Office of the Minister for the Environment

The Chair, Cabinet

Government Response to the Royal Commission on Genetic Modification: Legislative changes for new organisms – Paper 4: Conditional Release and Enforcement

EXECUTIVE SUMMARY

1. This paper proposes amendments to the Hazardous Substances and New Organisms (HSNO) Act 1996 to create a category of approval for the release of organisms called conditional release, which would enable ERMA to approve the release of new organisms with controls. This paper also addresses compliance and enforcement matters. It is recommended that genetically modified (GM) and non-GM new organisms be treated identically under these proposed provisions.

2. These proposals are consistent with the government's acceptance of the Royal Commission on Genetic Modification's overall direction of proceeding with caution while preserving opportunities[1], and their specific recommendation that the HSNO Act be amended to provide a 'further level of approval' called conditional release, which would act "as a further assurance of safety to enhance the management of risk".

3. The key policy decisions required in order to implement a cautious approach to conditional release are:

i) the purpose and framework of operation
ii) criteria for conditions and level of prescription
iii) Possible additional safeguards
iv) compliance and enforcement, and resourcing considerations

BACKGROUND

4. The HSNO Act currently provides that an approval by ERMA to release a new organism, including a genetically modified organism (GMO), can only be an approval to release the organism *without* controls. In the event that an approval is given for the release of a new organism, the organism is no longer classed as a new organism and is not subject to the HSNO Act.

5. Detailed proposals for imposing conditions on the release of new organisms (including but not limited to GMOs) were developed and provided for public comment in October and November 2002. Response to these proposals was polarised. There was general support for conditional release approvals from users of biotechnology (e.g. breeders, researchers) provided that reasonable, relevant and practicable controls were imposed on approvals. Researchers saw the ability to attach controls to releases as both facilitating research (in particular, environmental impact assessments) and providing for an added level of assurance about potential risks. This group also saw conditional release as an essential component of implementing coexistence for primary production.

[1] The Royal Commission's report states "We favour a strategy of preserving opportunities and proceeding selectively with appropriate care" (Report of the Royal Commission on Genetic Modification Chapter 13 Major Conclusion: Preserving Opportunities)

6. On the other hand a large group of submitters expressed doubts that suitable controls (e.g. buffer zones and minimum separation distances) could be implemented effectively for GMOs (none of these submissions addressed conditional release of non-GMOs), and considered also that there was a lack of information on possible long-term environmental adverse effects. Many also questioned the viability of the concept of co-existence of GM and non-GM organisms.

7. Maori expressed a similarly broad range of views to those of other submitters.

THE PURPOSE OF CONDITIONAL RELEASE

8. Conditional release would be a new category in the HSNO Act. Under this category, ERMA will have the ability to approve the release of new organisms (including genetically modified organisms) with conditions. For example, ERMA could impose a condition requiring the impact of the organism on the environment to be monitored, allowing only one sex of an animal to be released, or stipulating that certain management practices must be followed.

9. Creating a new category of conditional release will allow applications to ERMA for either the conditional release of new organisms, in which the applicant will propose conditions, or applications for the general release of new organisms (release without conditions). When assessing an application for conditional release, ERMA will have the ability to impose stricter controls that those proposed in the application. Similarly, when an application is made for general release, ERMA will have the ability to impose conditions and approve the application as a conditional release rather than a general release (meaning that the organism remains subject to the Act).

10. ERMA will continue to assess all the evidence relevant to the application before it, including evidence about co-existence, and will be able to impose appropriate conditions on the release of a new organism.

11. Conditional release may be particularly appropriate for approvals relevant to research purposes, biological control, some commercial applications, medicinal clinical trials, and emergency requirements. Conditions would enable the potential risks to be minimised, monitored, and subsequently better managed than under the current provisions of the HSNO Act.

12. Officials other than DOC consider that the ability to impose conditions on the release of new organisms would assist the Government's overall aim of proceeding cautiously while preserving opportunities. Conditions may assist in a range of areas, including:

- imposing requirements on when, where or how an organism is released, or the number or types of organisms
- researching environmental (and/or human health) effects of new organisms out of containment
- providing scope for review of approval requirements
- optimising the use and benefits of a new organism
- better managing and balancing specific risks associated with an organism
- having a new organism outside of containment that is not appropriate for field testing or general release

13. DOC considers that the potential benefits of adopting a general power for conditional release have not been well demonstrated and may be outweighed by risks to the environment and biodiversity in cases where conditions fail.

14. Taking all these factors into account it is concluded that the HSNO Act should be amended to provide for conditional release.

Framework for implementation of conditional release

15. Officials recommend that conditional release be implemented using essentially the same procedures for decision-making as are available already in the Act (including public process). An organism released with conditions will remain a new organism subject to the Act, meaning that the existing machinery for checking compliance with conditions and taking enforcement action can be used where needed, and the ability to reassess the organism is available. Some adjustment to these mechanisms may be needed and this is discussed later in this paper.

16. Some submissions proposed that conditional release should be a separate and compulsory stage before considering general release. I propose that conditional release is an intermediate category between fully contained conditions (i.e. laboratory and field tests) and general release (where there are no conditions), but that conditional release is not a compulsory stage between 'containment' and general release, or before approval for general release. Specifically, there will be circumstances where an approval for general release may be granted following importation into containment, as is done at present for new organisms, and other circumstances where there may be approvals for conditional release but not for general release. Requiring a particular sequence of approvals by making conditional release a compulsory stage between fully contained conditions and general release would undermine ERMA's ability to consider each application on a case-by-case basis. Therefore, the Act should not require any particular sequence of approvals.

17. By definition, the ability to apply conditions makes conditional release more restrictive than general release. An issue exists relating to how and when a conditional release approval could become a general release approval (i.e. one in which the organism is released without conditions and is no longer subject to the HSNO Act). A number of positions were put forward ranging from requiring that approval holders formally obtain a new approval, to conditional approvals automatically becoming general approvals after a certain time period.

18. Since conditional release is consistent with the objective of managing potential risks while retaining benefits, the automatic transfer of the organism to a status where it could not be controlled under the Act (i.e. conditions no longer applying) is contrary to the original purpose of imposing conditions. However, it may occur that the conditional release process provides information allowing a general release decision to be made.

19. Officials propose that any change of the controlled status of the organism should be done using the existing reassessment machinery in the Act, which includes a public hearings process (sections 59-62). This means that any change in the conditions imposed on a conditionally released organism (other than those mentioned in paragraph 40), including where this would result in the organism being generally released, use the current reassessment procedures. In addition, the suggested list of matters to be considered in imposing conditions could provide for a finite duration for certain approvals [see paragraph 34(x)]. If this provision was used, it is proposed that at the end of this duration a reassessment application could be made, but if it were not, the approval would lapse requiring that the organism be destroyed or contained.

20. The framework should maximise positive effects while minimizing adverse effects, including environmental, social and economic effects. However, the framework also needs to recognise that management of new organisms is complex and requires expert judgement. It is therefore critical that the framework is sufficiently flexible that ERMA can set appropriate case-specific conditions.

21. The key elements necessary to implementing this framework are:
   a) Determining how the minimum standards under the HSNO Act should apply to conditional release decision-making
   b) Determining the most effective level of legislative direction to ERMA for setting case specific conditions
   c) Providing for effective enforcement and ensuring this is properly resourced

Minimum standards – deciding when conditional release is possible

22. The present HSNO Act provides a set of minimum standards (section 36). An application for release must be declined (regardless of the benefits it might provide) 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 and safety; or*
   (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 the purpose of that importation or release is to import or release an organism to cause disease, be a parasite, or a vector for disease.*

23. Where an organism meets the minimum standards, before deciding if the positive effects of the organism and any inseparable organism outweigh the adverse effects, ERMA must take into account (section 37):

   (a) *The ability of the organism to establish an undesirable self-sustaining population; and*
   (b) *The ease with which the organism could be eradicated if it established an undesirable self-sustaining population.*

24. ERMA is obliged in decision making to consider the HSNO Act's purpose and principles (as set out in Part 2 of the Act) as well as the other relevant provisions of the Act.

25. Conditions imposed on an organism may affect the organism's ability both to exhibit some of the characteristics described in paragraph 22, and to establish an undesirable, self-sustaining population (as in paragraph 23). It is important, therefore, to be clear about whether the minimum standards should be applied before or after the setting of conditions, and also when consideration should be given to the potential to eradicate the organism, if required.

26. I consider that proposed conditions are integral to the management of risk and should, therefore, be integral to decision making. However, in many cases the risks posed will depend on how and where the organism is used. Therefore, I consider that ERMA should be given the flexibility to apply the most appropriate conditions for an organism, while proceeding cautiously in the face of uncertainty about the effectiveness of the conditions. Conditions should be applied to an approval taking into account, not only all the likely effects and innate risks posed by the organism, but also the ability to remedy adverse effects should conditions be breached. In this latter regard, organisms that are inherently difficult to recover or eradicate represent a higher risk.

27. I consider, therefore, that for conditional release ERMA must take into account the conditions when determining if the minimum standards are met. Secondly, in order to address the issue of remedying adverse effects in the event of failure of conditions, ERMA will need to consider the consequences of the ability to recover or eradicate the new organism if required. This

consideration would be driven by Part 2 of the Act. There will be some circumstances where considering the ability to eradicate the organism leads either to the application not proceeding, or to modification of the conditions. This may lead to some organisms posing high potential risk, and being difficult to eradicate or retrieve not being approved for conditional release, regardless of the ability to impose conditions.

28. Against this, allowing conditions to be considered when assessing an organism against the minimum standards might be perceived as lowering the current risk threshold for new organisms, rather than using conditional release "as a further assurance of safety". This is because conditionally released organisms are not completely contained and because of the possibility that conditions could become ineffective as a result of a breach (such as through neglect over the long-term). This risk is reduced, but not eliminated, by the above proposal to consider the ability to retrieve or eradicate in the decision making process. The risk would be avoided by requiring minimum standards to be met before any proposed conditions are considered. This stricter use of the minimum standards could preclude the conditional release of potentially valuable organisms that would pose no foreseeable threat to New Zealand's environment, should the conditions imposed on them operate as planned. This in turn could limit opportunities for advancement in New Zealand's biologically based industries.

29. In considering these advantages and disadvantages, on balance there is merit in providing for both consideration of conditions and consideration of the ability to retrieve or eradicate any organism in conditional release. I propose, therefore, that the HSNO Act be amended to provide for this in applying minimum standards to conditional release.

Criteria for conditions and level of prescription

30. The second key area in an effective framework for conditional release is in setting the appropriate level of legislative prescription to minimise or eliminate risks while providing flexibility for case-by-case decision making by ERMA (a purpose-built, expert body). Analysis shows three possible levels of prescription for conditions for release. These levels can be considered in relation to the following elements:

- Restriction on the types of organisms considered for conditional release
- Limitations on the purposes for which conditional release can be considered
- Rules about the controls that can or must be placed on approvals
- The nature of any review/reassessment of approvals

31. The levels or options to be considered are:

Option 1: ERMA has full discretion on imposing conditions on approvals to release new organisms on a case-by-case basis

Option 2: ERMA must consider the relevance of a specific list of matters when approving an application and where relevant decide if a condition should be used to address that matter

Option 3: ERMA must apply conditions to implement the requirements of a specific list of types of conditions

32. Option 1 would provide the maximum possible flexibility for ERMA to tailor conditions to match each specific case. However, it provides no direction or guidance on what conditions should be considered. This provides the government with less certainty about how the provisions would be implemented and also decreased certainty for applicants. Officials note that the general

provisions in the HSNO Act, the Methodology Order in Council, and the requirements of administrative law broadly constrain all these options.

33. Option 2 would, in addition to the general empowerment of option 1, insert into the Act a non-exclusive list of potential matters that could be covered by conditions. The list would not be restrictive, and so would not constrain ERMA's broad discretion to apply conditions on a case-by-case basis. ERMA would not be required to address any matters that, in their opinion, were not relevant to the application.

34. For option 2, the following matters are recommended for inclusion in the list:

(i) The extent and purposes for which organisms could be used
(ii) The nature of any monitoring, auditing, reporting and record-keeping requirements
(iii) The possible obligation to comply with relevant codes of practice or standards (e.g. to meet particular coexistence requirements)
(iv) Requiring contingency plans in the event of incidents
(v) Requirements to limit the dissemination or persistence of the organism or its genetic material in the environment
(vi) Requirements for disposal of any organisms or genetic material
(vii) Limiting proximity to other organisms, including those which could be at risk from the conditionally released organism
(viii) Requirements to be met in terms of any material derived from the organism
(ix) Obligations on the user of an approval including levels of training or knowledge, limits on the numbers of users who may hold an approval and the persons that they could deal with in respect of the organism
(x) Specifying a duration of the approval or a condition before review was required and the nature of any such review

35. Option 2 would provide guidance for both the decision maker (ERMA) and the applicant in formulating conditions. Providing for a non-exclusive list of matters also gives opportunity for extending the factors where needed and doesn't preclude any additional conditions including financial requirements (e.g. performance bonds) to ensure any other conditions are met. These would need to be applied in a manner consistent with New Zealand's international obligations.

36. Option 3 would insert into the Act specific matters on which conditions must be set, such as the list in option 2. In practice these closed lists are extraordinarily difficult to create and are not amenable to the full scope of possibilities available from the enormous diversity of new organisms and from the possible applications of genetic modification. Accordingly, I consider that this option is neither practical nor compatible with the evolving nature of the theme of proceeding with caution.

37. Of the remaining two options, I consider that providing a level of certainty and direction for applicants and for the decision maker outweighs the potentially greater flexibility that may result from a 'full discretion' option (option 1). I consider that the advantages of including such a list outweigh the disadvantages.

38. Accordingly, I consider that option 2, which provides for broad direction about the nature of conditions, be implemented in these amendments.

Review provisions

39. There will be circumstances where new information or new technologies justify a change to the conditions on a conditional release approval. Currently the HSNO Act only provides for this either by a minor in effect change [section 67(a)] or through a full publicly notified reassessment. The latter process would impose significant costs, which may not be justified, and could act as a disincentive to the applicant to propose new conditions that might improve protection of the public interest. It might also restrict ERMA's ability to quickly amend a condition to better achieve its objective.

40. Officials identified two circumstances in which a review of conditions without a full publicly notified reassessment would be justified:

- where the review is to amend a condition so it better meets the objective of the condition, and
- where the condition included a review requirement, specifying the circumstances in which the condition would be reviewed (the trigger) and the potential consequences of the review

41. It is proposed that ERMA be able to undertake such reviews, in consultation with relevant government agencies (including DOC), without a full publicly notified reassessment public process. Such reviews would be initiated by ERMA, which could take into account information provided by any party, including the applicant. The present HSNO Act requires that any decisions by ERMA (including conditions imposed) are made public, and this would also be the case for any change made as a result of a review of a conditional release approval.

POTENTIAL ADDITIONAL SAFEGUARDS

42. In addition to the above matters, the very broad possible effects of new organisms and the rapidly developing nature of biotechnology as a whole and genetic modification in particular, suggest the need to investigate other possible safeguards. I consider there are grounds for some additional safeguards to further protect New Zealand from the potential adverse effects of new organisms (including both GM and non-GM new organisms).

43. I propose consideration is given to such safeguards in three areas: the use of Schedule 2 to prohibit certain organisms or classes of organism based on their risk characteristics, an additional reserve ability of the chief executives of both the Ministry for the Environment and ERMA to take enforcement action in special circumstances (for either hazardous substances or new organisms), and extending some of the regulation making powers currently in the Act regarding hazardous substances to conditionally released new organisms.

ADDITIONS TO SCHEDULE 2 (PROHIBITED NEW ORGANISMS)

44. Section 50 of the HSNO Act prohibits any organism listed in Schedule 2 from being imported, released or developed in New Zealand. Additions to this schedule are done by Order in Council. ERMA can, after declining an application, recommend that organisms be added to Schedule 2.

45. The current provisions of the HSNO Act do not provide an explicit mechanism for adding intrinsic characteristics or properties of an organism to the schedule.

46. Such a power could be useful in situations where additional information about new organism behaviour or new technologies, raised significant new safety issues. For example, where research overseas provided early warning of particular lines of development in biotechnology that may place New Zealand at high risk. It could also be used as an additional tool to protect New Zealand's biodiversity, such as when there is evidence about unacceptable consequences of new organisms (including GM organisms) which might be considered for introduction to New Zealand. The use of this power would provide clear direction and certainty to potential applicants in areas not likely to be proceeded with in New Zealand.

47. It should be noted that there are inherent difficulties with the proposal to list, as prohibited, organisms with certain characteristics. Most notably, there are problems technically with specifying characteristics independently of an organism (e.g. some characteristics of a plant may be considered either a benefit or a risk - such as high seed production). There is a risk that this prohibited list process may in some circumstances, replace the assessment and decision-making process under Part 5 of the Act. The process to be used for placing organisms on the prohibited list is not the same as the process under Part 5; nonetheless, making an Order in Council must be done using the provisions of section 141, and does require consideration using normal Cabinet processes. However, I consider that there would be benefit in providing in the HSNO Act the ability to add organisms to Schedule 2 on the basis of such characteristics, provided it is managed in a strictly controlled, transparent, properly justified and legally precise manner, in line with the procedures for making Orders in Council set out in the Act.

48. I propose, therefore, that the HSNO Act be amended to enable additions to Schedule 2 based on innate risk characteristics of new organisms, or groups of new organisms.

DELETIONS FROM SCHEDULE 2 (PROHIBITED NEW ORGANISMS)

49. Prescriptive lists can be inflexible, difficult to amend, and unable to accommodate rapid technological advances. In the rapidly changing technological environment, it is foreseeable that developments may occur which mean that a prohibited organism, or group of organisms no longer poses the risks that led to their prohibition. Currently, removal of organisms from the Schedule 2 list is only possible with a legislative change. It is noted that organisms on the prohibited list cannot even be imported into strict containment.

50. I consider that the current process for removal of organisms from Schedule 2 may mean that prohibitions on organisms continue to be applied in the absence of proper justification. This could lead to potential negative effects, for example on researchers, who may be unable to undertake research and thus risk potential lost opportunities for technological advancement and the potential loss of innovation. Removal by Order in Council could become more important given the increased ability to add to Schedule 2.

51. I recommend that the procedure for removing organisms (or groups of organisms) from Schedule 2 be amended to enable this to be done by Order in Council. This would mean that any provision to change the status of a prohibited new organism to being no longer prohibited would be subject, before the decision was made, both to consultation with those people reasonably affected, and to the full rigors of the regulation making process.

52. It should be noted that this proposed amendment does not impact on the recommendations relating to changes to Schedule 2 outlined in Paper 7 (*Operational matters*) in this suite.

RESERVE ENFORCEMENT POWERS

53. I consider that there is a need for a mechanism for a senior official to have reserve powers to take enforcement action in special circumstances. A senior official would have immediate access to a broad range of advice and expertise (including scientific, legal and administrative expertise), which may be necessary in situations where there has been a breach of the HSNO Act. These situations would generally be exceptional circumstances where judgement is required on the extent and level of enforcement necessary, e.g. the level or nature of clean-up required.

54. I propose the chief executives of both the Ministry for the Environment and ERMA, as the senior officers of the two agencies most closely involved with the administration and operation of the HSNO Act, be given these powers.

55. These 'reserve' powers are not intended to alter, in any way, the need for clearly defined responsibilities and adequate resourcing to ensure sufficient routine enforcement in respect of new organisms (as set out in paragraphs 65-83 of this paper). Rather, this arrangement is intended to provide additional capacity to act in exceptional and difficult circumstances where immediate access to a broad range of expertise is necessary, or immediate advice to the government would be necessary (e.g. where special funding may need to be considered).

Reserve ability to regulate conditionally released organisms

56. The addition of the ability to approve new organisms for conditional release to the HSNO Act means that the management of new organisms under the Act has more similarity with the management of hazardous substances than previously. There are however some key differences. Unlike hazardous substances, new organisms are not amenable to any widely recognised system of hazard classification. This means that the structured approach to managing risks based on a system of hazard classification used for hazardous substances is not useable in the case of new organisms.

57. As a result, the 'regulatory toolbox' approach to hazardous substances management provided for in the Act cannot be used in setting conditions on new organisms. This precludes most types of regulation making for the control of conditionally released new organisms. However there may be circumstances where, as patterns emerge in setting conditions on conditionally released new organisms that regulation could be useful. Such uses may include; providing general direction on controls for conditionally released organisms in the interests of setting basic standards of environmental protection, and reducing costs of conditional release applications by providing some 'givens' when conditions are considered case-by-case. At the present stage of development of the conditional release concept, the form and extent of such regulations is at best difficult to foresee.

58. Nonetheless, on balance, I consider that it may be useful to provide a regulation making power to be used if the conditional release concept develops sufficiently to allow this. Accordingly, I propose to provide more complete regulation making powers in this area by extending the current regulation making power in the HSNO Act. This power allows for regulating hazardous substances to avoid or mitigate any adverse effects on the physical or chemical nature of the environment or for human health and safety. The proposal would extend the present power to regulate, for similar purposes, conditionally released new organisms. As the adverse effects of many new organisms are on the biological nature of the environment, it would be sensible that the provision include this possibility.

ENFORCEMENT

59. The final critical element in a framework for implementation of conditional release is an effective enforcement regime - this is fundamental to the precautionary approach ensuring conditions are complied with adequately to manage risk. The regime must provide sufficient inspection to ensure discovery of transgressions as well as necessary incentives and penalties to encourage compliance with conditions. As conditional release will have significant implications for the types of enforcement required for new organisms generally, this section examines and advises on the full spectrum of related enforcement activities.

60. The preceding sections of this paper advise on specifications for a new category of approval for the release of new organisms (conditional release). To establish an effective enforcement regime, several elements are needed. These elements are:

- provision of offences for breaching the conditions
- assignment of enforcement responsibilities and provision of powers for enforcement officers

Existing enforcement arrangements under the HSNO Act

61. The HSNO enforcement system was developed on the understanding that for new organisms there would be no effective control once released, and hence no need for enforcement. Therefore, existing enforcement agencies were specified largely with hazardous substances in mind.

62. Currently, the following agencies are assigned enforcement responsibilities for both hazardous substances and new organisms under the Act:

- The Occupational Safety Service (OSH) in places of work
- The Energy Safety Service in respect of gas systems and installations
- The Police and LTSA in respect of road or rail transport
- The Civil Aviation Authority in respect of any aircraft or aerodrome
- The Maritime Safety Authority in respect of any ship
- The Ministry of Health to protect public health
- The Chief Executive of a Territorial Authority in respect of other places.

63. ERMA has an oversight role and can also appoint enforcement officers, or authorize the chief executives of other agencies to appoint officers and/or enforce the provisions of the HSNO Act as it sees fit. The Act allows also for making other arrangements to ensure effective coverage. The agencies listed above generally have expertise only in the hazardous substance area. As a result the flexibility provided in the Act has been used by ERMA to make arrangements with MAF to undertake new organisms enforcement where new organisms are in containment, often as part of similar activities undertaken by MAF under the Biosecurity Act.

OFFENCES AND PENALTIES

64. Currently, there are offences and significant penalties for breaches of the Act including conditions imposed on new organisms in containment. Provision needs to be made to provide similar offences and levels of penalty for breach of conditions placed on release of new organisms.

POWERS OF ENFORCEMENT OFFICERS

65. The HSNO Act provides a broad set of powers for enforcement officers, e.g. entry for inspection, the ability to take samples etc. As these powers are general they are considered sufficient for enforcing conditions on conditionally released new organisms (e.g. current powers provide for enforcement for hazardous substances, most of which are 'conditionally released').

ENFORCEMENT RESPONSIBILITIES

66. In particular the following three areas are considered:

1. What agency should be responsible for enforcing 'conditional release' of new organisms
2. Whether to formalise existing arrangements for enforcement of new organisms in containment
3. Are unauthorised releases (i.e. organisms not approved under the HSNO Act) of new organisms adequately addressed by existing enforcement arrangements

1 Enforcement for conditional release

67. As already noted, the enforcement responsibilities in the present Act are for both new organisms and hazardous substances. As written this means these agencies would also have responsibility for conditionally released new organisms in their specified areas. However, it was never intended that these agencies have this function, and most are not equipped to undertake it.

68. To meet the objectives for conditional release it is essential that there is a clearly defined and adequately skilled and resourced agency to ensure compliance and undertake enforcement actions where necessary. The range of enforcement activity required for this new function includes:

- compliance checking of any conditions set by ERMA on a new organism (the range of conditions is set out in paragraph 34) anywhere in the New Zealand terrestrial or marine environment including multiple sites
- investigation and evidence gathering
- prosecution
- responding to emergency situations
- and related activity providing the interface with any practical tools for coexistence (e.g. codes of practice)

69. The criteria for an enforcement agency for conditional release include:

- adequate knowledge of new organisms and their effects
- the ability either to deliver a nationwide programme of checking the compliance of new organisms that have been conditionally released, or to contract for the delivery of such a programme
- the ability to investigate cases of non-compliance, and carry out appropriate responses, including by way of prosecution

70. Core business should have some synergies with new organisms enforcement (i.e. the agency should already be concerned with environmental issues and already have some

enforcement/prosecution capability/responsibility in managing environmental impacts). This synergy is essential when different functions within the organisation compete for limited resources.

71. There are three agencies that most closely meet these criteria and potentially could enforce approvals for conditionally released new organisms, although no one agency is perfectly aligned for this task. Potential enforcement agencies are ERMA, MAF or regional councils (the latter two are not currently included under HSNO).

72. ERMA has experience of new organisms through its application and approval process. Regional councils have some experience in managing pest organisms under the Biosecurity Act and in ecosystem management under the RMA. Both MAF and regional councils have enforcement experience using different legislation. MAF has new organisms experience through its Biosecurity Act work and its memorandum of understanding with ERMA regarding new organisms in containment.

73. MAF currently has some degree of nationwide coverage and infrastructure, due to its operations at the border and in meat processing premises. However, when MAF needs comprehensive nationwide coverage, such as would be required for the enforcement of conditional release, MAF contracts for that coverage. For example, the function of delivering emergency disease response actions is delivered by contract with the State Owned Enterprise AgriQuality. Coverage is required for both marine and terrestrial environments. ERMA would need to expand its current role to operate in this area in particular. It is possible for any agency to contract in the necessary services.

74. Clearly the synergies with core business of an agency fall most closely with MAF or ERMA. Enforcement of approvals for conditionally released new organisms is too far from the core business of regional councils.

75. MAF's current role in relation to enforcement of new organisms in containment builds on their roles in the approval of containment and quarantine facilities, and the fact that there is often quarantine or other bio-security roles that MAF perform in the same facility. The enforcement of conditional release would require MAF to operate across a much greater range of circumstances and places, and to enforce a much broader range of HSNO Act controls.

76. It is recommended that MAF be responsible for enforcement of conditions imposed on conditionally released new organisms. It is also recognised that MAF may need to contract to others to provide specialist compliance inspection. It is important that MAF is adequately resourced to carry out this new enforcement function and to have sufficient funding to contract specialist compliance needs to others.

2 Enforcement of new organisms in containment (authorized)

77. Currently the main compliance checking activity under the Act is in respect of new organisms (including GMO developments and field tests) in containment. The MAF Quarantine Service is the primary agency undertaking new organism enforcement activities for the MAF Biosecurity Authority. This work is carried out by using powers under the Biosecurity Act, and in accordance with a memorandum of understanding with ERMA. This arrangement has worked well in practice.

78. It is proposed that MAF's enforcement role for new organisms in containment under HSNO should be formalised by including them in the agencies assigned enforcement responsibilities by the Act, and giving them the flexibility to use HSNO provisions in circumstances where unauthorized new organisms are found in a containment facility. MAF has expertise in the field for undertaking enforcement of new organisms in containment and this work has strong links to other MAF core activities. Identifying MAF as the primary agency responsible for enforcement of new organisms in containment would provide certainty in this aspect of enforcement.

3 Enforcement of unauthorized releases (i.e. organisms not approved under the HSNO Act)

79. Enforcement in respect of new organisms that do not have approval under the HSNO Act is to a large extent carried out by MAF (or other biosecurity departments where appropriate) as part of its established biosecurity role. Biosecurity threats occur in both the terrestrial and marine environments. The Ministry of Fisheries has enforcement responsibility in the marine area. Biosecurity threats can also have particular impacts for public health, where the Ministry of Health would have a key interest in management of the threat. However, some unauthorized new organisms are not covered by Biosecurity Act provisions, because they do not meet the criteria for harm so as to fall within the definition of "risk goods" or "unwanted organisms". Of particular concern are situations where GMOs are found in New Zealand without an ERMA approval, as not all GMOs fall within the scope of the Biosecurity Act. The range of enforcement activity required for this function includes:

- surveillance both at the border and within New Zealand
- investigation and evidence gathering
- prosecution
- responding to emergency situations

80. The issue is therefore which agency should have overall responsibility for the enforcement function in relation to unauthorized new organisms that do not fall within the scope of the Biosecurity Act.

81. There are two agencies that could undertake this function, in either case an appropriate mechanism and funding would be required:

ERMA could take the lead in dealing with this situation, but this would be a change in role for the Authority,

or

MAF could undertake this function but this requires extending its role beyond its established role of responding to harmful organisms under the Biosecurity Act, to responding to all unauthorized new organisms under the HSNO Act, including GMOs.

82. It is recommended that MAF should be responsible. It is essential that MAF be adequately resourced for enforcement in relation to all unauthorized new organisms, an extension of this agency's present area of work.

83. For MAF to assume this role it is recommended that enforcement officers be able to use Biosecurity Act powers for all unauthorised new organisms. The advantage in enabling the use of Biosecurity Act powers is that this would enable enforcement officers to respond more quickly to

90. It is estimated that [Withheld under section 9(2)(f)(iv) of the Official Information Act] will be required for 2003/04 and that at present this is the best available estimate for outyears. This estimate does not provide for actions in response to large incidents (i.e. similar in scale to the painted apple moth incursion), which would require a separate request for funding. Funding for the basic level of enforcement activity described in paragraph 89 is sought as part of the recommendations in this paper. However, Ministers should note that at this stage the funding required is only an estimate and will depend to a large extent on the level and type of conditional releases approved and the enforcement activity required.

91. Treasury recognises the need for funding of enforcement activity, but considers that decisions on the final amount of additional funding should be taken as part of the upcoming 2003 Budget. Consideration during the Budget would allow the priority of this expenditure to be compared to all other government priorities, allow further refinements of the current cost estimates bearing in mind agency-specific factors, and establish a process to deal with the uncertainties around the amount of funding required.

Timetable implications

92. All timetable implications associated with this paper, have been outlined in *Paper 1: Overview*.

Human rights

93. All human right implications associated with this paper, have been outlined in *Paper 1: Overview.*

Legislative implications

94. All legal implications associated with this paper, have been outlined in *Paper 1: Overview.*

Regulatory impact and compliance cost statement

95. The Regulatory Impact and Business Compliance Cost Statement is attached in Annex 1 and complies with the requirements of Cabinet Office Circulars CO (98) 5 and CO (01) 2. Based on the information provided in the attached RIS/BCCS, the Business Compliance Costs Unit considers that the disclosure of information is adequate, and the level of analysis is appropriate given the likely impacts of the proposal.

96. With regard to the proposed regulation-making power in respect of new organisms, this was inserted into the RIS just prior to submission to Cabinet Office and after the BCCU provided the above statement as to adequacy.

97. The proposed amendments are intended to enable a cautious release of new organisms (including GMOs) by providing a robust risk management system, thereby preserving opportunities to optimise the use of new technologies and organisms. The parties affected directly by these proposals will be applicants importing or developing new organisms for conditional release in New Zealand. The sector is broad and highly significant in the New Zealand economy, covering all areas of biologically based industries interested in the commercialisation of new organisms. While it is anticipated that costs will result from a need for applicants to understand the new procedures, these costs are considered small relative to the applications themselves, as the

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procedure will be similar to applications for field trials and for general release with which the industry is familiar.

Gender implications

98. There are no gender implications associated with this paper.

Disability perspective

99. There are no disability perspective implications associated with this paper.

Publicity

100. All publicity implications associated with this paper, have been outlined in *Paper 1: Overview.*

Consultation

101. Details of the consultation for this suite of papers have been outlined in *Paper 1: Overview.*

RECOMMENDATIONS

102. It is recommended that Ministers:

CONDITIONAL RELEASE

a) **Note** that the HSNO Act currently only provides for approval to release a new organism without conditions at which time that organism is no longer subject to the Act

b) **Agree** that conditional release is a key element of the government's overall strategy of "proceeding with caution while preserving opportunities"

c) **Agree** to amend the HSNO Act to provide for conditional release as a new category of approval for the release of new organisms (including genetically modified organisms) and that such organisms remain new organisms subject to the Act

d) **Agree** that the procedures used for evaluating conditional release applications will follow those specified in the Act for the approval of release of a new organism

e) **Agree** that while conditional release is a separate intermediate category, it will not be a compulsory stage required for approval to release a new organism

f) **Note** that recommendations (c) to (e) above mean that the Act will not require any particular sequence of approvals and that applications can be made for the category of approval (conditional or general) most appropriate for the particular organism at the time

g) **Agree** that any change in the conditions imposed on a conditionally released organism [other than those referred to in recommendation (m)], including where this would result in

the organism being generally released, will use the reassessment procedures already provided for in the HSNO Act

MINIMUM STANDARDS AND DECISION-MAKING

h) **Note** that as part of the requirements for deciding on release of new organisms, the HSNO Act currently provides minimum standards and requires that ERMA decline an application if the standards are not met

i) **Agree** that when considering applications and before granting approvals for conditional release, ERMA must consider whether the new organism could be recovered or eradicated if desired, and must take into account conditions and their likely effectiveness when determining whether the minimum standards are met

LEVEL OF LEGISLATIVE DIRECTION TO ERMA

- criteria for conditions and level of prescription

j) **Agree** that ERMA be given broad discretion to impose appropriate conditions on a new organism which it approves for conditional release, and that the conditions imposed may include, but are not limited to, provisions to address any matter from the list in recommendation (l)

k) **Note** that ERMA, in imposing conditions on conditionally released organisms remains subject to Part 2 of the HSNO Act

l) **Agree** that, without limiting the broad discretion in recommendation (j), a list of matters that may be covered by conditions on a new organism considered for conditional release be included in the Act, and that the list cover, but not be limited to, the following matters:

(i) The extent and purposes for which organisms could be used
(ii) The nature of any monitoring, auditing, reporting and record-keeping requirements
(iii) The possible obligation to comply with relevant codes of practice or standards (e.g. to meet particular coexistence requirements)
(iv) Requiring contingency plans in the event of incidents
(v) Requirements to limit the dissemination or persistence of the organism or its genetic material in the environment
(vi) Requirements for disposal of any organisms or genetic material
(vii) Limiting proximity to other organisms, including those which could be at risk from the conditionally released organism
(viii) Requirements to be met in terms of any material derived from the organism
(ix) Obligations on the user of an approval including levels of training or knowledge, limits on the numbers of users who may hold an approval and the persons that they could deal with in respect of the organism
(x) Specifying a duration of the approval or a condition before review was required and the nature of any such review

- review provisions

m) **Agree** that ERMA may, in consultation with relevant government agencies (including DOC) and without a full publicly notified reassessment, review conditions on conditional release approvals:

- where the review is to amend a condition so it better meets the objective of the condition; or
- where the condition included a review requirement, specifying the circumstances in which the condition would be reviewed (the trigger) and the potential consequences of the review

n) **Note** that the present HSNO Act requires that decisions (including conditions imposed) are made public, and that this would also be the case for any changes to conditions made as a result of the review procedures in recommendation (m) above

Potential additional safeguards

o) **Agree** that the HSNO Act be amended to explicitly provide for the addition of organisms, or groups of organisms displaying specific risk characteristics, to Schedule 2 (Prohibited new organisms), by Order in Council following the existing processes in the Act for promulgating orders in council.

p) **Agree** that the HSNO Act be amended to enable removal by Order in Council of organisms (or groups of organisms) from the prohibited list in Schedule 2 (Prohibited new organisms)

q) **Note** that recommendations (o) and (p) will not impact on the recommendations relating to changes to Schedule 2 outlined in Paper 7 (*Operational matters*) in this suite

r) **Agree** to amend the HSNO Act to provide for the chief executives of both the Ministry for the Environment and ERMA to have the powers, obligations and protections afforded to enforcement officers under the Act

s) **Note** that it is expected that the powers in recommendation (r) above will only be used in exceptional circumstances where it would be difficult for actions to be undertaken using normal enforcement mechanisms because of considerations such as timing or scope of the action required

t) **Agree** that the HSNO Act be amended to extend the present power to make regulations to avoid or mitigate the adverse effects of hazardous substances on the chemical, or physical nature of the environment or to avoid or mitigate damage to the environment or harm to people, to include conditionally released new organisms

Offences and penalties

u) **Note** that the HSNO Act contains both a comprehensive set of inspection powers for enforcement officers, and offences and significant penalties for breaches of the Act (including the release of unapproved new organisms) or of conditions, and that these provisions can be applied to the enforcement of conditions imposed on released new organisms

v) **Note** that Paper 5 (*Liability issues*) in this suite contains proposals to reinforce compliance with the Act, including compliance with conditions under conditional release

w) **Agree** that offences and penalties under the Act be extended to include breach of conditions placed on conditionally released new organisms

Enforcement responsibilities

x) **Note** that new organism enforcement under the HSNO Act can be considered in three parts:
   (i) Conditions on conditionally released organisms
   (ii) In containment (currently undertaken by MAF)
   (iii) Unauthorised releases

Enforcement of conditions on conditionally released organisms

y) **Agree** that effective enforcement of conditions on conditionally released new organisms is essential to meet the objective of proceeding with caution

z) **Agree** to amend the HSNO Act to specify that MAF be responsible for enforcement in respect of conditions imposed on any conditionally released new organism

aa) **Note** that effective enforcement for conditional release will require adequate resourcing of the enforcement activity

Enforcement of new organisms in containment

ab) **Agree** to amend the HSNO Act to specify that MAF be responsible for enforcement of controls on new organisms in containment or as part of an approved field test

Enforcement of unauthorised releases (i.e. organisms not approved under the HSNO Act)

ac) **Note** that current agencies will remain responsible for enforcement in respect of unauthorised new organisms that are unwanted organisms under the Biosecurity Act

ad) **Agree** that MAF be responsible for enforcement in respect of all unauthorised new organisms that are not unwanted organisms under the Biosecurity Act

ae) **Agree** that Biosecurity Act powers be able to be used for enforcement actions taken for all unauthorised new organisms (including genetically modified organisms) and to amend either the Biosecurity Act or the HSNO Act or both accordingly

af) **Agree** that MAF be responsible to the Minister for Biosecurity for enforcement in respect of:
   (i) conditions on conditionally released organisms
   (ii) new organisms in containment (currently undertaken by MAF)
   (iii) unauthorised releases

Funding

ag) **Agree** that MAF prepare a bid for funding for enforcement activities in respect of unauthorised new organisms and of conditions imposed on conditionally released organisms as part of the 2003 budget process

ah) [Withheld under section 9(2)(f)(iv) of the Official Information Act.]

Hon Marian L Hobbs
Minister for the Environment

Annex 1

Regulatory impact statement

Implementation of conditional release under the Hazardous Substances and New Organisms (HSNO) Act

Nature and magnitude of the problem and need for Government action

Currently, the HSNO Act provides that a decision whether or not to release a new organism[2], including a genetically modified organism (GMO), must be based on release without conditions.

This leaves a gap in the regulatory framework in the case of new organisms that could be considered for release provided there were conditions applied. For example, some large animals (camels for tourist trekking) could be released provided there were limited numbers and they were rendered infertile. Others could be released provided there was ongoing monitoring to check for impacts.

By not allowing for releases with conditions, the current system is impeding the development and implementation of new organism technologies that could benefit the New Zealand economy.

Public policy objectives

The public policy objective is to enable a cautious release of new organisms (including GMOs) while maintaining a robust risk management system, thereby preserving opportunities to optimise the use of new technologies and new organisms.

Feasible options (regulatory and non-regulatory) for achieving objectives and the net benefits of the proposal

Status Quo

The current provisions of the HSNO Act for release of a new organism require the Environmental Risk Management Authority (ERMA) to consider the application on the assumption that there can be no conditions attached to the release. The net benefits of feasible options are therefore considered relative to the status quo.

Non-Regulatory Measures

As the HSNO Act requires a positive decision for the release of any new organism, there are no non-regulatory measures that can achieve the objectives to enable a cautious release of new organisms while maintaining a robust risk management system.

[2] A new organism is defined in the Act and includes an organism of a species not present in New Zealand immediately before 29 July 1998 and a genetically modified organism.

Regulatory Measures

The proposal is to create an approval for a release with conditions for new organisms under the HSNO Act. There are two layers to constructing the preferred option, the process for arriving at a decision, and definition of conditions. In addition, the proposal considers mechanisms to reduce some residual risks around the use of conditional release.

Deciding when conditional release is possible

For the process of making a decision, the HSNO Act currently requires the following considerations in relation to a new organisms release:

1. Minimum standards – no organism shall be considered for release if it is likely to cause significant adverse effects;
2. Additional matters – an organism is less likely to be released where it is likely to establish an undesirable self-sustaining population, and if it did, where it would be difficult to then eradicate;
3. If the above two tests are 'passed', an organism may be released only if on balance the positive effects outweigh the negative.

[Note that, in the case of a conditional release, ERMA would need to be satisfied that there is a net benefit from the release, including the costs of the conditions and checking for compliance.]

The options for combining these considerations in a decision to release with conditions are:

1. Require that the minimum standards test be passed assuming conditions are operative;
2. Require an organism to pass the minimum standard test (step 1 above) without consideration of the conditions to be applied;
3. Provide for the minimum standards test to be passed assuming conditions are operative, and with consideration of whether or not the new organism could be recovered or eradicated if desired.

Option 2 would limit release for a number of cases contemplated by this provision, reducing the expected net benefits of conditional releases to applicants (business). Its advantage is that it requires the potential for failure of conditions to be considered in terms of the likely costs to the environment, other types of business and society in general (e.g. to control or eradicate a released new organism that became a pest).

Conversely, option 1, enables more cases to be considered under conditional release, but may generate more costs to the environment, other types of business and society in general. These costs would arise in cases where the conditions failed. For example, DOC has had to spend money to control freshwater species that 'escaped' from designated catchments specified as a condition on their release.

Option 3 (which is the recommended option) provides for the advantages of option 1 with the added requirement to consider the feasibility of mitigation, for example, by 'recovering' the organisms, in cases where conditions fail, thus reducing potential costs.

Criteria for conditions and level of prescription

As organisms are enormously varied in their nature and potential effects, the only realistic option is to impose conditions case-by-case – e.g. conditions on large animals will be vastly different

from those that could be applied to micro-organisms. However, there are listed general matters that can be considered in imposing conditions although not all will be used in every case. The options define the different ways in which this list of general matters should be considered.

One option proposed is to give the decision maker (ERMA) full discretion over the conditions it chooses to impose on an application, as they deem appropriate and relevant to the specific circumstances. This option provides ERMA greater flexibility but at the expense of transparency for applicants about the set of conditions that could be applied, and accountability to the public that an appropriate set of conditions was examined explicitly. Option 1 is therefore expected to lower ERMA's costs for such applications, but has the potential to increase costs to applicants.

The second option is to provide ERMA general empowerment to set conditions as they see fit, on a case-by-case basis, but to provide additionally, a non-exclusive list of potential matters that could be covered by such conditions. That list would not be restrictive (other types of conditions could be imposed as ERMA sees fit), nor would it be prescriptive (ERMA would not be required to address any matters it did not consider relevant to the application). This process (which would be set out in the Act) would provide flexibility for the decision-maker, increased transparency to the public, and greater certainty to the applicant (and a consequential cost reduction) and is, therefore, the preferred option.

The third option is to require that all items on the list be considered and addressed, reducing flexibility and increasing cost for ERMA, but giving greater transparency.

Reducing residual risks – potential additional safeguards

In addition to the above options, the proposal presents a measure to allow for addition of types of intrinsic risk characteristics to the prohibited organisms list (Schedule 2 of the Act) which will prohibit certain organisms from entry to New Zealand, and which prevents ERMA from considering applications for these organisms. It also allows for a simpler mechanism to remove organisms from the prohibited list.

If this provision was adopted, the likely effect will be to remove from consideration some types of new organisms (and so any risks which arise from their possible approval) but there may be lost opportunities, through removal of species from consideration which might be used for example in research.

There would be positive effects of reduced risk by the removal of new organisms from consideration, which would accrue to society as a whole. However, this has to be balanced by the potential dynamic effects on researchers, who may not undertake research they would otherwise have considered, the negative effects of potential lost opportunities for technological advancement and the potential loss of innovation. These potential negative effects would accrue to any potential applicant for approval, be they either business or the government (who may wish to seek approval for biological control agents) and would affect researchers most directly, but would also accrue indirectly to society as a whole. The mechanism to simplify the removal of organisms from the prohibited list will address in part some of these negative effects, by allowing for the situation where new information or new techniques with an organism allow for its safe use.

A further component of this proposal is to strengthen the enforcement regime by providing reserve enforcement powers to the chief executives of the Ministry for the Environment and ERMA, for use in special circumstances. This proposal would operate in limited cases and add minor costs to the enforcement regime.

The possible regulatory impacts of the additional regulation-making power have not been determined. This proposal was inserted into the paper just prior to submission to Cabinet Office and, therefore, no analysis has been done on it.

OTHER COSTS AND BENEFITS OF CONDITIONAL RELEASE

Conditional release is a tool for enabling the greater use of new organisms for economic enterprises, by providing for release in cases where an uncontrolled release would generate too many risks for people and the environment.

Business is expected to apply for approvals for cases where the benefits of the release would outweigh the costs of meeting conditions. In addition, conditions on an approval will require checking for compliance. Currently, compliance and enforcement activity is a cost to the Government.

SUMMARY

Compared to the status quo of having only field trials and general release approvals, conditional release under any of the above options is considered to:

- accelerate use of new organisms (including genetically modified organisms) that are assessed by ERMA to generate a positive net benefit
- increase the economic benefits from application of this new technology
- while minimising the risks of negative impacts including on those for whom GMOs are offensive to their cultural, spiritual or ethical values

Consultative programme undertaken

This paper uses the submissions from an extensive public consultation on the discussion paper *"Improving the Operation of the HSNO Act for New Organisms: Including Proposals in Response to Recommendations of the Royal Commission on Genetic Modification"*. Officials encouraged submissions through meetings with many different stakeholder groups and at seven hui.

There was general support for conditional release approvals from users of biotechnology (e.g. breeders, researchers) provided that reasonable, relevant and practicable conditions were imposed on approvals. Researchers considered conditional release would facilitate research, particularly for environmental impacts by providing an added level of assurance about potential risks. This group also saw conditional release as an essential component of implementing coexistence for primary production.

On the other hand a large group of submitters expressed doubts that conditions such as buffer zones would work for GMOs. They were concerned that there was a lack of information on possible long-term environmental adverse effects and questioned the viability of co-existence.

Maori expressed a similarly broad range of views to those of other submitters.

The following government agencies were consulted and actively involved in the preparation of the Cabinet paper; Ministry of Agriculture and Forestry, Department of Conservation, Ministry of Economic Development, Ministry of Foreign Affairs and Trade, Ministry of Health, Ministry of Justice, Department of Prime Minister and Cabinet, Ministry of Research Science and

Technology, Te Puni Kokiri, the Treasury, the Environmental Risk Management Authority, and the New Zealand Food Safety Authority.

Government agencies have contributed to the proposed options for defining and implementing conditional releases as discussed above. Departments have differing views on the best options for putting together the regulatory package.

Business Compliance Cost Statement

1. Sources of compliance costs

The compliance costs from a conditional release cover the costs of identifying and understanding the regulatory requirements, and the costs of making an application. They may include costs of buying in specialist services, training or employing new staff.

2. Parties likely to be affected

The parties affected directly will be applicants importing or developing new organisms for conditional release in New Zealand. The sector is broad and highly significant in the New Zealand economy, covering all areas of biologically based industries interested in the commercialisation of new organisms. For example, it would encompass all agricultural, horticultural, forestry, and fisheries industries.

3. Estimated compliance costs of the proposal

The costs of understanding the new procedures for a conditional release are considered small relative to the application itself, as the procedure will be similar to applications for field trials and for general release with which the industry is familiar. The cost of conditional release applications are expected to be similar to other notified new organisms applications. To date these have ranged from an average of $47000 to $84000 depending on the type of application, with the costs presently shared between the applicant and the Government.

4. Longer term implications of the compliance costs

The application costs continue into the future. Over time, the costs of understanding the new process will reduce.

5. Level of confidence of compliance cost estimates

Because the assumptions for application costs are based on ERMA's experience, there is a good level of confidence for these costs.

6. Key compliance cost issues identified in consultation

Submitters generally proposed that the costs be borne by those who benefit. The research and business sectors considered that the government continue to support application costs because they considered there was a public benefit from introducing new technology. Other submitters

considered that the applicants received all the benefits and proposed that they bear the full cost of applications including the cost of checking compliance with conditions.

7. Overlapping compliance requirements

The proposed changes clarify the interface between the HSNO and Biosecurity Acts.
The Resource Management Act (RMA) has not been used to control the use or effects of genetically modified organisms to date. With the introduction of conditional release under the HSNO Act, territorial authorities may be asked to consider introducing additional controls under the RMA. Section 32 of the RMA will require a territorial authority to demonstrate why any such controls are necessary and what effects they are addressing which have not already been dealt with under the HSNO Act. However, conditional releases are a new provision and the Ministry for the Environment will monitor how the interface between the RMA and the HSNO Act is working.

8. Steps taken to minimise compliance costs

A communication strategy may be needed to inform applicants of the legislative changes and their potential obligations under the new legislation. ERMA will advise interested parties of any legislative changes, and their impacts, by means of seminars, information sheets, web-publishing and individual attention.

In terms of managing the information requirements at the time of application ERMA already provide significant support to applicants and this will apply to applicants for conditional release. Support is in the form of documentation such as application guides including outlining information requirements and technical guides on risk assessment. All of these initiatives serve to educate and inform applicants so that compliance costs in preparing applications are minimised.