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 3: Streamlining the Approval Process for Medicines That Are or Contain New Organisms

Proposal

1. This paper provides advice to Ministers on proposed amendments to the Hazardous Substances and New Organisms (HSNO) Medicines, and Agricultural Compounds and Veterinary Medicines (ACVM) Acts arising from recommendations of the Royal Commission on Genetic Modification. It covers amendments to streamline the assessment process for animal and human medicines that are or contain new organisms, and proposes the introduction of a scheme to allow regulatory agencies to quickly assess and approve agricultural compounds and medicines required urgently to manage an emergency.

Executive summary

2. This paper:

- discusses the recommendations made by the Royal Commission to modify the existing regulatory framework after it found significant problems with the approval process for medicines containing Genetically Modified Organisms (GMOs), and for medicines containing GMOs that may be required for use in an emergency

- responds to public consultation on a series of proposals disseminated in the discussion paper *"Improving the operation of the HSNO Act for new organisms"* and in the *"Governments response to the report of the Royal Commission on Genetic Modification"*

- proposes changes to the HSNO, Medicines and ACVM Acts to streamline and reduce the compliance costs associated with applications to market animal and human medicines that are or contain new organisms

- proposes changes to the HSNO, Medicines and ACVM Acts to remove a regulatory barrier which delays access to agricultural compounds or medicines required urgently to respond to environmental, or health emergencies or acts of bio-terrorism

Background

3. In 2001, in response to the report of the Royal Commission, Cabinet directed officials to report on options to reduce duplication and to streamline the approval processes for human medicines containing genetically modified organisms under the Medicines Act and the HSNO Act (Cab Min(01) 34/14 refers). A discussion paper was published in 2002 containing a number of proposals developed by officials.

Section A: Need to streamline approval process

4. Currently, human and animal medicines that are or contain new organisms (including GMOs) require a dual assessment and approval by either Medsafe or the ACVM Unit of the New Zealand Food Safety Authority (NZFSA) for safety, quality and efficacy under the requirements of the Medicines Act or the ACVM Act respectively, and by ERMA for public health and environmental effects by the HSNO Act. The Royal Commission identified that the cost of this dual evaluation may be so high that it will prevent animal and human medicines from entering the New Zealand market, depriving New Zealanders of potential health and other benefits.

5. While the assessments of human or animal medicines undertaken by Medsafe, ACVM and ERMA have many similarities with respect to safety, quality and efficacy, they are performed from fundamentally different perspectives i.e. Medsafe-human risk:benefit, ACVM-animal risk:benefit, ERMA-environmental and public health risk:benefit. In addition, only ERMA is required to consult on applications and to consider cultural aspects of applications.

6. [Withheld under sections 9(2)(f)(iv) and 9(j) of the Official Information Act in order to: maintain the constitutional conventions for the time being which protect the confidentiality of advice tendered by Ministers of the Crown and officials; and enable a Minister of the Crown or any Department or organisation holding the information to carry on, with out prejudice or disadvantage, negotiations (including commercial and industrial negotiations).]

Results of public consultation

7. The consultation document sought input on whether the public agreed that the approval process for GMO medicines, both animal and human, should be streamlined. The paper also canvassed opinion on whether all aspects of the current environmental risk assessment were essential for GMO medicines. Four models of evaluation that would reduce duplication and streamline the process were presented. The models ranged from modification of the status quo, through approval by Medsafe or ACVM only; to hybrid evaluations conducted by either Medsafe, ACVM or ERMA as lead agencies with input from appropriate agencies in the evaluation process.

8. The substantive submissions from industry, professional organisations and research organisations confirmed that the potential for high compliance costs to deprive the NZ public (and animals) of new safer, and possibly more effective human or animal medicines were of great concern. Evidence was provided that following the introduction of dual evaluation (both ACVM and HSNO Act) for animal medicines containing hazardous substances the number of applications received decreased by two thirds. Some submissions raise the issue that by deterring human or animal medicines from entering the market, the dual system may lead to the prolonged use of more toxic and less environmentally safe human or animal medicines in this country. Submissions from the general public made little or no reference to the impact of compliance costs.

9. Submissions from industry, professional organisations and research organisations favour streamlining. Amongst these submissions, there is a great deal of support for individualised risk:benefit assessments of GMO medicines, with the decision made outside of ERMA by Medsafe or ACVM. Countering these submissions members of the public, and "environmental" support groups, argue strongly for the maintenance of ERMA conducting a full environmental risk assessment and public consultation for all GMO medicines. The hui held to consult on the proposals contained in the discussion paper were similarly divided with some iwi supporting improved access to medicines containing GMOs, and others opposed to the introduction of any GMOs, including those used in human medicines.

Analysis of submissions

10. While the consultation paper discussed arrangements for new GMO medicines, officials noted that implementation of the proposed models would result in human or animal medicines containing non-GMO new organisms still requiring dual evaluation. As all new organisms are otherwise subject to the same regulatory controls it is clearly illogical to differentiate between GMO and non-GMO organisms. Officials therefore propose that any changes necessary to streamline the approval process should apply to all human or animal medicines that are or contain new organisms.

11. In addition, officials note that when considering the streamlining of assessment, the eventual framework must cover not only commercial supply of a finished human or animal medicine (as described in the consultation paper), but also approval for use in clinical trials, and the "compassionate use" of medicines containing new organisms for human and animal health.

12. Officials agree that the current "dual evaluation" process adds significant compliance costs on manufacturers and sponsors of medicines that are or contain new organisms. These costs may have adverse effects on a number of Government strategies designed to facilitate the growth of the knowledge economy and biotechnology sector in New Zealand. In addition, unless the compliance costs of entering the New Zealand market are reasonable, companies may choose not to market their human or animal medicines in this country.

13. While the requirements of HSNO contribute to compliance costs, and the fees may be considered to be high relative to the potential market, the need for pre-market environmental risk assessment is not unique to New Zealand. The European Union requires all GMO human or animal medicines to undergo an environmental risk assessment, including a public consultation phase, before entering the market. Where the human or animal medicine is undergoing evaluation by the centralised European Medicines Evaluation Agency procedure, the onus of conducting the environmental impact assessment falls on that agency; otherwise the evaluation is conducted by a country-specific competent agency. Irrespective of which agency performs the assessment, the information requirements and methodology of conducting the assessment is standardised. In Australia, the medicines regulator currently performs risk:benefit assessments on all human medicines, including those containing new organisms and provides an assessment of the public health impact of any medicines containing a GMO into the assessment undertaken by the Office of the Gene Technology Regulator (OGTR). The environmental risk assessment however, and final decision on controls on the medicine is conducted by the OGTR. These approaches provide possible models for streamlining the current New Zealand system.

14. As the international direction in medicines regulation is towards increased involvement of the medicines regulator, it is proposed that amendments to legislation be made to streamline assessment of applications for animal and human medicines that are or contain new organisms, by involving the appropriate medicines regulator in the process.

Proposed new regulatory model

15. The proposed regulatory model has three key elements:

(i) for animal and human medicines that are or contain new organisms (including GMOs) criteria will be established to define "low-risk circumstances"

(ii) for medicines that meet these low-risk criteria, ERMA will be given powers under the HSNO Act to delegate consideration of applications for release of medicines containing new organisms to the Chief Executive of any government regulatory agency responsible for assessment and approval of animal or human medicines prior to their entry onto the New Zealand market (e.g. the ERMA itself, the NZFSA or Medsafe)

(iii) approvals under HSNO Act for the release of animal and human medicines, that are or contain new organisms, can be given with or without controls

16. Any application to the lead agency (Medsafe, or ACVM), by a sponsor of a medicine for consent to market, to conduct a clinical trial, or import or administer a medicine that is or contains a new organism, would be required to supply an environmental and public health risk assessment. The lead agency would collect the fee specified by the HSNO Act for this activity and perform the risk assessment for these medicines. If the medicine meets the low risk criteria the lead agency would grant an approval for the human or animal medicine under the HSNO Act.

17. To further streamline the process and reduce compliance costs, it is proposed that the criteria that would define the low risk circumstances would be similar to that already required by Section 35 of HSNO, i.e. the minimum data and standards requirements for rapid approval of a new organism. The criteria would be based on the nature of the new organism (including its construct if it is a GMO), its likely dose and route of administration, its metabolism and excretion, the controls on its use, the likely environmental exposure (based on the number of patients likely to be exposed), the potential benefit and risk to human and/or animal health, an assessment of the likely effect and/or persistence of the GMO in the environment and consideration of the controls that can be placed on the human or animal medicine through the legislation administered by the lead agency and HSNO.

18. Where the application does not meet the low risk criteria, i.e. the medicine is assessed as posing significant public health, environmental, or cultural risks, a full ERMA application including public consultation would be required. At this point the lead agency would inform the human or animal medicine sponsor that it cannot approve the medicine using the low risk criteria and that the sponsor must submit an application to ERMA. Unless otherwise instructed by the human or animal medicine sponsor, the lead agency would then continue with its evaluation of the human or animal medicine. To clarify responsibilities and reduce sponsor confusion, where a human or animal medicine requires ERMA assessment, the lead agency must not be able to approve the human or animal medicine until such times as it has been provided with evidence that ERMA has completed its assessment and issued approval for that human or animal medicine. Given that the evaluation processes by the lead agency and ERMA can occur in parallel, and the statutory timelines for ERMA assessment are shorter than those required by the Medicines Act, (and are built into the requirements of the ACVM Act), this approach will not unduly delay the approval times for medicines.

19. To reduce duplication of work officials have proposed that where a human or animal medicine has to go through a full ERMA assessment, the lead agency should supply ERMA with its risk:benefit assessment to inform the ERMA decision-making process.

Implementing proposed new regulatory framework

20. The HSNO Act has powers that allow certain activities performed under the Act to be delegated to other persons or agencies. The HSNO Act also permits a rapid assessment of certain human or animal medicines. Officials have proposed that the regulatory model described above could be introduced by amending the HSNO Act to provide for the rapid approval of low risk animal and human medicines that are or contain new organisms. This section would include details of criteria for low risk, the minimum data required for risk assessment of medicines and include consideration of the controls which could be placed on access and use of any human or animal medicines contained in the legislation administered by the lead agency.

21. Once the HSNO Act is amended, this activity could be delegated to either the lead agency or some other third party e.g. Chief Executive Officer of ERMA. In delegating this function, the lead agencies would be administering HSNO, in addition to their own legislation, and where a

human or animal medicine meets the assessment criteria, would be granting approval under HSNO. The lead agency would also collect any fee required by HSNO for performing this function. The activities of the lead agencies with respect to administration of the specific section of HSNO would be required to consider the requirements of part II of the legislation (which relates to giving consideration to a range of matters including cultural issues relating to the application), and would be subject to oversight by ERMA, and all the other controls present within the HSNO legislation, including Ministerial call-in.

Implications of proposed new regulatory framework

22. A number of consequences follow from the above proposals, the most obvious being that not all medicines that are or contain a new organism will be subject to full ERMA assessment. Medicines that are or contain a new organism (including some GMOs) meeting the low risk criteria will not be subject to public consultation. . Implementation of the proposed framework is not a significant policy shift away from that adopted with the creation of the HSNO legislation, as the decision to approve the release of medicines containing new organisms that do not exceed the low risk threshold, while based on expert independent advice, will still be made under the HSNO Act and under the scrutiny of the Authority.

23. While the proposal gives ACVM delegated powers to approve animal medicines that are or contain new organisms, similar powers do not exist for animal medicines that are hazardous substances. This is partly because, at present, no low-risk criteria have been established for hazardous substances. Such criteria are, however, currently under consideration as part of a review of the substances side of the HSNO Act. Finished-dose form human medicines that are hazardous substances are exempt from the HSNO Act subject to the Ministry of Health completing regulations under the Medicines Act to control the environmental effects.

24. [Withheld under section 9(2)(g)(i) of the Official Information Act in order to maintain the effective conduct of public affairs through the free and frank expression of opinions by or between or to Ministers of the Crown.]

Conclusion

25. These proposals are consistent with the Governments desire to lower compliance costs of regulation and the Commission's desire to streamline the approval process and approve access to medicines.

26. In addition, requiring that applications to medicines regulators contain environmental and public health risk impact information is in keeping with the future direction of medicines regulation internationally.

27. [Withheld under section 9(2)(g)(i) of the Official Information Act in order to maintain the effective conduct of public affairs through the free and frank expression of opinions by or between or to Ministers of the Crown.]

28. The proposal creates the opportunity for a single agency assessment for medicines containing low risk new organisms. Many of the advantages in terms of reduced compliance costs, streamlining, and duplication of work, are deliverable irrespective of whether the low risk environmental risk assessment is delegated to the lead agency or not. Even should a decision be made that the trans-Tasman medicine regulator not perform environmental risk assessments, the introduction into the HSNO Act of these proposals will reduce compliance costs for many human or animal medicines and streamline the assessment of applications.

Section B: Need to streamline approval processes for agricultural compounds and medicines required urgently to manage emergencies

Background

29. As described in Cab Min(01) 34/14 the Royal Commission identified that the current legislative framework for approval of useful therapeutics including vaccines containing live genetically modified organisms could mean New Zealand may be at risk in an emergency situation. The Royal Commission recommended that steps be taken to resolve this problem by requiring regulatory agencies, such as Medsafe, to identify such therapeutics and then organise to have them approved through the normal assessment processes in advance of when they would be needed. Cabinet acknowledged the Commission's concerns and instructed officials to explore the possibility of implementing a risk management strategy to manage the risk of epidemics of animal or human infectious diseases.

30. Proposals for policy change did not form part of the discussion paper *"Improving the operation of the HSNO Act for new organisms"*, and there has been no public consultation, or consultation with Maori, on the following proposals. However, as it is proposed here to make amendments to the HSNO Act, the current HSNO Act (new organisms) amendment bill offers the opportunity to implement these changes. Because there has been no consultation, the scope of the proposed changes is limited.

Problems with current legislation

31. The Royal Commission identified that under the current legislative framework it may not be possible to quickly import vaccines or medicines containing live GMOs necessary to contain an epidemic. This situation arises as although the HSNO Act 1996 exempts hazardous substances and new organisms required for use in an emergency where the circumstances are unforeseeable from the need to be assessed by ERMA, it requires hazardous substances and new organisms required to manage an emergency where the emergency was foreseeable to undergo a pre-approval process involving full ERMA assessment and public notification and/or consultation. The approval process takes a minimum of 50 days. [Withheld under section 9(2)(h) of the Official Information Act in order to maintain legal professional privilege.] officials believe that the current laws require **all** human or animal medicines that are or contain a new organism, even those needed urgently to manage an emergency e.g. a vaccine for foot and mouth disease, must undergo full ERMA assessment, including public notification and consultation, irrespective of the immediate need to protect animal and public health.

32. Agricultural compounds and medicines required for use in biosecurity, animal health or public health emergencies could potentially contain hazardous substances or new organisms. A number of possible emergency scenarios beyond infectious diseases and bio-terrorism, which require emergency regulatory activity also exist e.g. loss of an essential medicine from the New Zealand market secondary to a manufacturing failure. It would therefore be prudent to ensure that any risk management strategy devised by officials for emergency supply of such agricultural compounds and medicines, is flexible enough to cope with the full range of possible emergencies that may arise.

Analysis of Royal Commission's recommendation

33. Officials have considered the pre-approval mechanism recommended by the Royal Commission and identified a number of deficiencies which make it unsuitable for managing the range of emergencies that may require urgent regulatory action including:

- pre-approval does not ensure that an agricultural compound or medicine will actually be available when it is needed
- the need to pre-approve all agricultural compounds or medicines within a certain class e.g. there are a number of smallpox vaccines, all would have to be pre-approved to ensure that an approved vaccine would be available
- the high compliance costs on both industry and Government of requiring a large number of applications to be submitted and assessed by ERMA and other regulators; when there is no market for the agricultural compound or medicine and no income for the sponsor unless an emergency occurs
- the potential negative perceptions of an approval of e.g. a vaccine for foot and mouth disease, to undermine agricultural exports by raising questions about the disease-free status of New Zealand
- the implications for companies marketing worldwide if an agricultural compound or medicine was assessed for pre-approval and declined

Proposed new regulatory framework

34. Officials have proposed that pre-approval should not form the sole basis of Government's risk management strategy and that legislation be amended to facilitate emergency approval of agricultural compounds or medicines needed in an emergency, within the shortest possible timescale.

35. Removing the clause relating to foreseeable emergencies from the HSNO Act would go some way towards correcting the regulatory barrier to quick action. However, officials have indicated that the end result of completely removing this clause i.e. that any agricultural compound or medicine necessary in an emergency does not require any form of ERMA or environmental oversight is not acceptable as it may place the public at unnecessary risk. Officials therefore propose that there should be, in the HSNO Act, a new "fast-track" assessment and approval process for agricultural compounds, and medicines required for use in an emergency. This assessment would be based upon the criteria for rapid approval described in Section 47 of the HSNO Act, amended to allow public health emergencies to be managed by this mechanism.

36. A consequence of this proposal would be that new organisms that breach the minimum standards described in HSNO, i.e. that can persist in the environment, or affect native species, could be introduced without consultation, if the severity of the emergency required these actions.

37. Changes to the Medicines Act will be also be required to facilitate "emergency access" to human medicines, as the minimum amount of information the current Act requires the Minister to consider before she can approve a medicine is in excess of that which may be available or appropriate in a serious emergency. Amendment to the ACVM Act may also required to remove the need for public notification within that Act for agricultural compounds where approval is necessary to manage an emergency situation.

38. While legislation may include processes to allow Ministers to formally declare emergencies, in most cases, agricultural compounds or medicines required to resolve particular problems are managed outside of formally "declared emergencies". When a possible emergency presents itself, officials in the lead regulatory agencies construct management plans and institute whatever steps are necessary to obtain whatever agricultural compound or medicine required to manage the emergency. For the purposes of the proposed amendments to legislation, an emergency would be any adverse event considered to be an emergency by any one of the Health or Biosecurity Ministers where, senior officials in the lead agency, having formed a management plan, recommend that a particular agricultural compound or medicine is required urgently. In formulating the management plan, senior officials will take into consideration: the nature of the emergency; the treatments available to manage the emergency including any data concerning risks

and benefits, and the risks and benefits of using the agricultural compound or medicine recommended for approved under the "fast-track" approval mechanism against the risks of not treating or inadequately treating the emergency.

39. In normal circumstances the minimum dataset likely to be considered for "fast-track" approval may include: any expert reports available from the sponsor company or overseas regulatory agencies; confirmation that the agricultural compound or medicine is made in to appropriate Good Manufacturing Practices; examination of the labelling of the agricultural compound or medicine; provision of data that the agricultural compound or medicine is approved in an overseas market which is recognised as competent by the New Zealand regulator e.g. Australia, EU, UK, USA, Canada; and methods to manage the agricultural compound or medicine during the emergency. Depending on the circumstances of the emergency, the minimum dataset could, if necessary, require data to support a minimum environmental risk assessment. Where it is deemed necessary to introduce a new organism that breaches the minimum standards described in HSNO, the ERMA "fast-track" assessment" should involve input from affected government agencies, e.g. the Department of Conservation.

40. In view of the restricted dataset to be examined, it is proposed that approvals based on "fast-track" assessment be limited in their duration to a defined time limit e.g. a maximum of two years. Depending on the clinical circumstances, access to the agricultural compound or medicine, may need to be constrained to only certain persons e.g. medical practitioners, MAF officials, veterinarians. In addition, agricultural compounds or medicines introduced on the basis of "fast-track" approval for emergency purposes will continue to be considered "new" for the purposes of the HSNO Act and use beyond the emergency period, or for other purposes, an application and approval by ERMA will still be required. This issue links to paragraph 13 of Paper 4 "Conditional Release".

41. Officials do not propose to amend the controls or requirements for invoking emergency powers in the Health and Biosecurity Acts, other than to introduce emergency approval of medicines into the Medicines Act.

Conclusions

42. The ability to respond to an emergency in a timely and appropriate manner must be weighed against due process of law. In officials opinion it is appropriate in a biosecurity, animal health or public health emergency that agencies have the flexibility to respond quickly to the emergency risk while doing their best to protect the public health and the environment. Officials believe that the proposal to still require safety, quality, efficacy and environmental risk from use and disposal, based on an assessment of an abbreviated dataset meets these requirements.

Timetable implications

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

Financial implications

44. There are no financial implications associated with this paper.

Human rights

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

Legislative implications

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

Regulatory impact and compliance cost statement

47. The Regulatory Impact and Business Compliance Cost Statement is attached to this paper 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.

48. There are no business compliance costs associated with the proposal for expediting emergency use approvals for medicines. There are important reductions in business compliance cost for the proposals for approval of medicines, which are or contain new organisms. These are offset to a small extent by the costs for business applicants to become familiar with the revised process.

Gender implications

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

Disability perspective

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

Publicity

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

Consultation

52. Details of the consultation for this suite of papers have been outlined in *Paper 1: Overview*. With respect to emergency approvals, pproposals for policy change were not included in the discussion paper *"Improving the operation of the HSNO Act for new organisms"*.

Recommendations

53. It is recommended that Ministers:

a) **Agree** to streamline the evaluation process for animal and human medicines that are or contain a new organism, including medicines containing Genetically Modified Organisms (GMOs) by:

I Amending the Hazardous Substances and New Organisms Act to:

(i) create a new rapid assessment process for animal or human medicines that are or contain low risk new organisms, consisting of,

(a) criteria that define the circumstances for low risk including

- its likely dose and route of administration
- its metabolism and excretion
- the likely environmental exposure
- the likely effect and/or persistence of the new organism in the environment

(b) information that would be provided with applications

(c) the ability to approve applications that meet the low risk criteria with or without controls

(ii) enable the power to consider and approve applications for release of animal and human medicines that are or contain low risk new organisms (including GMOs) to be delegated to the Chief Executive of any government regulatory agency responsible for assessment and approval of animal or human medicines prior to their entry onto the New Zealand market

II Amending the Medicines Act to allow Medsafe (the current human medicines regulator) to:

(i) perform rapid approvals under delegated authority from Environmental Risk Management Authority (ERMA)

(ii) require a sponsor company to obtain the consent of Medsafe before providing a medicine that is or contains a new organism under any exemption contained within the Medicines Act

(iii) require a practitioner, or any other person, to seek the approval of Medsafe before procuring a medicine that is or contains a new organism under any exemption to the Medicines Act

(iv) provide its risk:benefit assessment to ERMA of any medicines that require a full ERMA assessment

(v) approve human or animal medicines requiring a full ERMA assessment only after it has received approval from ERMA

b) **Note** that ERMA will conduct a full assessment of applications for the release of new organism only where the organism is either not a medicine, or does not meet the rapid approval criteria

c) **Agree** to amend legislation to introduce a "fast-track" approval mechanism for any agricultural compound or medicine urgently required for use in an emergency by:

(i) introducing into the HSNO Act (and if required the ACVM and Medicines Acts) the ability to quickly assess and approve in an emergency any agricultural compound or medicine where an emergency is any adverse event considered to be an emergency by any one of the Health or Biosecurity Ministers

(ii) introducing a requirement ensuring that ERMA consult with affected government agencies when it conducts a "fast-track assessment" for an agricultural compound or medicine required urgently to manage an emergency, and that the existing provision that the ERMA have particular regard to the views of DoC is retained

(iii) introducing a requirement that an agricultural compound or medicine approved under the HSNO "fast-track" approval process for use in an emergency continue to be considered "new" with respect to that legislation

(iv) creating within the Medicines Act, and if necessary the ACVM Act, the ability to conduct "fast-track" approvals defining the minimum data requirements for such approval

(v) removing the need for public notification from the ACVM Act for agricultural compounds identified as required urgently to manage both declared and undeclared emergencies

d) **Agree** that agricultural compounds or medicines introduced on the basis of "fast-track" approval for emergency purposes will continue to be considered "new" for the purposes of the HSNO Act

Hon Marian L Hobbs
Minister for the Environment

Annex 1

Regulatory impact and compliance cost statement

Nature and magnitude of the problem and the need for government action

Medicines

Human and animal medicines are being developed that contain or are new organisms (including genetically modified organisms).

The current regulatory framework requires that such medicines be approved under the HSNO Act by the Environmental Risk Management Authority (ERMA) for the new organism, and also approved as a medicine. If the medicine is a human medicine it is approved by Medsafe under the Medicines Act, and if it is an animal medicine, it is approved by the Agricultural Compounds & Veterinary Medicines (ACVM) Group under the ACVM Act.

The dual approval involves duplication of the processing costs of each agency. The assessment of a new organism release under the HSNO Act requires public notification and involves the costs of a hearing where this is requested. This level of regulatory cost is considered inappropriate for medicines involving new organisms that fit the category of low risk organisms under the HSNO Act.

Emergency Approvals

Currently government agencies responsible for emergency management relating to health and bio-security matters are expected to anticipate likely emergencies and obtain prior approval through the public processes of the HSNO Act for emergency use approval.

Experience suggests that anticipating likely emergencies is impractical and the public process would further delay emergency response. For health and bio-security emergencies, there can be significant risks to the health and safety of people and environment from any delay in emergency response.

Public policy objective

The policy objectives are:

- to reduce the regulatory costs for approval of human and animal medicines containing low risk new organisms

- to reduce the delay to assessing any agricultural compound or medicine needed for response to a health or bio-security emergency

Feasible options for achieving the desired objective

Non-Regulatory Measures

No non-regulatory measures exist which are capable of achieving the objective for the approval of human and animal medicines containing low risk new organisms, nor for the rapid approval of medicines needed to respond to a health or bio-security emergency.

Status Quo

Medicines

The current requirements for a human medicine that is or contains a new organism are:

- a new organisms approval from ERMA in terms of its risks to health and safety of people and the environment
- a medicines approval by Medsafe in terms of its safety and efficacy as a medicine administered to a person

The current requirements for an animal medicine that is or contains a new organism are:

- a new organisms approval from ERMA in terms of its risks to health and safety of people and the environment
- a veterinary medicine registration by the ACVM Group in terms of its safety and efficacy as a medicine administered to an animal and any risks to trade, bio-security and food standards associated with its use

Emergency Approvals

Government agencies are required to obtain a prior approval through the public processes of the HSNO Act for any agricultural compound, animal or human medicine that might be needed in a health or bio-security emergency.

Regulatory Measures

Options for reducing the costs of approving medicines containing low risk new organisms based only on one approval under one of either the medicines or new organisms legislation were rejected as leaving important gaps in the assessment.

Accordingly the following package of regulatory measures was devised that integrated the considerations from each of the legislative requirements:

- Within the HSNO Act:
  - providing a rapid assessment process for animal and human medicines containing new organisms that meet low risk criteria
  - providing the ability to approve such applications with controls
  - enabling the Authority to delegate these applications its Chief Executive or to other government regulatory agencies (which will allow one agency (Medsafe or ACVM as appropriate) to do the work)

- Within the Medicines Act:
  - enabling Medsafe to perform rapid approvals under delegation from ERMA
  - in the case of these new organism medicines, limiting the exemptions that apply under Medicines Act (e.g. exemptions that allow medical practitioners and veterinarians to use medicines without Medsafe approval)
  - in the case where the new organism is not low risk and requires ERMA assessment, enabling the ERMA consideration to be integrated as part of the Medsafe approval

To reduce the delay to assessing any agricultural compound or medicine needed for response to a health or bio-security emergency; there were no regulatory options available other than the following:

- Within the HSNO Act:
  - removing the distinction of foreseeable and unforeseeable emergencies (a foreseeable emergency expected that an agency could anticipate and plan for the emergency and required a prior approval)
  - to enable the use of agricultural compounds and medicines in an emergency, provide for "fast-track" assessment by the ERMA, i.e. an approval without public notification but requiring consultation between affected government agencies
  - limiting such approvals to emergency use

- Within the Medicines and ACVM Acts:
  - for human medicines, and agricultural compounds and veterinary medicines, enabling Medsafe and ACVM Group respectively to approve by a "fast-track" assessment; i.e. by the same process as proposed in the HSNO Act

Net benefit of the proposal

Medicines

Industry and professional and research organisations have advised that, with costs under the current dual application, companies were choosing not to market their product in this country, depriving New Zealand of new, safer, more effective medicines. Current costs may therefore be adversely affecting Government strategies to facilitate the growth of the knowledge economy and biotechnology sector in New Zealand.

The costs to importers and manufacturers for obtaining a single approval for release of a low risk new organism medicine are expected to reduce from $47000 (ERMA's estimate for a notified new organism release) to $5000 (estimate for a non-notified release).

This cost reduction is expected to overcome the reduction in new human and animal medicines coming onto the New Zealand market identified above, with consequential benefits to the health and wellbeing of people and to our domestic and commercial animals.

Without any data at this point, it seems reasonable to assume that the impact on ERMA's budget and workload would be neutral, that is, the increase in the volume of applications would counteract the reduced revenue per application.

Emergency approvals

Facilitating emergency approval of agricultural compounds and medicines for health and bio-security emergencies will avert significant risks to the health and safety of people and environment from any delay in emergency response. Constraints on the approval process are considered to limit the risks of not enabling public input to the process.

Consultation

This paper is based on an extensive public consultation process. Submissions were received in response to the public 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 by attending meetings organised by a wide range of different stakeholder groups. In addition, seven hui were held for Maori and detailed notes taken by officials. Group and individual submissions on the discussion document were also received from the Maori community. All submissions have been considered in preparing this paper and a detailed summary of submissions is in preparation by an independent contractor for publication.

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.

The government agencies needing agricultural compounds and medicines for use in health and bio-security emergencies were key advocates for these proposals and fully support the agreed options.

Business Compliance Cost Statement

There are no business compliance costs for emergency approvals because the process is confined to affected government agencies. Accordingly, the following relates to the compliance costs for medicines approvals.

Sources of compliance costs

Time to understand the revised procedures for a medicines approval. The significant reduction in application costs is identified in the RIS above.

Parties likely to be affected

The parties affected are applicants for (importers and manufacturers of) medicines that are or contain new organisms. Medsafe estimate that approximately 5 importers and manufacturers of human medicines might be expected to make application for new organism medicines. The ACVM Group estimate that a similar number of applications from importers and manufacturers of new organism animal medicines.

Estimated compliance costs of the proposal

No quantifiable analysis of the costs to understand the revised procedures for a medicines approval has been done. However, the costs are considered to be minor. The reduction in compliance costs by enabling a single approval using the low risk criteria is estimated as $42,000 per application.

Longer-term implications of the compliance costs

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

Level of confidence of compliance cost estimates

Because the assumptions for the estimated costs are based on ERMA's experience, there is a high level of confidence that the compliance costs will be greatly reduced.

Key compliance cost issues identified in consultation

Consultation with interested and affected parties identified the compliance costs of the dual approval.

Overlapping compliance requirements with other agencies

There are no overlapping compliance requirements with other agencies following this proposal.

Steps taken to minimise compliance costs

The ERMA, Medsafe and ACVM will ensure potential applicants receive information on the revised medicines approval process through information sheets made available through ERMA, ACVM and Medsafe websites, and through agency newsletters.