



To obtain a determination of whether an organism is a new organism

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 is used when you wish to apply for a statutory determination under section 26 of the Hazardous Substances and New Organisms (HSNO) Act 1996 as to whether or not an organism is a new organism (i.e. whether the organism is regulated under the HSNO Act or not).
2. If you wish to make an application for approval of for use of a new organism, 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 and 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

Genetically Modified Organism (GMO)	<p>Any organism in which any of the genes or other genetic material:</p> <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	<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

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 organism

2.1. Name of organism

Identify the organism as fully as possible

Organism name:

Briefly describe the biological characteristics of the organism:

2.2. 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

3. Evidence regarding whether the organism meets the definition of a new organism

Does the organism meet the definition of a new organism under the HSNO Act?

For example, does it belong to a species that was not present in New Zealand before July 29 1998? Is it a genetically modified organism? etc.

Describe the evidence you have to support this view, providing supporting materials in an appendix as appropriate.

4. 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)