



To obtain approval to release new organisms

(Through importing for release or releasing from containment)

Send to Environmental Protection Authority preferably by email (neworganisms@epa.govt.nz) or alternatively by post (Private Bag 63002, Wellington 6140)
Payment must accompany final application; see our fees and charges schedule for details.

Application Number

Date

Completing this application form

1. This form has been approved under section 34 of the Hazardous Substances and New Organisms (HSNO) Act 1996. It covers the release without controls of any new organism (including genetically modified organisms (GMOs)) that is to be imported for release or released from containment. It also covers the release with or without controls of low risk new organisms (qualifying organisms) in human and veterinary medicines. If you wish to make an application for another type of approval or for another use (such as an emergency, special emergency, conditional release or containment), a different form will have to be used. All forms are available on our website.
2. It is recommended that you contact an Advisor at the Environmental Protection Authority (EPA) as early in the application process as possible. An Advisor can assist you with any questions you have during the preparation of your application including providing advice on any consultation requirements.
3. Unless otherwise indicated, all sections of this form must be completed for the application to be formally received and assessed. If a section is not relevant to your application, please provide a comprehensive explanation why this does not apply. If you choose not to provide the specific information, you will need to apply for a waiver under section 59(3)(a)(ii) of the HSNO Act. This can be done by completing the section on the last page of this form.
4. Any extra material that does not fit in the application form must be clearly labelled, cross-referenced, and included with the application form when it is submitted.
5. Please add extra rows/tables where needed.
6. You must sign the final form (the EPA will accept electronically signed forms) and pay the application fee (including GST) unless you are already an approved EPA customer. To be recognised by the EPA as an "approved customer", you must have submitted more than one application per month over the preceding six months, and have no history of delay in making payments, at the time of presenting an application.
7. Information about application fees is available on the EPA website.
8. All application communications from the EPA will be provided electronically, unless you specifically request otherwise.

Commercially sensitive information

9. Commercially sensitive information must be included in an appendix to this form and be identified as confidential. If you consider any information to be commercially sensitive, please show this in the relevant section of this form and cross reference to where that information is located in the confidential appendix.
10. Any information you supply to the EPA prior to formal lodgement of your application will not be publicly released. Following formal lodgement of your application any information in the body of this application form and any non-confidential appendices will become publicly available.

11. Once you have formally lodged your application with the EPA, any information you have supplied to the EPA about your application is subject to the Official Information Act 1982 (OIA). If a request is made for the release of information that you consider to be confidential, your view will be considered in a manner consistent with the OIA and with section 57 of the HSNO Act. You may be required to provide further justification for your claim of confidentiality.

Definitions

Containment	Restricting an organism or substance to a secure location or facility to prevent escape. In respect to genetically modified organisms, this includes field testing and large scale fermentation
Controls	Any obligation or restrictions imposed on any new organism, or any person in relation to any new organism, by the HSNO Act or any other Act or any regulations, rules, codes, or other documents made in accordance with the provisions of the HSNO Act or any other Act for the purposes of controlling the adverse effects of that organism on people or the environment
Genetically Modified Organism (GMO)	Any organism in which any of the genes or other genetic material: <ul style="list-style-type: none"> • Have been modified by <i>in vitro</i> techniques, or • Are inherited or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by <i>in vitro</i> techniques
Medicine	As defined in section 3 of the Medicines Act 1981 http://www.legislation.govt.nz/act/public/1981/0118/latest/DLM53790.html?src=qs
New Organism	<p>A new organism is an organism that is any of the following:</p> <ul style="list-style-type: none"> • An organism belonging to a species that was not present in New Zealand immediately before 29 July 1998; • An organism belonging to a species, subspecies, infrasubspecies, variety, strain, or cultivar prescribed as a risk species, where that organism was not present in New Zealand at the time of promulgation of the relevant regulation; • An organism for which a containment approval has been given under the HSNO Act; • An organism for which a conditional release approval has been given under the HSNO Act; • A qualifying organism approved for release with controls under the HSNO Act; • A genetically modified organism; • An organism belonging to a species, subspecies, infrasubspecies, variety, strain, or cultivar that has been eradicated from New Zealand; • An organism present in New Zealand before 29 July 1998 in contravention of the Animals Act 1967 or the Plants Act 1970. This does not apply to the organism known as rabbit haemorrhagic disease virus, or rabbit calicivirus <p>A new organism does not cease to be a new organism because:</p> <ul style="list-style-type: none"> • It is subject to a conditional release approval; or • It is a qualifying organism approved for release with controls; or • It is an incidentally imported new organism
Qualifying Organism	As defined in sections 2 and 38I of the HSNO Act

Release	To allow the organism to move within New Zealand free of any restrictions other than those imposed in accordance with the Biosecurity Act 1993 or the Conservation Act 1987
Unwanted Organism	As defined in section 2 of the Biosecurity Act 1993 http://www.legislation.govt.nz/act/public/1993/0095/latest/DLM314623.html?src=qs
Veterinary Medicine	As defined in section 2(1) of the Agricultural Compounds and Veterinary Medicines Act 1997 http://www.legislation.govt.nz/act/public/1997/0087/latest/DLM414577.html?search=ts_act%40bill%40regulation%40deemedreg_Agricultural+Compounds+and+Veterinary+Medicines+Act+ resel 25 a&p=1

1. Applicant details

1.1. Applicant

Company Name: (if applicable)

Contact Name:

Job Title:

Physical Address:

Postal Address (provide only if not the same as the physical):

Phone (office and/or mobile):

Fax:

Email:

1.2. New Zealand agent or consultant (if applicable)

Company Name:

Contact Name:

Job Title:

Physical Address:

Postal Address (provide only if not the same as the physical):

Phone (office and/or mobile):

Fax:

Email:

2. Information about the application

2.1. Brief application description

Approximately 30 words about what you are applying to do

2.2. Summary of application

Provide a plain English, non-technical description of what you are applying to do and why you want to do it

2.3. Background and aims of application

This section is intended to put the new organism(s) in perspective of the wider activitie(s) that they will be used in. You may use more technical language but all technical words must be included in a glossary.

3. Information about the new organism(s)

3.1. Name of organism

Identify the organism as fully as possible

Non-GMOs - Provide a taxonomic description of the new organism(s).

GMOs – Provide a taxonomic description of the host organism(s) and describe the genetic modification.

Both -

- Describe the biology and main features of the organism including if it has inseparable organisms.
- Describe if the organism has affinities (e.g. close taxonomic relationships) with other organisms in New Zealand.
- Could the organism form an undesirable self-sustaining population? If not, why not?
- How easily could the new organism be recovered or eradicated if it established an undesirable self-sustaining population?

3.2. Regulatory status of the organism

Is the organism that is the subject of this application also the subject of:

An innovative medicine application as defined in section 23A of the Medicines Act 1981?

Yes No

An innovative agricultural compound application as defined in Part 6 of the Agricultural Compounds and Veterinary Medicines Act 1997?

Yes No

4. Māori engagement

Discuss any engagement or consultation with Māori undertaken and summarise the outcomes. Please refer to the EPA policy 'Engaging with Māori for applications to the EPA' on our website (www.epa.govt.nz) or contact the EPA for advice.

5. Risks, costs and benefits

Provide information of the risks, costs and benefits of the new organism(s).

These are the positive and adverse effects referred to in the HSNO Act. It is easier to regard risks and costs as being adverse (or negative) and benefits as being positive. In considering risks, cost and benefits, it is important to look at both the likelihood of occurrence (probability) and the potential magnitude of the consequences, and to look at distribution effects (who bears the costs, benefits and risks).

Consider the adverse or positive effects in the context of this application on the environment (e.g. could the organism cause any significant displacement of any native species within its natural habitat, cause any significant deterioration of natural habitats or cause significant adverse effect to New Zealand's inherent genetic diversity, or is the organism likely to cause disease, be parasitic, or become a vector for animal or plant disease?), human health and safety, the relationship of Māori to the environment, the principles of the Treaty of Waitangi, society and the community, the market economy and New Zealand's international obligations.

You must fully complete this section referencing supporting material. You will need to provide 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, and provide that information with this application.

6. Pathway determination and rapid assessment

Under sections 38I and 35 of the HSNO Act your application may be eligible for a rapid assessment. The pathway for your application will be determined after its formal receipt, based on the data provided in this application form. If you would like your application to be considered for rapid assessment (as per the criteria below), we require you to complete one of the below sections. **Fill in the section that is relevant to your application only.**

6A. New organism that is or is contained within a veterinary or human medicine (section 38I)

6.1. Controls for organism

Describe the controls you propose to mitigate potential risks (if any). Discuss what controls may be imposed under the ACVM Act (for veterinary medicines) or the Medicines Act (for human medicines)

6.2. Discuss if it is highly improbable (after taking into account controls if any):

- The doses and routes of administration of the medicine would have significant adverse effects on the health of the public or any valued species; and
- The organism could form an undesirable self-sustaining population and have significant adverse effects on the health and safety of the public, any valued species, natural habitats or the environment

Do not include effects of the medicine or new organism on the person or animal being treated with the medicine

6B. New organism (excluding genetically modified organisms) (section 35)

6.3. Discuss if your organism is an unwanted organism as defined in the Biosecurity Act 1993

6.4. Discuss if it is highly improbable, after taking into account the proposed controls, that the organism after release:

- Could form self-sustaining populations anywhere in New Zealand (taking into account the ease of eradication)
- Could displace or reduce a valued species
- Could cause deterioration of natural habitats,
- Will be disease-causing or be a parasite, or be a vector or reservoir for human, animal, or plant disease
- Will have adverse effects on human health and safety or the environment

7. Other information

Add here any further information you wish to include in this application including if there are any ethical considerations that you are aware of in relation to your application.

8. Checklist

This checklist is to be completed by the applicant

Application		Comments/justifications
All sections of the application form completed or you have requested an information waiver under section 59 of the HSNO Act	<input type="checkbox"/> Yes <input type="checkbox"/> No (If No, please discuss with an Advisor to enable your application to be further processed)	
Confidential data as part of a separate, identified appendix	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Supplementary optional information attached:		
<ul style="list-style-type: none"> Copies of additional references 	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<ul style="list-style-type: none"> Relevant correspondence 	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Administration		
Are you an approved EPA customer?	<input type="checkbox"/> Yes <input type="checkbox"/> No If Yes are you an: Applicant: <input type="checkbox"/> Agent: <input type="checkbox"/>	
If you are not an approved customer, payment of fee will be by: <ul style="list-style-type: none"> Direct credit made to the EPA bank account (preferred method of payment) Date of direct credit: Cheque for application fee enclosed 	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Payment to follow <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Payment to follow	
Electronic, signed copy of application e-mailed to the EPA	<input type="checkbox"/> Yes	

Signature of applicant or person authorised to sign on behalf of applicant

- I am making this application, or am authorised to sign on behalf of the applicant or applicant organisation.
- I have completed this application to the best of my ability and, as far as I am aware, the information I have provided in this application form is correct.

Signature

Date

Request for information waiver under section 59 of the HSNO Act

- I request for the Authority to waive any legislative information requirements (i.e. concerning the information that has been supplied in my application) that my application does not meet (tick if applicable).

Please list below which section(s) of this form are relevant to the information waiver request:

Appendices and referenced material (if any) and glossary (if required)