt.nz)

## **Section One – Applicant Details**

### **1.1 Name and postal address in New Zealand of the organisation or private 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 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 >**

## **Section Two – Purpose of the Application**

This form is to be used for an application to import for release or release from containment qualifying organisms under section 38I of the HSNO Act. If a qualifying organism is not approved by rapid assessment under section 38I of the Act, then it must be fully assessed under section 38.

- 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). What medical or veterinary purpose will these organisms be used for?**

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- 2.2 Provide a short description of the background and aims of the medicine or veterinary medicine suitable for lay readers.**

Describe the rationale for the overall purpose and use of these organisms so that people not directly connected with the prescription or use of the qualifying organism can understand why they are required. This explanation is particularly important if the qualifying organisms have been genetically modified, and especially if DNA from native flora and fauna, or human genes have been inserted into the organism.

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

If more than one type of qualifying organism is to be imported or released, this section must be completed separately for each organism. If there are commercial reasons for not providing full information here alternative approaches must be discussed with and agreed by ERMA New Zealand.

#### 3.1 Provide unique name(s) for the new organism(s) that can be used on the public register.

(Maximum 100 characters). For example, “Live attenuated SARS coronavirus vaccine 575-G” or “*Vibrio cholerae* CVD 103-HgR”.

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#### 3.2 Is the new organism genetically modified? Yes / No

For non-genetically modified organisms, complete sections 3.2 and 3.4 (do not fill out section 3.3). For genetically modified organisms complete sections 3.2, 3.3 and 3.4.

#### 3.3 Give the unequivocal identification of the new organism or host organism (if the organism is genetically modified)

Please include details on the following:

**Latin binomial, including full taxonomic authority and taxonomic class, order and family:**

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Common name(s), if any:

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**Type of organism**(eg bacterium, virus, fungus, plant, animal, animal cell):

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**Strain(s)** if relevant:

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**Other information**, including presence of any inseparable or associated organisms, and whether a prohibited organism is involved:

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### **3.4 Details of the genetic modification if the qualifying organism is genetically modified**

How was the organism developed? Please attach any experimental data and information relating to how the genetically modified organism was developed to the application. Also provide details of the following:

**Identify the category or categories of experiment(s) as described in the HSNO (Low-Risk Genetic Modification) Regulations 2003.**

Identify the specific class of experiment(s) (eg Category A genetic modification of a Category 1 host organism) and explain your characterisation.

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**Vector system(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
Does this application use native flora or fauna as <b>host organism(s)</b> ? <i>If Yes, provide additional details below.</i>		
Does this application use <b>genetic material</b> from native flora and fauna? <i>If Yes, provide additional details below.</i>		
If native flora and fauna are involved, are the species concerned endemic to New Zealand?		
Does this application involve <b>human</b> cell lines? <i>Answer Yes if human cell lines in any form are used, ie obtained directly from humans (either Maori or non-Maori) or from a commercial supplier etc. Please provide additional details below.</i>		
Does this application use cell lines obtained <b>directly</b> from human beings?		
Does this application involve <b>human</b> genetic material? <i>Answer Yes if human genetic material in any form is used, ie obtained directly from humans (either Maori or non-Maori), from a gene bank, synthesised, copied and so on. Please provide additional details below.</i>		
Does this application use genetic material obtained <b>directly</b> from human beings?		

**If native flora and fauna are involved, from where in New Zealand or elsewhere was this material obtained?** Be as specific as possible as this information will be needed to decide whether Maori have been appropriately involved.

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**If genetic material or cells are derived from humans provide details of where the material was obtained from, and whether approval was obtained from an Ethics Committee, and/or consultation with Maori has taken place.**

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**Other relevant details of the development of the organism** (such as what techniques or experimental procedures were used, if any unusual manipulations were carried out, and if the foreign genetic material is expressed):

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### **3.5 Characteristics of the qualifying organism(s).**

Provide information on the main features or essential characteristics of the new organism(s). For genetically modified organisms you should note characteristics of the host organism as well as any new characteristics introduced by the genetic modifications. For example, note pathogenicity, production of spores/cysts, conditions for growth and reproduction. This information should be relevant to the identification of the risks of the organism (sections 4.1 and 4.2).

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### **3.5 Provide details of the doses and routes of administration of the qualifying organisms**

## **Section Four – Identification and Assessment of Adverse Effects**

This section should include information on the adverse effects of the type referred to in the HSNO Act, particularly in section 38I(3). The Authority will take into account (i) whether the dose and routes of administration of the medicine or veterinary medicine would have significant adverse effects on public health or any valued species; and (ii) whether the qualifying organism could form an undesirable self-sustaining population that would have significant adverse effects on:

- The health and safety of the public
- Any valued species
- Natural habitats
- The environment

It is expected that the qualifying organism meeting the criteria for low risk in section 38I(3) will not normally have any *significant* biological risks associated with them, so that an assessment of adverse effects will not normally be required. However, there may still be some adverse effects that need to be identified and assessed.

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

Describe the ability of the organism to establish a self-sustaining population and whether such a population would be considered undesirable.

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### **4.2 Identify and assess any potential adverse effects which relate to whether or not the organism is a qualifying organism under section 38I(3) of the HSNO Act:**

Consider effects under the following headings. Indicate whether or not it is highly improbable that significant adverse effects should occur. Consider both the doses and routes of administration of the medicine or veterinary medicine, and whether the qualifying organism could form an undesirable self-sustaining population.

#### **A. Potential significant adverse effects on the health and safety of the public (This does not include effects on people being treated with the medicine):**

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**B. Potential significant adverse effects on any valued species (This does not include effects on animals being treated by the veterinary medicine):**

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**C. Potential significant adverse effects on natural habitats:**

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**D. Potential significant adverse effects on the environment:**

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**4.3 Identify and assess any other potential adverse effects:**

Consider any other adverse effect, especially adverse effects which are not covered under section 4.2 above but which are relevant to matters set out in Part II of the HSNO Act. Consider effects under the following headings:

**A. Potential effects relating to the relationships of Maori 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). This section is best completed after consultation with Maori. Please provide details of consultation undertaken and the outcome.

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**B. Potential adverse economic and related effects derived from the use of the qualifying organism:**

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**C. Potential adverse effects related to New Zealand's international obligations:**

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**D. Potential adverse social, cultural, ethical or spiritual effects:**

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## **Section Five – Application of controls**

5.1 Potential controls imposed under the ACVM Act or Medicines Act

Qualifying organisms will have controls imposed under other legislation as well as the HSNO Act. List controls which are expected to be imposed under the ACVM Act (for veterinary medicines) or the Medicines Act (for human medicines).

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### **5.2 Potential controls proposed under the HSNO Act:**

The Authority has discretion under section 38I(1) as to whether to approve the release of a qualifying organism with or without controls. The assessment of whether a new organism meets the criteria set out in section 38I(3) to be considered as a qualifying medicine or qualifying veterinary medicine must also take into account all the controls that will be imposed (if any) on the release of that medicine. Therefore, if your medicine does not meet these criteria to be considered as a qualifying organism in the absence of controls, you must clearly state the potential controls that may be imposed in order for the organism to meet these criteria.

If you consider that imposing a particular type of control will not reduce risks to people and the environment, you should say so, and justify your position. If you consider that some risks may be reduced by imposing controls in this section, you should suggest a control, and explain why you think this proposed control will reduce risks. When proposing controls you must consider the practical implications and application of the controls.

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## **Section Six – Additional Information**

### **6.1 Do any of the organism(s) need approvals under any other New Zealand legislation (apart from the ACVM or Medicines Acts)?**

For example, the development may involve modification of whole animals, which also requires an approval under the Animal Welfare Act 1999; or if genetic material from species listed by CITES is used, then approval is required from both the importing and exporting countries.

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

For example, has the organism(s) already been approved under HSNO for import or development in containment or has the organism been approved under another country's regulatory system? If the answer is yes, please provide details of any relevant approvals (including approval codes) and any risk assessments that were performed.

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

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

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### **6.5 List of appendices**

Give the names of any appendices included with this application.

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### **6.6 List of references**

Please include a list of the references cited in and supplied with this application. Originals of the references must be supplied in full.

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## **Section Seven – Application Summary**

Summarise the application in clear, simple language that is able to be understood by the general public. Include a description of the new organism(s), the purpose for which they will be developed, how they will be developed, the proposed containment system, and any risks and benefits associated with their development or use. 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, Local Authorities etc) and for members of the public who request information. **Note:** Do not include any commercially sensitive information in this summary. Confidential information should be attached as a separate appendix and clearly marked as “confidential”.

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## Checklist

Please check 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
Application signed and dated	Yes
If application submitted to ERMA New Zealand:	
Initial fee enclosed (incl. GST)	Yes
Electronic copy of application e-mailed to ERMA New Zealand	Yes

\*NA – not applicable

**Signed:**

**Date:**