

# INFORMATION SHEET

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## Information requirements for applications to release a new organism in a special emergency

### Introduction

1. The HSNO Amendment Act 2003 introduced a new section 49D *Application for approval to use agricultural compound or medicine in special emergency* which allows the rapid assessment of applications to release a new organism in the case of a special emergency declared under section 49B of the Act. Medicines regulated under the HSNO Act include human or animal medicines that are or contain viable new organisms.
2. In the case of a special emergency being declared by the responsible Minister, the agency will be required to quickly assemble the information required to enable the Authority to complete a rapid assessment of the application “as soon as practicable after receiving an application under section 49D”.
3. A number of potential information requirements are described in section 49E of the Act. This information sheet sets out the minimum information requirements for an application to release a new organism in a special emergency.

### Essential Information

1. The nature of the emergency and an indication of how long it may last.
2. Why the new medicine (as opposed to existing medicines) is necessary for use in a special emergency.
3. Clear and unambiguous identification of the new organism to be used in the emergency.
4. The biological characteristics of the new organism including whether the new organism has the potential to establish an undesirable self-sustaining population.
5. How the organism would be used to deal with the emergency (i.e. proposed **emergency management plan**) including dose and route of administration for a medicine.

6. What would happen if the new organism wasn't approved, including the availability of other alternatives.
7. Data to demonstrate the efficacy of the new organism for the proposed use (e.g. for a vaccine, data to show that the vaccine would be effective against the infectious disease agent).
8. Identifies potential adverse effects on the environment, human health, Maori, economy or society.

**Emergency Management Plan must include (as well as the relevant information from the list above):**

9. Proposes measures to mitigate the identified potential adverse effects or explains why such measures would be unfeasible. These proposed measures should specifically address any concerns raised by the Department of Conservation.
10. Any requirements for disposal of the medicine and any waste products or why such measures are unnecessary or unfeasible.
11. Any requirements to eradicate or control the new organism or why this is unnecessary or unfeasible.

**Other Information:**

1. Any reports by experts available from the applicant or any overseas regulatory agencies
2. Written confirmation by the applicant that the medicine satisfies all relevant manufacturing practices and standards
3. Information on whether the medicine has been approved for use in an overseas country.
4. Information on whether approval for use of the medicine has been declined in an overseas country.
5. Information on the labelling of the medicine.

**Further information or feedback**

For further information on making an application to release a new organism in a special emergency, or to provide any feedback or comment on the new initiatives described above, just contact us at ERMA New Zealand, or visit the website at **[www.ermanz.govt.nz](http://www.ermanz.govt.nz)**.

ERMA New Zealand publishes information sheets on a range of topics to provide background information on current issue or proposals being dealt with by the Authority. All publications may be viewed and downloaded from our website at [www.ermanz.govt.nz](http://www.ermanz.govt.nz) or may be requested by contacting ERMA New Zealand, P O Box 131, Wellington. Ph +64 4 916 2426 Fax +64 4 914 0433 Email [info@ermanz.govt.nz](mailto:info@ermanz.govt.nz)