



To obtain approval for new organisms in 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 40 of the Hazardous Substances and New Organisms (HSNO) Act 1996. It only covers importing, development (production, fermentation or regeneration) or field test of any new organism (including genetically modified organisms (GMOs)) in containment. If you wish to make an application for another type of approval or for another use (such as an emergency, special emergency or release), a different form will have to be used. All forms are available on our website.
2. If your application is for a project approval for low-risk GMOs, please use the Containment – GMO Project application form. Low risk genetic modification is defined in the HSNO (Low Risk Genetic Modification) Regulations:
<http://www.legislation.govt.nz/regulation/public/2003/0152/latest/DLM195215.html>.
3. 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.
4. 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.
5. 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.
6. Please add extra rows/tables where needed.
7. 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.
8. Information about application fees is available on the EPA website.
9. All application communications from the EPA will be provided electronically, unless you specifically request otherwise.

Commercially sensitive information

10. 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.
11. 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.
12. 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

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| 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 |
| New Organism | A new organism is an organism that is any of the following: <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, |

| | |
|----------------|---|
| | <p>strain, or cultivar that has been eradicated from New Zealand;</p> <ul style="list-style-type: none">• 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 |
| Project | An individual or collaborative endeavour that is planned to achieve a particular aim or research goal |

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. Type of containment activity

Tick the box(es) that best describe your application

| Application type | Type of new organism |
|--|----------------------------------|
| Import into containment | <input type="checkbox"/> GMO |
| | <input type="checkbox"/> Non-GMO |
| Develop in containment i.e. regeneration, fermentation or genetic modification | <input type="checkbox"/> GMO |
| | <input type="checkbox"/> Non-GMO |
| Field test in containment | <input type="checkbox"/> GMO |
| | <input type="checkbox"/> Non-GMO |

2.2. Brief application description

Approximately 30 words about what you are applying to do

2.3. Summary of application

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

2.4. Background and aims of application

This section is intended to put the new organism(s) in perspective of the wider activities 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. Information about the containment

4.1. For field tests: The nature and method of the field test

Describe the nature and method of the field test and the experimental procedures to be used

4.2. Proposed containment of the new organism(s) (physical and operational)

Describe how you propose to contain the new organism(s) after taking into account its ability to escape from containment (i.e. the possible pathways for escape)

5. 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.

6. 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.

7. Alternative methods and potential effects from the transfer of genetic elements

This section is for developments of GMOs that take place outdoors and field tests of GMOs only

- Discuss if there are alternative methods of achieving the research objective.
- Discuss whether there could be effects resulting from the transfer of genetic elements to other organisms in or around the site of the development or field test.

8. Pathway determination and rapid assessment

This section is for the imports of GMOs only

Under section 42B 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 this section.

8.1. Discuss whether the GMO(s) to be imported fulfil the criteria

The criteria are:

- The host organism(s) are Category 1 or 2 host organisms as per the HSNO (Low Risk Genetic Modification) Regulations
- The genetic modifications are Category A or B modifications as per the HSNO (Low Risk Genetic Modification) Regulations and the modifications are not listed in the Schedule of these Regulations
- The minimum containment of the GMO(s) will be as per the HSNO (Low Risk Genetic Modification) Regulations (PC1 or PC2 as per AS/NZS2243.3:2002)

9. 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.

10. 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)