



Application for approval to use new organisms in a special emergency

under the Hazardous Substances and New Organisms Act 1996

Send by post to: Environmental Protection Authority, Private Bag 63002, Wellington 6140 OR email to: noinfo@epa.govt.nz

Application number

Applicant

Key contact

Important

This form is to be used to apply to use new organisms (including genetically modified organisms) in a special emergency.

An approval to use a new organism in a special emergency is a fast-tracked approval that allows new organism(s) within an agricultural compound or medicine to be used in New Zealand when a special emergency occurs. The new organism(s) can only be used once the special emergency has been formally declared by a person with the authority to do so and only during that special emergency.

This application is not publicly notified and will be processed as soon as practicable.

There is no fee for this application.

This application form will be made publicly available so any confidential information must be collated in a separate labelled appendix.

If you need help to complete this form, please look at our website (www.epa.govt.nz) or email us at noinfo@epa.govt.nz.

This form was approved on 1 May 2012.

1. Brief application description

Provide a short description (approximately 30 words) of what you are applying to do.

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.

3. Information about the special emergency and the agricultural compound or medicine

Include here:

- What the agricultural compound or medicine is (including its nature) and the new organism(s) contained within the agricultural compound or medicine.
- The nature of the special emergency and why the new organism/medicine is necessary to deal with the special emergency.
- If there are any reports from experts available.
- If the agricultural compound or medicine satisfies all relevant manufacturing practices and standards.
- Information on labelling of the agricultural compound or medicine.
- If the agricultural compound or medicine has been approved for use overseas (or been declined).

4. Information about the new organism(s) contained within the medicine or agricultural compound

- Provide a taxonomic description of the new organism(s) (if the organism is a genetically modified organism, provide a taxonomic description of the host organism(s) and details of the genetic modification).
- 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?
- What is the ease with which the organism could be recovered or eradicated if it established an undesirable self-sustaining population?

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

- a. an innovative medicine application as defined in section 23A of the Medicines Act 1981. Yes No
- b. an innovative agricultural compound application as defined in Part 6 of the Agricultural Compounds and Veterinary Medicines Act 1997. Yes No

5. Detail of Māori engagement (if any)

Discuss any engagement or consultation with Māori undertaken and summarise the outcomes.

6. Identification and assessment of beneficial (positive) and adverse effects of the new organism(s)

Adverse effects include risks and costs. Beneficial or positive effects are benefits.

- Identification involves describing the potential effects that you are aware of (what might happen and how it might happen).
- Assessment involves considering the magnitude of the effect and the likelihood or probability of the effect being realised.

Consider the 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.

7. Proposed plan use of the new organism(s) in the special emergency

Provide a proposed plan for dealing with the use of the new organism(s) in the special emergency. It should include:

- The measures required to avoid, remedy or mitigate adverse effects from the use of the new organism(s) or any inseparable organism (identified above).
- The requirements for the eradication or control of the new organism(s).

Explain how the proposed plan adequately controls the adverse effects of the new organism(s) or any inseparable organisms including adequate control of the organism(s) if the organism is likely to establish an undesirable self-sustaining population, taking into account the ease of destroying such a population.

8. 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.

9. Appendices(s) and referenced material (if any) and glossary (if required)

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

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

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