

4 Conditional Release

4.1 Summary

Once released to the environment, new organisms (including both GMOs and imported species) are no longer considered 'new'. Currently, they are not subject to the HSNO Act and can be used freely by anyone, anywhere in the country. There is no intermediate stage between release and field-test, where new organisms must be held in containment. Some problems have been raised with this approach, such as the inability to carry out research on the environmental effects of a new organism in less contained conditions, or to monitor the impacts of organisms after they are released, or to limit their location (for example, to facilitate the co-existence of GM and conventional or organic agriculture).

The Royal Commission recommended that the HSNO Act be amended to provide for an additional category of approval, called 'conditional release' (Recommendation 6.8). This would allow ERMA to attach *controls* to approvals to release new organisms. The Royal Commission suggested that conditional release be used "as a further assurance of safety to enhance the management of risk".

Work on conditional release is at a relatively early stage, and this section seeks your response to the options and proposals discussed below. However, if the category is introduced, certain things are clear:

- ERMA would not be able to release any organism that breached the minimum environmental standards
- ERMA would still have to carry out a full risk assessment of the organism, including consideration of the ability of the organism to establish an undesirable self-sustaining population (and the ease of eradication if it did so), and
- conditional release would not replace full release, and the ability for ERMA to approve organisms without controls would remain.

Various uses have been suggested for conditional release, including enabling certain research outside strict containment, monitoring for impacts of released organisms, limiting the dissemination of the organism or its ability to persist, and controlling where and how organisms are used. Examples of possible controls include granting approval for extended field trials to a single user and stipulating how and where the research can be carried out; requiring monitoring of the effects of the organism on non-target organisms; requiring buffer zones, post-harvest segregation and identification of GM crops; and limiting the use of certain organisms to trained individuals only.

Compliance with and enforcement of controls on release would be an important issue, and possible measures to maximise and check compliance are discussed. The section also covers how the legislation could guide ERMA in setting controls. Guiding principles could stipulate, for example, that controls should be cost-effective and practicable, relevant to the organism, and enforceable. Finally the financial implications of introducing a new category of release are discussed.

In presenting options, the section includes the range of possible uses for a conditional release category. Feedback is sought on which if any of these possible uses should be allowed and whether there are other situations where conditional release should be used.

4.2 Why would we introduce conditional release?

4.2.1 How does the HSNO Act control new organisms at the moment?

The current regime for new organisms consists of the following approval categories:³

- development in containment/importation into containment – only for organisms held in laboratories, or other secure locations that are specially designed to prevent escape
- field-testing in containment – research outside the laboratory, strictly controlled so that the organism, and any heritable material, can be recovered after the trial (limited in time and location)
- importation for release or release from containment – no controls allowed, no time limit, no subsequent approvals required. Once approved for release, organisms can be used anywhere and by anyone. Persons releasing an approved organism within five years of its approval must notify ERMA.

Therefore, under the HSNO Act there are currently two possibilities: either the organism is a new organism and so fully contained in one of the above ways, or a decision has been made to release the organism, so it is no longer new, and it is not subject to any controls under the HSNO Act.

4.2.2 The ERMA decision-making process for releases

ERMA is required to assess release applications in accordance with the purpose of the HSNO Act⁴ and the risk assessment and management processes set out in the Act. Applications are considered on a case-by-case basis after an assessment of risks and benefits, and after considering any public submissions. ERMA is required to take a precautionary approach when considering the scientific evidence relating to the application.

Because of the minimum standards in section 36, ERMA must decline a release application if the organism is likely to:

- a) Cause any significant displacement of any native species within its natural habitat; or*
- b) Cause any significant deterioration of natural habitats; or*
- c) Cause any significant adverse effects on human health or safety; or*

³ As of 20 March 2002 ERMA had approved five new organisms (all non-GM) for release, 128 new organisms for import or development in containment, and 13 GMOs for field-testing. No applications for a GMO release have been received (www.ermanz.govt.nz/applications/tableApps.htm).

⁴ To protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms.

- d) *Cause any significant adverse effect to New Zealand's inherent genetic diversity; or*
- e) *Cause disease, be parasitic, or become a vector for human, animal, or plant disease [unless that is the purpose of the application].*

Section 38 of the Act states that ERMA can approve an application to import or release a new organism:

- if there is sufficient information available to assess the adverse effects
- if the organism meets the minimum standards, and
- if after considering the ability of the organism to establish an undesirable self-sustaining population (and the ease of eradication if it did so), the *positive effects of the organism outweigh the adverse effects*.

This introduces the concept of risk–benefit analysis: ERMA weighs up the benefits of the new organism against the risks. Because ERMA cannot put any controls on releases, when weighing up the risks and benefits they must assume that a new organism will spread to all parts of New Zealand.

4.2.3 Why controls were not included in the HSNO legislation

The policy work for new organisms regulation under the HSNO Act started during the 1980s. The legislation governing imports of new species at the time was much less restrictive than the HSNO Act and controls could only be placed on new organisms for the purpose of disease control. Controls used under the previous regime had been found to be either difficult to enforce or outside the power of the legislation, and several potential pest species were introduced to New Zealand; for example, the chinchilla, originally introduced for a fur industry, and freshwater marron crayfish, imported for a fish-farming venture. Both had the potential to breed, spread and cause environmental damage, could not be effectively contained, and were difficult to locate and control. The one breeding population of marron was eventually destroyed. Chinchilla farms proved to be uneconomic and the animals began to be sold as pets throughout New Zealand. There is still a risk they may form a wild population and breed.

Because of this, discussion about controls largely focused on the difficulty of *containing* animals in the farming environment. The inability to effectively confine such potential pest species led to the view that any new organism introduced to New Zealand (other than in strict containment) would eventually find its way to other parts of New Zealand, and that controls would not be able to prevent this. This was the basis for the HSNO Act having no provision to place controls on the release of new organisms.

However, little consideration was given to controls for species that did not have the potential to become pests and for which absolute containment was not essential. Similarly, little consideration was given at the time of the initial policy work to the possibility of using controls to manage GMOs. The commercialisation of GM crops did not begin until the 1990s, and the potential range of uses of GM technology had not been contemplated. GMOs present their own specific issues. For example, cows used as bioreactors for therapeutic proteins would not become pests, but would need to be carefully controlled to prevent them escaping and cross-breeding with non-GM cattle and entering the food supply.

4.2.4 Potential shortcomings with the current regime

Once a new organism has been approved for release, the HSNO Act allows the organism to be used at any time, by anyone and in any way. Because of this, ERMA has to assess the positive and adverse effects in all environments and in all parts of the country. This approach ensures that all known potential adverse effects are taken into account. However, it does not reflect the fact that the adverse effects of a new organism may depend on how and where it is used.

Since the Act came into force, thinking has changed on some aspects of how releases of new organisms should be handled. The following points have been made.

- The assumption that all new organisms will inevitably spread and establish may not be appropriate for *some* species that are easier to control in the environment than pest species. Even if escape is assumed, some species will be retrievable because they cannot persist without intervention (for example, highly domesticated crops) or are easily identified and retrieved (such as large mammals).
- Because GM field tests must be fully contained, it can be difficult to obtain all the necessary information about likely environmental impacts. Controlled research out of full containment (for example, to study the environmental effects of pollen from a GM plant) is not possible under the current legislation.
- There is no provision for monitoring organisms after release, which means that any unforeseen effects may not be detected unless they become a problem.
- (For GMOs specifically) Coexistence of GM and non-GM agriculture was not considered at the time of the policy development. A strategy of preserving opportunities may benefit from an intermediate stage before full release, and several Royal Commission recommendations may not be able to be implemented without the ability to set controls on GMO releases.

4.2.5 How would conditional release address these problems?

The conditional release category would enable ERMA to approve certain new organisms for release with controls attached to the approval. ERMA would still have to be satisfied that the positive effects of the organism outweighed the adverse effects, and would have to decline an application that failed to meet the minimum standards (see above).

Controls on release would change the assumption that all released organisms inevitably breed and spread throughout New Zealand. Controls would enable some effects of new organisms to be prevented or managed. ERMA would use controls to reduce potential adverse effects, and would take account of controls in their decision-making process. This would solve some of the difficulties with the current system. It could also lead to some new organisms being permitted for conditional release that would not be suitable for full release. Conditional release would not replace full release – ERMA could still approve organisms for release without controls.

Controls could be used to:

- limit the spread of genetic material from field research that is not fully contained, thus enabling research on environmental impacts that otherwise could not take place (see the potato example below)
- monitor for unforeseen impacts of new organisms (for example, on non-target insects or surrounding vegetation)
- limit the dissemination or persistence of the organism or its genetic material in the environment once it is out of containment (including managing the co-existence of GM and non-GM agriculture)
- control how a new organism is used (for example, to reduce the risk of insects developing resistance to incorporated pesticides such as Bt).

Not all of these suggested purposes would be appropriate for all organisms because different organisms will have different characteristics that determine their potential effects on the environment. Conditional release could potentially cover a large range of situations, from what are essentially larger and less stringently controlled field tests, to releases with very few controls. It would be possible to specify that some purposes would not be allowed for certain types of organisms, or that conditional release should not be used at all for some of these purposes.

For example, using conditional release to limit the spread of new organisms would rely on the controls being fully effective. If controls were breached, and if the organisms had the ability to establish, potential damage could result. ERMA would have to consider this possibility as well as the effectiveness of any proposed controls, the ability to identify a breach, the potential consequences of an escape, and the suitability of contingency plans when considering whether to approve the conditional release of an organism. An alternative would be to specify that conditions should only be used to limit the spread of organisms that do not pose additional risks to the environment (e.g. bioreactor cows).

Another approach might be to apply specific criteria to conditional release decision-making, such as requiring ERMA to assess organisms without taking controls into account, i.e. as if they were being fully released. Controls would thus be used only as an additional assurance of safety. Criteria could also ensure that less stringently controlled research was only undertaken if it could not be carried out in containment, and that any risks of irreversible impacts were negligible or able to be managed. Options for defining purposes, organisms, and controls for conditional release are discussed in section 4.3.2.

The range of purposes are discussed in more detail in the next section, together with some examples to highlight how they might work. This document seeks feedback on the overall objectives of the category, rather than the detailed mechanisms of how particular controls may be placed on organisms. It is also important to remember that some of the objectives of conditional release may more usefully be achieved using other pieces of existing legislation, for example those regulating food safety. In some cases organisms will automatically be subject to controls under these other laws.

4.3 How would the category work in practice?

Many aspects need to be considered when looking at how conditional release might work in practice. This subsection covers the controls that might be used, how the category may change the application process, how compliance with controls could be checked and enforced, and what the financial implications might be. A diagram representing some of the options is presented in Annex 1 at the end of this section. Examples of controls are summarised in Annex 2.

4.3.1 What could conditional release be used for, and how would it be used?

Research

Research on new organisms currently takes place in laboratories or glasshouses and in small-scale, tightly contained field tests. However, some research cannot be done under these conditions. Because the organism and any heritable material arising from it must be able to be removed and destroyed after the end of the field test, plants such as GM crops are not usually allowed to produce pollen or seeds. This makes it difficult to evaluate the performance and environmental effects of the crop – information which is important for ERMA in deciding whether the organism is suitable for release into the wider environment. Similarly, a clinical trial of a GM medicine may not be possible under the current regime. It would be difficult to get a release approval for such an organism, given that there would be uncertainty about its effects.

The controls that could be applied to conditional releases for research include:

- limits on the number of released organisms
- limits on where the organism can be released
- restrictions on how the organism is grown, raised or used (for example, using buffer zones)
- granting approval to a single user
- prohibiting commercial transactions involving the organism
- ensuring suitable disposal of a new organism at the end of the research.

Example – disease resistant potatoes

New Zealand researchers have developed a GM potato that is resistant to a certain virus. Field tests have shown that the modification works in a small plot in one location. However, before the positive and adverse effects of full release can be considered, performance must be tested in different soils and climates, and the environmental effects fully investigated. This is not possible in strictly contained field tests, where reproductive material must be removed from the plants. Although ERMA can use information from overseas to help in its assessments, such information may not always be available, and may not help to assess the effects on the New Zealand environment.

Release with controls might allow a single research institution to carry out trials in several different locations to compare the performance against conventional potatoes. Researchers could be required to monitor insect and neighbouring plant populations for any unintended effects, and ensure that all potatoes are destroyed at the end of the study. This use of conditional release would be close to the ‘field test’ end of the range of potential uses.

Monitoring for the impacts of new organisms

Monitoring the spread of the new organism and its effects on the surrounding environment would increase the chance of detecting any adverse effects – foreseen or unforeseen – before they became a significant problem. Users would be required to supply regular data to the relevant agency and notify it if adverse effects were seen. Adverse effects could lead to remedial action or the removal of the organism, if this was possible (eradication of pest species, for example, has proven a difficult and expensive task). Monitoring results would feed back into the risk assessment framework. If monitoring was the only control attached to an organism, this use would be very close to the ‘full release’ end of the spectrum of uses of conditional release.

Various factors could be monitored, including:

- spread from the point of release
- effects on non-target organisms (for example, insects, soil biota, surrounding vegetation)
- the level of out-crossing (breeding with related species).

Example – insect predator introduced for biological control

Biological control is the use of one organism to suppress another, and is commonly used to control populations of insect and plant pests. The five new organisms approved for release since 1998 have all been biological control agents imported for the control of a specific pest. Although laboratory experiments can test many features of such an organism, conditional release could specify that populations of non-target organisms and vegetation in the area surrounding release be monitored at regular intervals for adverse effects.

As with other controls, the user would be responsible for ensuring that monitoring was carried out and data supplied. However, the user may not be the most suitable person to carry out the work, and may need to contract out the work; for example, to a Crown Research Institute.

Monitoring could be time-consuming, technical and costly, depending on the amount and frequency of information required. Analysis and review of this information would impose administrative costs on the agency responsible, so the value and costs of any monitoring would need to be carefully assessed before these requirements were imposed.

Limiting dissemination or persistence (including enabling and managing co-existence of GM and non-GM agriculture)

As noted above, the assumption that an organism will inevitably spread and establish in New Zealand is not true in all cases. Many organisms do not have the characteristics required to persist in the New Zealand environment, such as highly domesticated crops, or species that only survive in a hot climate. For others, their spread by human or natural means and persistence in the environment could be prevented through controls such as limiting their ability to reproduce, or strictly limiting where they can be used.

Controls to limit dissemination could be used to enable and manage the co-existence of GM and non-GM agriculture in New Zealand. Co-existence was a major theme of the Royal Commission's report, and the Government has agreed to investigate it further, including the ability to place controls on releases of GMOs.

Controls may include:

- limits on where the organism can be released
- using buffer zones or other physical barriers to gene flow
- using sterility technology or other biological barriers to gene flow
- post-harvest segregation and identification
- labelling of seeds and nursery stock
- double fencing, electronic tagging and clear identification of animals
- strict controls on disposal of carcasses
- strict controls on disposal of GM medicines
- exclusion from the food chain, unless assessed by the Australia New Zealand Food Authority (ANZFA) and approved by the Australia New Zealand Food Standards Council (ANZSC) (specifically for GM animals).

Example – camels for tourism

Camels are not present in the wild in New Zealand, and could damage the environment if released without controls. Conditional release might allow a single tourism operator to import a certain number of camels, with a requirement that they were all either of one sex or sterilised and therefore unable to reproduce, along with controls to ensure that any adverse effects of the animals were managed.

Example – 'bioreactor cattle'

Cows have been genetically modified to produce pharmaceutical proteins in their milk. These are highly valuable animals and their owners have strong commercial incentives to keep them secure. A conditional release might allow a small number of herds of these animals to be commercially farmed, but with strict requirements for security, labelling, and tracking to prevent them escaping and breeding with non-GM stock.

Controlling the way organisms are used

Sometimes the way an organism is used, rather than the organism itself, can lead to risks to the environment. Controls on use may be able to manage these potential risks.

Controlling the way an organism is used could, for example, help delay pest resistance developing to either pest-protected GM crops or biological control agents. Pests commonly develop resistance against control agents: this is a well-documented phenomenon and happens with both chemical and biological control agents, in insect and mammalian pests. Controls could also be used to restrict the use of biological control agents, maximise effectiveness, and hence manage risk (see below).

Controls could include:

- limits on when a new organism can be released
- limits on the numbers of new organisms released
- limits on the conditions under which a release can be made
- use only by trained individuals.

Example – Bt crops

GM crops have been developed to be resistant to insect pests through the expression of the toxin produced by the bacterium *Bacillus thuringiensis* (Bt). Bt has been used as an insecticide in New Zealand for many years, and is one of the few pesticides available for insect control on organic crops. It is clearly in New Zealand's interests to maintain the effectiveness of Bt as an insecticide and to delay the development of resistance. In areas overseas where Bt crops are being grown, resistance management is acknowledged as a priority for ensuring the long-term efficacy of Bt as a pesticide. Controls used include limits on the extent of use of the crop, refuges (areas of non-GM plants) within the crop, and requirements to monitor the crop for resistant pests and to notify authorities in case of suspected resistance development. Bt crops can also only be used by individuals who are trained in resistance management techniques. The Royal Commission recommended that a strategy for preserving the effectiveness of Bt be developed before Bt-crops are released in New Zealand.

Example – rabbit haemorrhagic disease (RHD)

One suggestion for using conditional release came out of the 1997 report by officials investigating the potential of using rabbit haemorrhagic disease (RHD) as a biological control agent for rabbits. The effectiveness of this virus was compromised by the way in which it was disseminated when farmers released it illegally in late 1997. Although conditional release could no longer be used for this particular agent, it shows how a strategy for use of biological control agents (for example, only under optimal conditions) could increase the chance of effectiveness in controlling environmentally damaging pests.

Location and land management controls

The Royal Commission recommended that ERMA have the ability to protect non-GM industries that could be vulnerable to contamination by GM crops. They considered the possibility of using the land management controls of the Resource Management Act 1991 to declare GM-free areas, but decided that the implementation of this approach would raise considerable practical difficulties, due to the potential for dividing communities and the potential for impinging on the rights of certain individuals. They also stated that blanket bans of GMOs in regions may be unnecessary since certain GM and non-GM crops, for example crops that cannot cross with one another, may be able to coexist.

Conditional release may provide another mechanism for location controls, but on a case-by-case basis rather than by declaring GM-free areas. ERMA could, for example, decide that a particular GM crop could only be used in a certain region of New Zealand. Alternatively, it could require the use of buffer zones to prevent contamination of nearby crops. The advantage here would be that the control could be applied wherever the crop was used, and would therefore not require a restriction on where the crop could be grown. Alternatively, ERMA could be required to recognise decisions to be GM-free on the basis of locality or industry that have been made by some other body; for example, the relevant industry association (based on the views of its members) or the local council. If this was the case, ERMA would not be able to set controls that were inconsistent with or overrode such decisions.

There are disadvantages to this approach in that other bodies do not necessarily have the expertise to assess the effects of new organisms. Parliament has established both special-purpose legislation (the HSNO Act) and a national, technical and non-political body (ERMA) to carry out these assessments. The HSNO process already involves a process for public input, and this mechanism provides an opportunity for citizens to have their say. It would not be desirable to duplicate processes or change the basis for decision-making.

- 4a In what situations should controls be used to manage organisms after release?**
- 4b Are there any purposes outlined in the preceding section for which conditional release should not be used?**
- 4c Are there any additional purposes that conditional release could be used for?**
- 4d Should agencies other than ERMA be able to decide where GMOs are permitted? If so, on what basis?**
- 4e Are there other ways in which location controls could be managed in practice?**

Please explain your views and, if possible, illustrate them with examples.

4.3.2 Defining purposes, controls and organisms for conditional release

Conditional release spans a large range of possible situations, from specific and highly controlled research projects to commercial releases with few controls. Biotechnology is also rapidly changing, so that the future range and uses of new organisms is very difficult to predict. For both these reasons, ERMA will need some discretion about how and when to apply controls on releases. An important question is: How much discretion should ERMA have?

Overly prescriptive legislation or regulations are likely to require frequent amendments, which create extra costs without improving the management of new organisms. For example, it would not be feasible to try to prescribe lists of organisms that would or would not be suitable for conditional release. However, there are certain changes that could be made to the HSNO Act in order to give some structure and guidance to the control-setting process.

Firstly the Act could specify the purposes that conditional release could be used for, for instance:

- research
- monitoring for impacts of new organisms
- limiting dissemination or persistence (including enabling and managing the coexistence of GM and non-GM agriculture)
- restricting the way the organism is used.

There could also be the provision for ERMA to extend purposes to cope with unexpected circumstances.

Secondly, it may be appropriate to set some guiding principles for setting controls, such as:

- controls must be:
 - cost-effective and practicable (achieve the purpose at the least cost)
 - specific and relevant to the organism and its characteristics
 - enforceable and should not duplicate those applied via other pieces of legislation
- for research, whereby:
 - research should only be undertaken outside of strict containment if it is impossible for the same research to be carried out in containment, and if any risk of irreversible impacts is negligible or able to be managed
- for monitoring, whereby the:
 - purpose of the monitoring must be clearly defined
 - requirements must be cost-effective
 - benefits of monitoring must outweigh the costs
 - requirements should be reviewed, and monitoring could be scaled down or stopped, depending on the results of data analysis
- reassessment, whereby:
 - organisms released with controls should be reassessed after x years – this would require amendments to sections 62–63; controls should be reassessed if information arises to suggest a superior alternative approach.

There may also be certain standard controls applied to all conditional release approvals; for example, informing ERMA if the applicant, user or approval-holder becomes aware of additional information such as risks to health or the environment.

Finally the Act could provide a set of mechanisms that ERMA could use for increasing compliance with controls (see subsection 4.4.1).

4f How could purposes for the conditional release category be defined?

4g How tightly should ERMA's setting of controls be defined in the HSNO Act?

Please explain your reasons fully.

4.3.3 The application process

Currently, applicants who wish to release a new organism apply to ERMA for a release approval. There are two possible approaches for introducing another release category:

- **Option 1:** The applicant applies to release a new organism (a single release category) and ERMA decides whether the release should be made with or without controls.
- **Option 2:** The applicant applies specifically for either unconditional or conditional release (two release categories). For applications for conditional release, ERMA would make a decision on suitable controls.

Option 1 would leave the decision over whether or not controls should be applied, and which controls were suitable, to ERMA. ERMA would be guided in this decision-making by new criteria added to the HSNO Act.

Option 2 would give the applicant the choice of which type of release to apply for. The question then is: What would happen if a full release application was unsuccessful and ERMA considered the organism suitable for conditional release instead? If ERMA automatically approved the organism for the category they considered suitable, this would effectively be the same as Option 1. If correspondence between ERMA and the applicant and the submission of a new application form was required, this would increase compliance costs and may lead to a delay in a decision being made. The impact on costs of the two-category option would therefore depend on the ease of transition between one type of application and the other.

4h What would be the advantages and disadvantages of a separate approval process for conditional release?

4i How would you see the application process working?

Please fully explain your views and provide examples, if possible.

Reassessment and the interface with full release

Controls imposed on an organism may need to be changed over time. This means there should be a mechanism to review each approval and its controls. There are two options:

- **Option 1:** The applicant applies to ERMA to have the approval reviewed.
- **Option 2:** Put time limits on controls so that ERMA would be required to review them regularly.

It is possible that for some organisms all controls would eventually be removed (the organism would be approved for full release). Reassessment is already provided for in the HSNO Act (sections 62 and 63), covering both new organisms in containment and hazardous substances.

Reassessment can occur if new information becomes available about the effects or use of an organism or substance, and an application for reassessment is made. It is not an automatic event; which is to say, it does not happen after a specific time period.

- 4j How should the controls on conditional release approvals be reviewed?**
- 4k Are the existing reassessment provisions in the HSNO Act sufficient for this purpose. If so why?**
- 4l What alternatives would you propose and why?**

4.4 Compliance and enforcement

Compliance means that users abide by the controls attached to the approval. Enforcement is the process of taking action against or prosecuting people who breach those controls.

Compliance and enforcement are major issues for conditional release. Because of the difficulties of recognising and detecting certain new organisms (especially GMOs), and the fact that organisms – unlike hazardous substances – can reproduce and spread, checking that controls are being complied with may be difficult. As with any law there is a chance of non-compliance. This will be affected by factors such as the cost of compliance, the potential penalties involved and the commercial incentives to comply.

ERMA would need to take these factors, and the feasibility and cost of checking compliance, into account when deciding on appropriate controls. It would need to be satisfied that the controls would manage adverse effects, that an acceptable level of compliance could be achieved, and that the enforcement agency has the capacity and ability to carry out its functions.

There is further discussion of liability issues relating to possible adverse effects from GMOs in chapter 8, which may be relevant to compliance and enforcement issues.

4.4.1 How could compliance be ensured and checked?

An important question for all legislation is how far authorities should go in checking compliance and prosecuting those breaking the law. For conditional release, controls may differ both in their importance in risk management and in their ease of checking.

The HSNO Act and the regulations for management of hazardous substances already contain mechanisms for different levels of compliance checking. The majority of controls on hazardous substances rely on levels of compliance checking being set by the relevant enforcement agency in conjunction with ERMA. However, in certain situations additional mechanisms are used for compliance checking. These include the requirement:

- for a test certificate for anyone permitted to handle the substance
- to notify an enforcement agency before certain activities are undertaken
- that substances are only permitted at certain locations meeting certain pre-conditions.

Similar machinery could be used to assure high levels of compliance with the controls on releases of new organisms. An analogue for test certificates, for example, might only allow certain qualified people to use the organism, or require that the systems used for managing the organism (such as an electronic tagging system) are subject to a certificate.

Requirements that help ensure controls are complied with would be set by ERMA at the same time as the controls themselves. For example, ERMA may approve a Bt-crop for conditional release, and attach controls not only governing how the crop should be used, but also stipulating that anyone using the crop must notify the enforcement agency of the location, time of planting and other matters concerning the crop, so that it would be able to check that the controls were being complied with.

This system of allowing ERMA to use special mechanisms to maximise compliance with controls gives a high degree of flexibility, and would allow the compliance mechanism to be tailored to the nature of the organism and the level of assurance required. This in turn may depend on various factors (for example, the consequences of non-compliance, or community concerns).

Knowing where an organism is being used is important for checking compliance with certain controls. This knowledge could be obtained either by requiring notification, as described for the Bt-crop example above, or by limiting the use of the organism to certain people.

Using different approval types

Different approval types could be used to enable limits to be placed on use of the organism. This would therefore act as an alternative mechanism for assuring compliance with certain controls. There are three options for approval:

- **Option 1:** single-user approval – a separate application is required from each person and in each location.
- **Option 2:** multi-user approval with permit – approval is given to an applicant who is then able to supply the organism to others; controls would state that any other users require a ‘permit’ from ERMA before they obtain the organism.

- **Option 3:** multi-user approval with supplier notification – approval is given to an applicant who is then able to supply the organism to others; controls would state that the supplier must provide ERMA or the enforcement agency with a list of users.

Option 1 would give the highest level of control, both in terms of the ability to check compliance and also for limiting the location of use of the organism. However, this system would be time-consuming if many different parties wanted to use the organism, or if the organism was being commercialised. Compliance costs would be high. It would be most useful for organisms used in research projects, or for cases where it was important to limit the location of the organism. The first application to release the organism would require a full assessment of all potential positive and adverse effects of the organism, including the cost–benefit analysis. Subsequent applications would only require an analysis of location-specific impacts. Compliance costs for the first application would therefore be higher than for subsequent applications, although the first applicant would be likely to gain from being first in the market.

Multi-user approvals would be less time-consuming and would impose lower compliance costs, but the enforcement agency would still have information on all users. The requirement for a permit from ERMA (Option 2) may give greater assurance of this, as a permit would be needed before the user was supplied with the organism. Option 3 (supplier notification) would rely on the supplier providing information to ERMA or the enforcement agency. The two multi-user options would carry similar costs, but they may be borne by different parties.

In fact using different approval types would have much the same effect as requiring notification as a condition of approval, but through a different mechanism. In all cases the aim is the same – to find out where the organism is being used so that compliance with controls can be checked. Using different approval types would not be essential for compliance checking, but does provide an alternative mechanism for obtaining knowledge about the location of organisms.

4m To what lengths should authorities go to check compliance with controls on release of new organisms?

4n What other mechanisms could be used to achieve a high level of compliance with controls placed on organisms under conditional release?

Please illustrate with examples, where possible.

4.4.2 Who would be responsible for compliance and enforcement?

The HSNO Act lists a number of agencies as being responsible for enforcing provisions of the Act that fall into areas covered by them for other reasons. For example, the chief executive of the Department of State, currently responsible for the Gas Act 1992, must ensure that the HSNO Act is enforced in, on, at or around any gas distribution system, installation or appliance. In addition, ERMA can appoint enforcement officers or authorise the chief executives of other agencies or local authorities to appoint officers and/or enforce the provisions of the HSNO Act as it sees fit. The Act also envisages and encourages the making of other arrangements for effective coverage.

This implies that each agency listed in section 97 has responsibility for hazardous substances and new organisms within its areas of coverage. No agency is separately listed in the HSNO Act as an enforcement agency for new organisms.

The provisions covering new organisms in containment are currently enforced by MAF under the Biosecurity Act. The Biosecurity Act requires new organisms to be held in containment facilities approved under that Act unless ERMA has given approval for release. MAF-appointed inspectors check containment facilities and their operators and ensure that HSNO controls are being met. A memorandum of understanding has been established between MAF and ERMA to outline the responsibility of each agency under their respective Acts. In section 10 we discuss formalising MAF's role as an enforcement agency for new organisms in containment.

However, controls on release would be out of containment and could not be enforced under the Biosecurity Act. Consideration therefore needs to be given to which agency or agencies might be responsible for enforcing these controls. The following table shows the types of task that enforcement officers would need to carry out, and the skills and knowledge they would require.

Tasks that would need carrying out	Knowledge required by enforcement officers
<ul style="list-style-type: none"> • Inspect organisms • Identify the organism (including its genetic modification if a GMO) • Inspect premises and places • Check documentation • Audit systems • Take action – in some cases immediately • Investigate alleged breaches • Obtain evidence and prepare cases for prosecution • Report to ERMA 	<ul style="list-style-type: none"> • The biology or ecology of the organism • The environment in which the organism is located • The locality • Quality systems • Production systems or the industry • Elements of physical or behavioural containment • Nature of the genetic modification (if a GMO) • The law

Based on these requirements, there are three main options:

- **Option 1:** List an enforcement agency or agencies in the HSNO Act.
- **Option 2:** List an enforcement agency or agencies in the HSNO Act and enable other central or local government agencies to enforce specified controls.
- **Option 3:** Status quo.

Under Option 1, one or more agencies could be listed in the HSNO Act as being responsible for ensuring compliance with conditional release controls. The areas for which each agency is responsible would need to be defined clearly, and enforcement agencies would need to be able to either employ or contract suitable staff. Potential agencies include:

- Ministry of Agriculture and Forestry
- Department of Conservation
- regional councils
- city/district councils.

Under Option 2, as well as the agency or agencies listed for enforcement in defined areas of responsibility, ERMA would also have the ability to name another agency on a case-by-case basis as being responsible for ensuring that specific controls are complied with. The alternative agencies would be selected from a list of central and local government agencies. This option would provide greater flexibility, and a mechanism for controls to be enforced by the most appropriate agency. A process of consulting and gaining agreement with those agencies would be needed.

As an example, ERMA might give an approval for an organism to be held in certain regions only. Regional councils might be the most appropriate agencies to enforce such controls, although they would need to ensure that appropriately skilled personnel were employed to carry out such activities. ERMA could then specify those agencies as the enforcement agencies rather than rely on the ones listed as enforcement agencies for the majority of new organism controls.

Option 3 is the status quo. If no agency was listed as responsible for the enforcement of provisions of the Act relating to new organisms out of containment, the obligation would fall to the agencies listed in section 97. However:

- ERMA could continue to appoint enforcement officers or authorise the chief executives of other agencies or local authorities to appoint officers and/or enforce the provisions of the HSNO Act as it sees fit
- agencies could continue to make arrangements among themselves to ensure coverage (as they do at present for hazardous substances).

Whoever appointed officers would need to ensure they were suitably qualified.

Checking compliance with all these three options would rely on using the powers available under the HSNO Act. The HSNO Act contains powers to (among other things) enter premises, inspect organisms and undertake certain enforcement functions. Enforcement officers can require people to do certain activities within a specified period, or prevent people from doing certain things. If action was needed quickly, then the emergency provisions of the HSNO Act would need to be invoked.

4o What would be the most appropriate way to assign responsibility for ensuring compliance with and enforcement of conditional release controls?

4p Are there other models that could be effective?

Please explain your views with reference to specific circumstances or examples.

4.4.3 What would compliance and enforcement of controls on release cost?

Costs would depend greatly on which controls are attached to organisms, and (to a certain extent) which agency or agencies are chosen. If an agency does not already have a compliance-checking capacity there will be significant set-up costs. If local government were responsible, funding would be a particular issue. The work could be funded by the local body itself, central government or cost-recovered. Each of these funding options has different implications for who finally bears the cost – ratepayers, taxpayers or users.

Option 2 above, which gives ERMA most flexibility in setting enforcement agencies, could lead to a number of different agencies establishing and maintaining this capability, leading to increased costs. However, these costs could also be managed by several agencies utilising the same pool of expertise and reporting systems.

Compliance checking costs could be cost-recovered – this already happens under legislation such as the Biosecurity Act and the Resource Management Act 1991. Cost-recovery issues are dealt with in section 4.6.

4.5 What are the financial implications?

Specific financial implications have been discussed in other subsections. This subsection outlines the more general issues.

The financial costs arising from the creation of a conditional release category would consist of one-off set-up costs to central government, compliance costs to applicants and users of the category, and administration costs to the government agencies responsible for making the system work. The actual size of the costs would depend on the final policy chosen from among the options discussed above.

4.5.1 Cost recovery and the balance between compliance and administration costs

The need to assess costs against benefits is an overriding concern in the choice of policy instruments. Imposing controls is likely to generate compliance and administrative costs, and may have knock-on effects such as the loss of innovation opportunities or artificial impacts on investment decisions. These costs must be balanced against the benefits that will be derived from imposing controls. ERMA will need to assess these costs against the benefits – including risk reduction – given the circumstances of the individual application.

Whether the financial burden falls predominantly on government or applicants will depend on the options chosen. For example, if much of the cost of processing applications and subsequent enforcement is cost-recovered, then compliance costs are likely to be larger than administration costs. Conversely, if government funding is chosen in place of cost recovery, then administration costs are likely to be larger than compliance costs and the burden will probably fall on government rather than applicants.

There is a well-established precedent of cost recovery for applications in the areas of hazardous substances, new organisms and biosecurity. Applicants under the HSNO Act currently pay approximately 54 percent of the cost of processing their applications. The Government has signalled its intention to move towards full cost recovery for HSNO applications, although no date has been set for achieving this. A review of HSNO cost-recovery policy is scheduled for 2003, so any decision to deviate from current cost-recovery policy for the category of conditional release would seem premature. It is therefore likely that applications would be cost-recovered in the same way as applications under the HSNO Act.

The issue of cost recovery for compliance checking and enforcement is less clear. As outlined in subsection 4.4.2, under the Biosecurity Act the costs of compliance checking are cost-recovered from those with containment approvals. However, no enforcement agencies listed in section 97 of the HSNO Act cost-recover, except for territorial authorities under the Local Government Act. Cost recovery for checking compliance with conditional release controls would be possible, either by a levy, or individual cost recovery, or both. However, issues of precedent, practicality, equity, consistency and the economic impact of further cost recovery would need to be carefully considered before any decision could be made.

4q Is full/partial cost recovery appropriate for conditional release applications?

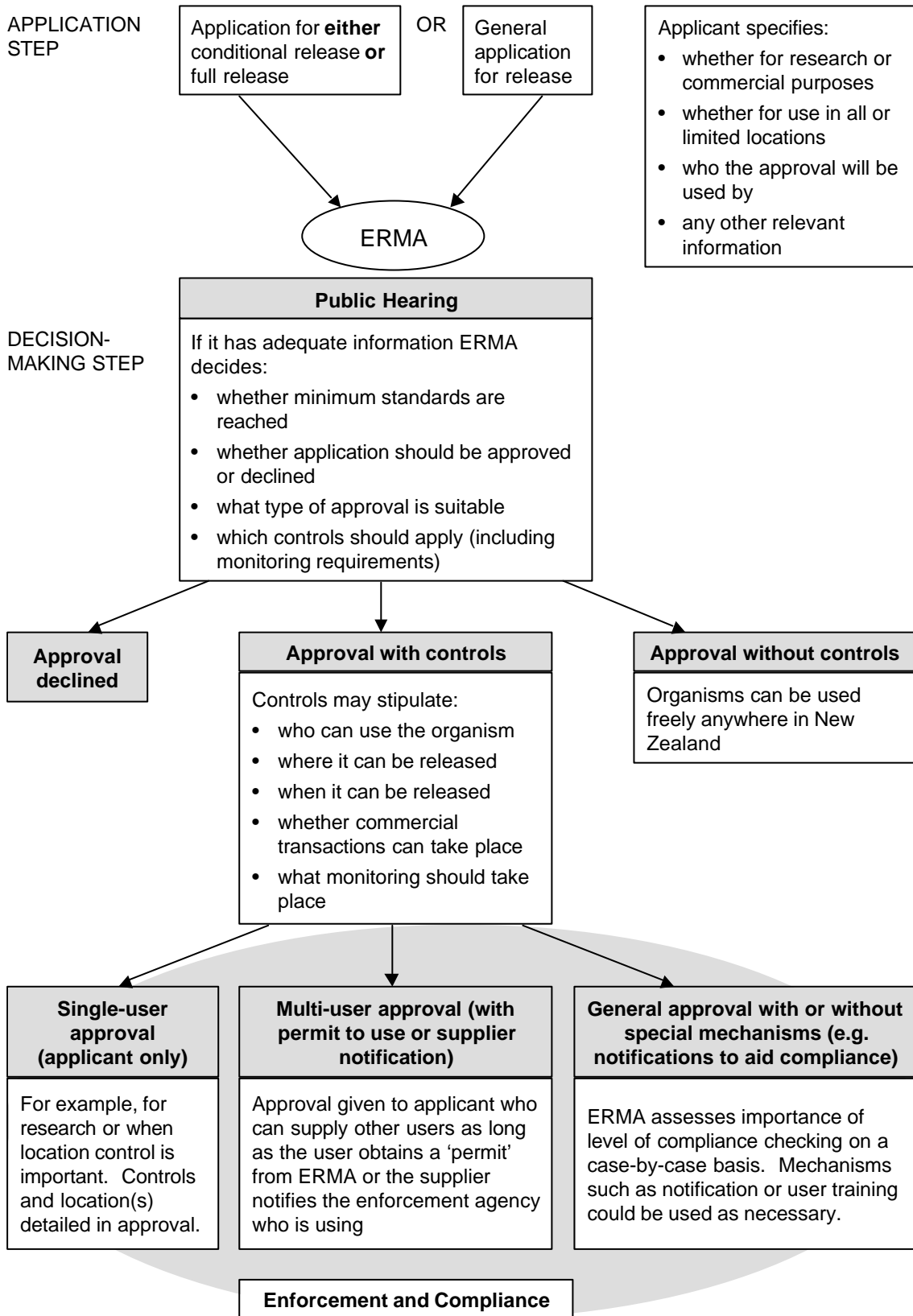
4r Who should bear the costs of compliance checking and enforcement of controls under conditional release?

4s After reading section 4, what do you believe the potential advantages and disadvantages of conditional release to be?

4t Should all releases continue to be made without controls (should the status quo remain)?

Please provide an explanation and/or examples to illustrate your views.

Annex 1: Decision-making steps for conditional release



Annex 2: Examples of the use of the conditional release category

Type of use	Research	Monitoring for impacts	Limiting the dissemination or persistence of the organism in the environment	Controlling how a new organism is used
Problem	Inability to carry out certain types of research without a full release approval, particularly research involved with studying environmental impacts	No provision for monitoring – unforeseen effects may not be detected until they become a problem	Assumption that organisms cannot be controlled in the environment is not true in all cases. Controls can limit the location of organisms and their ability to reproduce	Sometimes the way the organism is used, rather than the organism itself, has an effect that needs to be managed. Controls may be able to manage these effects
Example	Field trial of a GM potato to study the environmental effects of pollen release	Exotic insect used for biological control	A pharmaceutical company would like to raise GM cattle for the production of human proteins in their milk	Inappropriate use of Bt-crops can lead to resistance development in the pest population
Solution, including types of control	Research permitted with the following controls: <ul style="list-style-type: none"> • approval only granted to one applicant • temporal and locational restrictions • buffer zones around plot • limited number of GMOs used • no commercial transactions involving GMO 	Approval given with the following controls: <ul style="list-style-type: none"> • area around release site to be checked for the organism used, adverse effects to surrounding vegetation, and impacts on native insect populations • monitoring results to be sent to ERMA • further use or spread of organism to be stopped if any adverse effects identified 	Raising cattle permitted with the following controls: <ul style="list-style-type: none"> • GM cattle to be kept in a specific location • cattle to be double fenced, electronically tagged and identified as GM • animals to be disposed of in a suitable way, so that carcasses cannot enter the food chain 	Use of Bt-crop permitted with the following controls: <ul style="list-style-type: none"> • limits on the total acreage of the crop • use limited to those individuals who have an approval and have been trained to use it • refuges planted within the crop to prevent the development of resistance • requirement to monitor crop for resistant insect pests, and to notify authorities in case of resistance development