



ERMA NEW ZEALAND

INFORMATION SHEET

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Conditional Release

Introduction

The Hazardous Substances and New Organisms (HSNO) Act was amended in 2003 to include a new category of application – **conditional release**. This means that it is now possible to apply to the Environmental Risk Management Authority (ERMA New Zealand) for approval to release new organisms (including genetically modified organisms) in to the environment **with controls**.

Conditional releases can apply to conventional new organisms (plants, animals and micro-organisms) as well as to GMOs. Conditional release can also cover a wide range of circumstances including a scientific trial (which is much like a field test) at one end of the range, through to a full commercial release at the other.

An example of a conditional release would be the importation of camels for trekking on the condition that only castrated males are imported and released so that a self-sustaining population does not establish. Another example would be the conditional release of a GM crop (for example resistant to certain pests) in a particular location for the purpose of gathering information rather than producing material for commercial sale. And of course a conditional release might apply to the same GM crop being grown for commercial purposes.

Still a new organism

An organism for which a conditional release approval has been granted remains a new organism under the HSNO Act. MAF will monitor compliance with the controls imposed by the ERMA New Zealand and will take appropriate enforcement action when needed. For further information on new organisms refer to the ERMA New Zealand Information Sheet Number 4: "*New Organisms under the HSNO Act*".

How does a conditional release differ from a field test or full (unconditional) release?

Prior to the HSNO Act being amended it was not possible to obtain a release approval that was able to set controls to manage risks. Instead applicants could only choose between either fully contained approvals (including field trials) or full (unconditional) releases with no controls. Conditional release approvals are

intended to fill the gap between containment and full (unconditional) release approvals by allowing controls to be imposed on releases. The key differences between the different application types are set out in the table below:

Containment (including field tests)	Conditional Release	Full (Unconditional) Release
<ul style="list-style-type: none"> • Strictly contained • Strict regulations • Fully monitored • New organism • Limited users 	<ul style="list-style-type: none"> • Flexible controls • Regulated (case-by case) • Able to monitor • New organism • Limited users <u>or</u> anyone, anywhere 	<ul style="list-style-type: none"> • No controls • Unregulated • No monitoring • Not a new organism • Anyone, anywhere, no limitations

What criteria does the Authority use in making a decision?

In deciding on an application for conditional release the Authority must consider the proposed use of the organism, its ability to establish an undesirable self-sustaining population, and the ease with which it could be eradicated.

Controls may be imposed on a case-by-case basis to minimise any environmental, health, economic, cultural, social or other risks associated with the release of the organism. Applicants are invited to propose controls in their application.

The Authority will take account of the controls it intends to impose in deciding whether the organism meets the minimum standards set out in section 36 of the HSNO Act, and whether the organism could be recovered or eradicated if it formed a self-sustaining population. After taking all these factors into account, the Authority will decide whether the positive effects of the organism (and any inseparable organism) outweigh the adverse effects. If they do, the application will be approved (with controls) if they don't, the application will be declined.

What sort of controls might be applied?

The HSNO Act contains an indicative list of controls to be imposed on a conditional release approval, but it does not limit the flexibility of Authority to impose any type of controls it considers appropriate. The approach of the Authority will be to consider controls to manage risks or to meet other defined objectives.

Applicants for a conditional release approval are expected to provide comprehensive, high quality information on the environmental, cultural, economic, social and other effects of the organism(s) involved. For example, in cases where co-existence issues are important, the applicant will be required to submit detailed information on the range of possible environmental and economic effects, and the likely effectiveness of possible controls in mitigating any potential adverse effects.

The Authority may also set monitoring controls, not only for monitoring potential adverse effects, but also for monitoring benefits. Monitoring the success or otherwise of an approval is an important risk management technique. The information gathered through monitoring could also be applied to future decisions, leading to an improvement in the quality of decision-making.

The HSNO Act provides for the Authority, on its own initiative, or on application from the user of an approval, or from a person or agency responsible for enforcing the HSNO Act, to review any controls, and to amend them if the Authority considered that to be appropriate to achieve the objectives of any controls.

Duration of conditional release approvals

The HSNO Act sets out provisions that could restrict the duration of a conditional release approval. The Authority has adopted the following approach to deciding on the duration for conditional release approvals:

- Where the Authority considers that an expiry date is warranted, then an expiry date will be explicitly set as part of the approval. Expiry dates will take account of requirements for monitoring an approval and for disposal requirements.
- Where it is inappropriate to set an expiry date, the Authority will, in accordance with the section 38E(1) of the HSNO Act, explicitly state that the approval does not expire. Controls that are not time-bound will be explicitly stated to apply in perpetuity.

This policy is consistent with the concept that if controls are no longer required then there is no reason for maintaining a conditional release approval. In the case of a conditional release, the organism remains a “new organism” when all controls have expired, and a new HSNO approval would be needed for its continued use.

Disposal of the organism

The organism must be disposed of **if** the conditional release approval is set to expire. However, there will be cases where disposal is not possible. In those instances the HSNO Act allows for an application to be made to put the organism back into containment or to have it fully (unconditionally) released. In either case a HSNO approval would be required prior to the expiry of the conditional release approval

Where disposal is applicable, the Authority will set conditions that ensure that all new organisms for which a conditional release approval has been granted, can be identified and located at the time of expiry of an approval; this will include heritable material viable at the expiry of an approval.

Making a conditional release application

An application for a conditional release can be made on ERMA New Zealand’s form NOCR which is available from our website at www.ermanz.govt.nz. This application form comes with a User Guide that provides additional and essential information for completing the form.

Further information or feedback

For further information on Conditional Release, 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.

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 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