Environmental Protection Authority
Te Mana Rauhī Taiao

APPLICATION FORM

Containment – GMO Project

To obtain approval for projects to develop genetically modified 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 42A of the Hazardous Substances and New Organisms (HSNO) Act 1996. It only covers projects for development (production, fermentation or regeneration) of genetically modified organisms in containment. This application form may be used to seek approvals for a range of new organisms, if the organisms are part of a defined project and meet the criteria for low risk modifications. 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.
2. 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.
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.
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

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: • Have been modified by *in vitro* techniques, or • Are inherited or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by *in vitro* techniques
New Organism	A new organism is an organism that is any of the following: • 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 A new organism does not cease to be a new organism because: • 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. 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. Technical description

Briefly describe the host organism(s) and the proposed genetic modifications. Please make sure that any technical words used are included in a glossary. Note if any part of this research project is already covered by an existing HSNO Act approval that your organisation holds or uses.

3. Information about the new organism(s)

3.1. Identity of the host organism(s)

For each host organism:

- Provide its taxonomic name and describe what type of organism it is.
- Provide a description of the strain(s) being applied for (if relevant).
- If the host organism is derived from humans (eg, cell lines) or may have cultural significance (e.g. sourced from native biota), provide details of its source.
- State the category (Category 1 or Category 2) of the host organism (as per the HSNO (Low Risk Genetic Modification) Regulations).

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 project

4.1. Describe the nature and range of the proposed genetic modifications

- Describe the nature and range of the proposed genetic modifications (e.g. the range of elements that the vectors or gene constructs may contain, and the type, source and function of the donor genetic material).
- State the category (Category A or Category B) of the genetic modifications (as per the HSNO (Low Risk Genetic Modification) Regulations).

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

- State which Containment Standard(s) your facility is approved to.
- State the minimum containment level (PC1 or PC2 as per AS/NZS2243.3:2002) required to contain the GMOs (as per the HSNO (Low Risk Genetic Modification) Regulations).
- Discuss whether controls in addition to the requirements listed in the Standard(s) are necessary to adequately contain the GMOs.

5. Risks, costs and benefits

Provide information of the risks, costs and benefits of the GMOs in the following areas of impact:

- The environment.
- Human health and safety.
- The economy (e.g. the ability of people and communities to provide for their economic wellbeing).
- The relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga, and the principles of the Treaty of Waitangi (The details of any engagement or consultations with Māori that you have undertaken in relation to this application should be discussed here).
- Society and community.
- New Zealand's international obligations.

6. 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.

7. 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	☐ Yes ☐ 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	☐ Yes ☐ No	
Supplementary optional information attached:		
• Copies of additional references	☐ Yes ☐ No	
• Relevant correspondence	☐ Yes ☐ No	
Administration		
Are you an approved EPA customer?	☐ Yes ☐ No If Yes are you an: Applicant: ☐ Agent: ☐	
If you are not an approved customer, payment of fee will be by:		
• Direct credit made to the EPA bank account (preferred method of payment) Date of direct credit:	☐ Yes ☐ No ☐ Payment to follow	
• Cheque for application fee enclosed	☐ Yes ☐ No ☐ Payment to follow	
Electronic, signed copy of application e-mailed to the EPA	☐ 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)