

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY  
 NGĀ KAIWHAKATUPATO WHAKARARU TAIAO



## FORM SER-1

**Application for approval by rapid assessment to  
 IMPORT FOR RELEASE,  
 MANUFACTURE,  
 RELEASE FROM CONTAINMENT,  
 OR USE  
 ANY AGRICULTURAL COMPOUND OR MEDICINE  
 IN  
 SPECIAL EMERGENCIES**

**under section 49D of the  
 Hazardous Substances and New Organisms Act 1996**

**Application Title:**

**Applicant Organisation:**

**Name of Agricultural Compound or Medicine:**

**ERMA Office use only**

Application Code:

Formally received: \_\_\_/\_\_\_/\_\_\_

ERMA NZ Contact: \_\_\_\_\_

Initial Fee Paid: \$

Application Status:

# Application for approval to import for release, manufacture, release from containment or use any agricultural compound or medicine in a special emergency under Section 49D of the Hazardous Substances and New Organisms Act 1996

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### IMPORTANT

1. This application form only covers approval to import for release, manufacture, release from containment or use any agricultural compound or medicine in the event of a special emergency or impending special emergency.
2. It is recommended that you talk, as early as possible, to an Applications Advisor at ERMA New Zealand who can help you scope and prepare your application. Quality information up front will speed up the process.
3. This application form may be used to seek approvals for more than one hazardous substance and/ or new organism where the substances and/or organisms are used for the same purpose in a special emergency, and are of a similar nature.
4. 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.
5. Commercially sensitive information must be collated in a separate appendix. You need to justify why you consider the material to be commercially sensitive, and make sure it is clearly labelled as such.
6. 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.
7. The application must include the information required by the Authority that the applicant can provide in the time available, having regard to the particular circumstances of the special emergency.
8. Please provide an electronic version of the completed application form, as well as sending a **signed hard copy**.

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

ERMA New Zealand  
20 Customhouse Quay  
PO Box 131  
Wellington  
NEW ZEALAND  
Telephone: 64-4-916 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)

20 Customhouse Quay,  
Cnr Waring Taylor & Customhouse Quay  
PO Box 131, Wellington  
Phone: 04-916 2426 Fax: 04-914 0433  
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**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 >**

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**Section Two – Purpose of the Application**

This form is to be used for an application to import for release, manufacture, release from containment or use any agricultural compound or medicine only in the event of a special emergency or impending special emergency.

- 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).  
What is applied for, and how does this application address the needs of the special emergency?

>

- 2.2 Give details of the special emergency, and the relevant Gazette notice.**  
Refer to sections 49A and 49B of the HSNO Act.

- (i). Describe the special emergency:**

>

- (ii). Which responsible Minister has declared/will declare the special emergency?**

>

- (iii). If the special emergency has not yet been declared, when is it likely to be declared?**

>

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(iv). When was/will notice of the declaration of the special emergency be published in the *Gazette*?

>

(vi). When will the special emergency expire, (if known)?

>

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**Section Three – Information on hazardous substances and new organisms that  
are or are contained within agricultural compounds or medicines to be used in  
the special emergency**

If more than one agricultural compound or medicine is applied for, this section must be completed separately for each agricultural compound and medicine. If more than one new organism is or is contained within an agricultural compound or medicine, this section must be completed separately for each new organism. If there are time constraints or commercial reasons for not providing full information here, alternative approaches should be discussed and agreed with ERMA New Zealand.

**3.1 Provide a unique name for the agricultural compound or medicine that can be used on  
the public register:**

>

**A. Hazardous Substances**

**3.2 If the agricultural compound or medicine is a hazardous substance, state the  
unequivocal identification of the substance.**

- **Chemical Name (Chemical Abstracts Preferred Index name or IUPAC name):**
- **Common Name :**
- **Synonyms :**
- **Trade Names:**
- **Molecular Formula:**
- **Structural Formula:**
  
- **CAS Registry Number:**

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- **Significant impurities:**

>

For mixtures, in addition to the above information being provided on the actual substance, information is also required on the composition of the mixture i.e. the chemical name, CAS number, function (e.g. active ingredient, emulsifier, surfactant, filler) and percentages of **ALL** components of the mixture (including non-hazardous components and impurities) should be provided. This information may be best expressed in tabular form. If the composition is variable, please ensure to state the limits.

>

### 3.3 Provide information on the chemical and physical properties of the substance

[at 20°C and 1 atmosphere unless otherwise stated], for example:

- **Appearance (colour, odour, physical state or form):**

>

- **pH:**

>

- **Density**

>

- **Vapour pressure:**

>

- **Boiling/melting point:**

>

- **Solubility in water:**

>

- **Water/octanol partitioning co-efficient:**

>

For mixtures, information is required on the chemical and physical properties of the substance itself. However, if this information is not available, you should provide information on the chemical and physical properties of EACH hazardous component of the mixture.

>

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### 3.4 Provide information on the hazardous properties the substance:

Information in this section should be provided on the hazardous properties of the substance, preferably under the headings set out below. If the substance is a mixture, and you cannot provide information on the hazardous properties of the mixture, you can apply mixture rules to the hazardous components of the mixture. If you do this, then you will need to provide information on the hazardous properties of each hazardous component of the mixture, and show your workings. Details of the mixture rules can be found in the User Guide for HSNO Thresholds and Classifications.

- **Explosiveness:**

>

- **Flammability:**

>

- **Oxidising properties:**

>

- **Corrosiveness:**

>

- **Toxicity:**

>

- **Ecotoxicity:**

>

>

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**B. New Organisms**

**3.5 Provide unequivocal identification of new organisms that are or are contained within the agricultural compounds or medicines:**

- **Taxonomic level at which approval of the new organism 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).  
>
  
- **Provide a full taxonomic identification (e.g. class, order, family, genus, species), including the full taxonomic authority for the species:**  
>
  
- **Common name(s) of the new organism, if any:**  
>
  
- **Type of organism**(e.g. bacterium, virus, fungus, plant, animal, animal cell):  
>
  
- **Strain(s) and genotype(s) of the new organism(s), if relevant:**  
>
  
  
- **Describe any likely inseparable organism:**  
>
  
  
- **Is a prohibited organism involved?**  
Refer to Schedule 2 of the HSNO Act.  
>

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**3.6 Characteristics of the new organism(s) which are or are contained within the agricultural compound or medicine:**

Provide information on the biology, ecology, and the main features or essential characteristics of the organism(s) that are the subject of this application.

>

**3.7 If the new organism is a genetically modified organism, provide details on the development of the 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, provide relevant information to the extent possible:

>

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

>

**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 the organism contain <b>genetic material</b> from native flora and fauna?		
If native flora and fauna are involved, are the species concerned indigenous to New Zealand?		
Does this organism involve <b>human</b> genetic material? <i>Answer Yes if human genetic material in any form is used, ie obtained directly from humans, from a gene bank, synthesised, copied etc.</i>		
Does this organism contain genetic material obtained <b>directly</b> from human beings? <i>If Yes, provide additional details below.</i>		

**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 may be needed to decide whether Maori have been appropriately consulted.

>

**If material was sourced directly from humans provide details of where the material was obtained from, and give details of all ethical approvals that have been obtained.**

>

**3.8 Provide unique name(s) for the new organism(s) that can be used on the public register.**  
(Maximum 100 characters). For example, "Escherichia coli DH5a; pBluescript".

>

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## Section Four – Identification and assessment of risks

Identify and assess any non-negligible risks (adverse effects) having regard to the matters set out in Part II of the HSNO Act. The assessment should desirably be sufficiently comprehensive to explain the steps set out in the required plan (see Section 5.2 of this application) for managing adverse effects. Provide the best assessment possible in the time available. If time has limited the work possible, briefly describe and explain the limitations.

### 4.1 Environmental effects of the agricultural compounds or medicines:

This includes effects on the life-supporting capacity of air, soil water and ecosystems, and the sustainability of all native and valued introduced flora and fauna, on the intrinsic value of ecosystems (refer to sections 5(a), 6(a) and 6(b) of the HSNO Act).

>

### 4.2 Public health effects of the agricultural compounds or medicines:

Note that section 2 of the HSNO Act defines “public health” as having the same meaning as section 2 of the Health and Disabilities Services Act 1993.

>

### 4.3 Effects on relationships of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga, of the agricultural compounds or medicines:

Refer to section 6(d), and also to section 8, of the HSNO Act.

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**4.4 Economic and related effects of the use of the agricultural compounds or medicines:**

Note that section 6(e) of the HSNO Act requires account to be taken of the economic and related costs and benefits to be derived from the use of a particular hazardous substance or new organism.

>

**4.5 Effects related to New Zealand's international obligations:**

Refer to section 6(f) of the HSNO Act.

>

**4.6 Social, cultural, ethical or spiritual effects:**

Effects of this type relate to section 5(b) of the HSNO Act, and are also referred to in section 68(1) on Ministerial call in.

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**Section Five: Information required under section 49 of the HSNO Act.**

This section of the application should include information required by the Authority under sections 49E, 49G and 49K of the HSNO Act, that, having regard to the particular circumstances of the special emergency, the applicant can provide in the time available.

**5.1 Explain how and why the agricultural compound or medicine is necessary to deal with the special emergency.**

Refer to section 49E(2)(b) of the HSNO Act.

>

**5.2 Outline the plan for dealing with the use of the agricultural compound or medicine in the special emergency.**

Section 49E(2)(c) of the HSNO Act states that the Authority may require from the applicant a plan for dealing with the agricultural compound or medicine in the special emergency. Outline the main features of the plan here; the full plan should be attached as an appendix to the application. The plan should include coverage of matters set down in section 49G of the Act, namely:

- (a) the measures that be taken to avoid, remedy, or mitigate any actual or potential adverse effects from the use of the agricultural compound or medicine:
- (b) the requirements for the disposal of the agricultural compound or medicine:
- (c) the requirements for the eradication or control of any new organism.

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**5.3 Expert reports:**

Refer to section 49E(2)(d) of the HSNO Act

List reports received from experts, and summarise the main features of the reports (copies of the full reports should be attached to the application as appendices):

(i) Reports from the applicant (if any):

>

(ii) Reports from overseas regulatory agencies (if any):

>

**5.4 Confirmation that the agricultural compound or medicine satisfies all relevant  
manufacturing practices and standards.**

Refer to section 49E(2)(e) of the HSNO Act

Provide details:

>

**5.5 Provide information on approvals for use of the agricultural compound or medicine in  
overseas countries.**

Refer to section 49E(2)(f) of HSNO Act.

>

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**5.6 Provide information on decisions to decline approval for use of the agricultural compound or medicine in overseas countries:**

Refer to section 49E(2)(g) of the HSNO Act.

>

**5.7 Provide information on the labelling of the agricultural compound or medicine.**

Refer to section 49E(2)(j) of the HSNO Act.

>

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**Section 6 – Other Information**

Applicants are invited to provide here any other information they consider may be relevant.

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Please check the following before submitting your application:

All sections completed	Yes/NA*
Plan for dealing with the agricultural compound or medicine in the special emergency	Yes
Other 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:**