Office of the Minister for the Environment

Chair

Cabinet Business Committee

Regulations prescribing information that must be provided with applications to conditionally release genetically modified organisms under the Hazardous Substances and New Organisms Act 1996

Proposal

1. This paper recommends that the Cabinet Business Committee authorise the submission to the Executive Council of regulations under section 140(1)(l) of the Hazardous Substances and New Organisms (HSNO) Act 1996.

2. The Hazardous Substances and New Organisms (Genetically Modified Organisms - Information Requirements for Segregation and Tracing) Regulations prescribe information on segregation and traceability that applicants must provide to the Environmental Risk Management Authority (ERMA) with applications for conditional release of genetically modified organisms (GMOs).

Executive summary

3. I recommend that the Governor General, by Order in Council, promulgate regulations under section 140(1)(l) of the Hazardous Substances and New Organisms (HSNO) Act 1996 to prescribe information that must be provided to ERMA with any application to conditionally release a genetically modified organism (GMO) submitted under section 38A of the HSNO Act (*Application for approval to import or release new organism with controls*).

4. The proposed regulations give effect to policy approved on 14 July 2008 by the Cabinet Business Committee (having been authorised by Cabinet with Power to Act [CAB Min (08) 27/5]) and confirmed on 21 July 2008 by Cabinet to prescribe:

   > *requirements for segregation and traceability schemes that the Environmental Risk Management Authority (ERMA) would have particular regard to imposing as controls when considering applications to conditionally release a GMO, particularly any [genetically modified (GM)] crop*. [CBC Min (08) 20/24 and CAB Min (08) 28/1C refer].

5. ERMA would use the information applicants provide under the new regulations to determine what controls it considers necessary to prevent or manage risks following conditional release of a GMO. The proposed Order in Council would serve to reinforce ERMA's existing discretion to require relevant information to be provided in applications for the conditional release of GM crops.

6. The mandatory requirement to provide this information will signal clearly to all parties that ERMA will specifically consider controls relating to segregation and traceability during consideration of applications to conditionally release GMOs.

Background Policy

7. The purpose of the HSNO Act is to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms (including GMOs).

8. The regulations have been developed as a means to give effect, in part, to the Labour-led Government Co-operation Agreement with the Green Party of Aotearoa New Zealand on GMOs [CAB (08) 334; CBC Min (08) 20/24 and CAB Min (08) 28/1C refer].

9. The Co-operation Agreement states:

> *Both parties to this agreement accept that it is important that New Zealand consumers and producers must maintain the right to grow and/or choose to consume GE [genetic engineering] free products. To this end it is agreed that during this term of Parliament work will be undertaken to increase the certainty around the ability of non GM producers to maintain GM Free production and be able to identify their product as such to meet market access requirements.*

10. The policy intent of the regulations is to provide:

> *a greater level of transparency, increased accountability and greater public openness of GM crop management. It is aimed at ensuring that non-GM growers have a heightened level of assurance about the integrity and marketability of their product, while still allowing GM crops to be approved by ERMA subject to their standard assessment practices based around associated risks and benefits* [CAB (08) 334 refers].

Scope of regulations

11. The regulations relate only to the new organisms provisions of the HSNO Act, and only to those new organisms that are GMOs. The regulations relate specifically to the information applicants would be required to provide to ERMA on applications assessed under section 38A of the HSNO Act (i.e. with controls) to conditionally release any GMO, including veterinary and human medicines that are, or contain, GMOs.

12. Such information is integral to enabling ERMA to make decisions on controls (conditions) that it considers appropriate for ensuring an appropriate level of segregation and traceability of a conditionally released GMO in order to facilitate coexistence between GM and non-GM production systems.

13. The scope of the new regulations reflects the requirements of the current draft code of practice template for the seed crop industry [CBC (08) 20/24 refers].

Comment on related work

14. On 14 July and 21 July 2008, Cabinet Business Committee and Cabinet (respectively) decided on a number of other initiatives, in addition to the proposed regulations submitted with this paper, that were also designed to give further effect to the Co-operation Agreement (see paragraphs 8 and 9, above).

15. Concerning traceability in relation to GMOs, officials were directed to report back to Cabinet Policy Committee (POL) by 31 August 2008 about how the European Union's (EU) framework on the traceability and labelling of genetically modified organisms (GMOs) and the traceability of food and feed products produced from GMOs may be adapted to be consistent with New Zealand's regulatory system for GMOs.
16. The Ministry for the Environment was also directed to provide further advice to POL by 1 December 2008 on any amendments to the HSNO Act that might be required to implement the proposal addressed by the regulations submitted with this paper as mandatory controls under the HSNO Act.
17. The matters addressed by these two separate reports back are closely related with some overlap in substance. I therefore intend to incorporate the report back on how to adapt the European Union's (EU's) traceability framework for GM crops to be consistent with New Zealand's regulatory system into the advice I am scheduled to provide to POL by 1 December 2008.

Financial implications

18. There are no fiscal implications associated with this paper.

Gender implications

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

Disability perspective

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

Timing and the 28 day rule

21. I intend to promulgate the proposed regulations as soon as practicable. An exemption to the 28-day rule is not required.

Compliance

22. The proposed regulations comply with
    a) the principles of the Treaty of Waitangi;
    b) the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993;
    c) the principles and guidelines set out in the Privacy Act 1993;
    d) relevant international standards and obligations; and
    e) guidelines in the Legislation Advisory Committee's report *Legislative Change Guidelines on Process and Content*.

Regulations Review Committee

23. I do not consider there are grounds for the Regulations Review Committee to draw these regulations to the attention of the House under Standing Order 382.

Certification by Parliamentary Council

24. These draft regulations were given a qualified certification by Parliamentary Counsel as being in order for submission to Cabinet. The qualification relates to the explanatory note which, in the view of Parliamentary Counsel, goes beyond the usual ambit of an explanatory note by expressing a view on the effect of the regulations.

Regulatory Impact Statement

25. A regulatory impact statement (RIS) is appended to this paper as foreshadowed in the policy submission to this proposal [CAB (08) 334 refers].

26. The Ministry for the Environment does not confirm compliance with the principles of the Code of Good Regulatory Practice or the regulatory impact analysis (RIA) requirements, including the RIA consultation requirements. The Ministry of Economic Development considers the analysis and the regulatory impact statement to be inadequate.

Publicity

27. As Minister for the Environment I will issue a press release when the proposed regulations are published in the *New Zealand Gazette*.

28. I also intend to publicly release this paper and Cabinet's decisions on the Ministry for the Environment's website once Cabinet has made a decision on this paper and that the annexed regulatory impact statement will be published in accordance with the Cabinet publication requirements for regulatory impact statements set out in Cabinet Office Circular CO (07) 3.

Consultation

29. On 30 July 2008, in accordance with the requirements of section 141(1) of the HSNO Act, I asked ERMA to conduct a public consultation on the proposed Order in Council to be made under section 140(1) of the Act. I specifically requested that ERMA do everything reasonably practicable on its part to advise all persons, who or which in its opinion may be affected, of the proposed terms of the Order in Council; and to give such persons a reasonable opportunity to make submissions on them. To enable compliance with Cabinet's invitation to me to submit a proposal to Cabinet Legislation Committee by 31 August 2008, I asked ERMA to report back to me with a summary of submissions by 22 August 2008.

30. ERMA carried out a two-week public consultation, starting on 31 July and ending on 15 August 2008. Consultation documents posted on ERMA's website invited comment from all interested and potentially affected parties. ERMA also directly notified a wide range of potentially affected parties of the consultation.

31. A total of 635 submissions were received during the submission period. Key sectors represented included: Crown Research Institutes and universities; deer, meat and wool producers; grain and seed producers and distributors; farmers' and gardening organisations; medical and veterinary professional bodies; plant breeders; wine makers; biotechnology companies and advocacy groups; members of the beekeeping and organics sectors (including Māori organic producers), key civil society groups and church organisations. Australian research and industry organisations also forwarded submissions.

32. Of the submissions received, 464 were based at least in part on a form submission circulated through a website promoting a "GE-Free" New Zealand. Proponents of increased regulation (predominantly form submitters and individuals or civil society groups) considered the proposed regulations would provide a "heightened level of assurance" for non-GM growers. Many, however, stressed a preference for an outright ban on all GMO release if the regulations could not provide 100% prevention of contamination of non-GM production.

33. Opponents of the new regulations (over 25 percent, predominantly from the production and research sectors and industry professional bodies) considered the current regulatory regime untested and as such has not been found deficient, therefore no change is warranted. They considered the regulations would have a negative impact on perceptions of ERMA's autonomy, increase uncertainty, damage New Zealand's scientific skill base, reduce competitiveness and stifle innovation and economic growth. They opposed new, prescriptive information requirements; preferring self-regulation by industry, based on current best-practice models.

Departmental consultation

34. The following departments and agencies were consulted during the preparation of this paper:

    Ministry of Agriculture and Forestry; Ministry of Economic Development; Ministry of Research Science and Technology; Ministry of Foreign Affairs and Trade; Ministry of Consumer Affairs; Ministry of Justice; Department of Conservation; Te Puni Kokiri; Treasury; Environmental Risk Management Authority; New Zealand Food Safety Authority and New Zealand Customs.

35. The Department of the Prime Minister and Cabinet was also informed.

Recommendations

I recommend that the Cabinet Business Committee:

1. **note** that the proposed regulations prescribe
   requirements for segregation and traceability schemes, that the Environmental Risk Management Authority (ERMA) would have particular regard to imposing as controls when considering applications to conditionally release a GMO [genetically modified organism], particularly any GM [genetically modified] crop;

2. **note** that the proposed regulations, under section 140(1)(l) of the Hazardous Substances and New Organisms (HSNO) Act 1996, give effect to policy approved on 14 July 2008 by the Cabinet Business Committee (having been authorised by Cabinet with Power to Act [CAB Min (08) 27/5]) and confirmed on 21 July 2008 by Cabinet [CBC Min (08) 20/24 and CAB Min (08) 28/1C refer];

3. **note** that the regulations have been developed as a means to give effect, in part, to the Labour-led Government Co-operation Agreement with the Green Party of Aotearoa New Zealand on GMOs [CAB (08) 334; CBC Min (08) 20/24 and CAB Min (08) 28/1C refer];

4. **authorise** the submission to the Executive Council of the Hazardous Substances and New Organisms (Genetically Modified Organisms - Information Requirements for Segregation and Tracing) Regulations 2008;

5. **agree** that this Cabinet paper, the annexed regulatory impact statement and the relevant Minutes of Cabinet's decisions should be released publicly once Cabinet has made a decision on this paper;

Related work

6. **note** that on 14 July and 21 July 2008, Cabinet Business Committee and Cabinet (respectively) [CAB (08) 334, CBC Min (08) 20/24 and CAB Min (08) 28/1C refer] also:

   a. directed the Ministry for the Environment to provide further advice to the Cabinet Policy Committee (POL) by 1 December 2008 on any amendments to the HSNO Act required to implement the proposal addressed by these regulations as mandatory controls under the HSNO Act; and

   b. directed officials to report back to POL by 31 August 2008 about how to adapt the European Union's (EU's) traceability framework for GM crops to be consistent with New Zealand's regulatory system;

7. **agree** that, as the matters addressed by the two directions referred to in recommendation 6 (above) are closely related, the report back on the EU traceability framework referred to in recommendation 6(b) should be deferred and incorporated into the advice I am scheduled to provide to POL by 1 December 2008 as referred to in recommendation 6(a).

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Hon Trevor Mallard
Minister for the Environment

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Annex: Regulatory Impact Statement

THE HAZARDOUS SUBSTANCES AND NEW ORGANISMS (GENETICALLY MODIFIED ORGANISMS - INFORMATION REQUIREMENTS FOR SEGREGATION AND TRACING) REGULATIONS 2008

EXECUTIVE SUMMARY

The proposed regulations considered in this paper aim to provide increased transparency, accountability and public openness in the management of genetically modified organisms (GMOs)[1], particularly for genetically modified (GM) crop management [CAB (08) 334 refers].

This proposal is one of a range of measures designed to give effect to the Labour-led Government Co-operation Agreement with the Green Party of Aotearoa New Zealand in relation to GMOs.

These measures are intended particularly "to increase the certainty around the ability of non-GM producers to maintain GM Free production and be able to identify their product as such to meet market access requirements" (Co-operation Agreement, page 2)

> "while still allowing GM crops to be approved by the Environmental Risk Management Authority (ERMA) subject to their standard assessment practices based around associated risks and benefits" [CBC Min (08) 20/24 and CAB Min (08) 28/1C refer].

The proposed regulations will require applicants seeking approval under the Hazardous Substances and New Organisms (HSNO) Act 1996 for conditional release of a GMO to provide, with their application to ERMA, information on segregation[2] and traceability[3] schemes the applicants propose using if the GMO was approved. ERMA would then be able to use this information in its assessment of suitable controls to impose on an approval to address segregation and traceability issues, should it deem them necessary to prevent or manage risks of the conditionally released GMO.

ADEQUACY STATEMENT

The Regulatory Impact Analysis Unit Reference Panel of the Ministry for the Environment has reviewed this Regulatory Impact Statement (RIS) according to the adequacy criteria and considers the RIS does not meet adequacy criteria as it does not meet the efficiency, effectiveness or transparency principles of the Code of Good Regulatory Practice. The Ministry also considers the regulatory impact analysis (RIA) consultation requirements have not been complied with adequately.

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[1] In summary, genetically modified organisms or GMOs are defined in the HSNO Act as organisms that have had their genes or other genetic material modified by *in vitro* techniques (in an artificial environment outside the living organism) (with some exclusions).

[2] Segregation in this context refers to the act of (and mechanisms for) keeping GM crops (or other GMOs where practicable) separate to avoid mixing or combining with (commingling) other organisms during planting, harvesting, loading and unloading, processing, storage and transport.

[3] In this context 'traceability' means the ability to trace GMOs and products that are or contain GMOs at all stages of their placing on the market through production and distribution chains.

Consulted parties advised they were not given enough time for some to be able to provide considered responses. Officials also had insufficient time to assess whether the consultation process was effective.

The draft RIS was circulated with the draft Cabinet paper for departmental consultation and the final RIS was sent to the Regulatory Impact Analysis Unit of the Ministry of Economic Development for assessment. The Regulatory Impact Analysis Unit has reviewed the RIS and considers the RIS is **inadequate** according to the adequacy criteria set out in Cabinet Office Circular CO (07) 3. The RIA and RIS do not identify a clear policy problem with the status quo, which currently enables ERMA to seek information on segregation and traceability in applications to conditionally release GMOs. The limited time available to discuss the proposal with stakeholders and to respond to their concerns also means that consultation on the proposal has been inadequate. The final RIS was circulated with this Cabinet paper for departmental consultation.

STATUS QUO AND PROBLEM

Background

New Zealand manages the importation and release of new and genetically modified organisms (GMOs) through provisions of the Hazardous Substances and New Organisms (HSNO) Act 1996. The purpose of the HSNO Act is "to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms".

The Environmental Risk Management Authority (ERMA) is the independent decision-making body given mandate under the HSNO Act to grant regulatory approval for all new organisms, including GMOs. The Ministry of Agriculture and Forestry (MAF) has responsibility for enforcing the new organism's provisions of the HSNO Act.

The provisions of the HSNO Act relating to new organisms took effect in July 1998. Amendments to the HSNO Act that came into effect in October 2003 provided, inter alia, for a new category of new organism release approval called 'conditional release'. This enables ERMA to approve the release of new organisms with controls.

Since that time, ERMA has received only two applications for conditional release of any new organism. The first, for a non-GM insect biological control agent to combat a pasture pest, was approved by ERMA on 8 November 2005. The second, for a GM vaccine to combat equine influenza (horse flu), was publicly notified on 13 June 2008 but it has yet to be decided.

<u>Current statutory provisions</u>

Applications for conditional release are made under section 38A of the HSNO Act (Application for approval to import or release new organism with controls).

Several subsections of section 38A are relevant to considerations of traceability and segregation.

Section 38A (1) provides that a person may apply to ERMA for a conditional release approval to import for release or to release from containment a new organism with controls.

Section 38A(2)(a) of the HSNO Act provides that a conditional release application must include all prescribed information while section 38A(2)(g) requires information on the proposed use for the organism. In addition, section 38A(2)(h) of the Act requires that applications must include the controls that the applicant proposes the organism would be subject to on its release.

Comment

Genetically modified (GM) and non-GM new organisms were treated identically under the new conditional release provisions enacted in 2003. Consequently, the above provisions apply to all applications for conditional release of any new organism, including, but not only, GMOs.

Unlike the existing conditional release provisions of the HSNO Act, the proposed regulations relate specifically and exclusively to requirements for applications for conditional release of GMOs. The regulations will not affect non-GM new organisms.

Current decision-making process

Section 38D of the Act gives ERMA a wide discretion to impose controls on conditional release approvals. It also specifically provides that the Authority may impose, inter alia, the following controls relating to segregation and traceability:

- controlling the extent and purposes for which organisms could be used [section 38D(1)(a)]
- imposing any obligation to comply with relevant codes of practice or standards (for example, to meet particular co-existence requirements) [section 38D(1)(c)]
- limiting the dissemination or persistence of the organism or its genetic material in the environment [section 38D(1)(e)]
- limiting the proximity of the organism to other organisms, including those that could be at risk from the conditionally released organism [section 38D(1)(g)]
- setting requirements that must be met for any material derived from the organism [section 38D(1)(h)].

Consequently, requirements for segregation and traceability are already matters that ERMA would be likely to consider when deciding on the controls to be imposed on any GMO conditional release approval.

As noted, section 38A(2)(a) of the HNSO Act states that applications must include all "prescribed information". Furthermore, ERMA can require an applicant to provide such information as ERMA deems sufficient to support its decision-making. Section 38(1) provides that ERMA may, in its discretion, decline an application if insufficient information is available to enable it to assess the adverse effects of the organism. However, the nature of the information ERMA would require to support a conditional release GMO application has not been prescribed in either the statute or regulations.

Problem

This lack of statutory prescription of the information required to support a conditional release application provides uncertainty for applicants. This in turn leads to uncertainty for all parties regarding the nature of the information that ERMA would have regard to in assessing a conditional release GMO application and in determining what controls it considers may be appropriate for an organism should it be approved.

This proposal seeks to address such concerns around the current statutory provisions and decision-making process. Specifically it seeks to increase transparency and certainty around the information on proposed segregation and traceability measures required to support such a GMO conditional release application.

Controls to address segregation and traceability issues would not be mandatory for every conditional release. ERMA would still have the discretion provided for under section 38D(2) of the HSNO Act to impose only those controls it considers necessary.

Nonetheless, the new regulatory requirement would clearly signal to all parties that ERMA will specifically consider controls relating to segregation and traceability in considering GM conditional release applications.

The nature of information to be provided by the applicant in relation to segregation and traceability is not currently either prescribed by regulation or described through non-statutory guidance.

OBJECTIVES

Objectives of the proposal

The primary objective of this proposal is to give effect, at least in part, to an initiative negotiated under the Labour-led Government Co-operation Agreement with the Green Party of Aotearoa New Zealand on GMOs.

This proposed regulation (Order in Council) is intended to give effect to the policy approved by the Cabinet Business Committee on 14 July 2008 (and subsequently confirmed by Cabinet on 21 July 2008) by prescribing, under the Hazardous Substances and New Organisms (HSNO) Act 1996

> *requirements for segregation and traceability schemes, that the Environmental Risk Management Authority (ERMA) would have particular regard to imposing as controls when considering applications to conditionally release a GMO, particularly any GM crop* [CBC Min (08) 20/24 and CAB Min (08) 28/1C refer].

The key public policy objective of the proposed regulations is to increase transparency and certainty in decision-making regarding conditionally released GMOs. The proposal aims

> *to provide a heightened level of assurance to non-GM growers about the integrity and marketability of their product, while still allowing ERMA to approve GM crops subject to its standard assessment practices* [CAB (08) 334 refers].

The new regulations will be subordinate to the parent HSNO Act. ERMA will retain its discretionary power under the Act to impose controls in respect of conditional release approvals for new organisms as it deems appropriate. Controls are set to meet the purposes of the Act, namely to prevent or manage the adverse effects of conditionally released GMOs so as to protect the environment, and the health and safety of people and communities.

Specifically prescribing information requirements for segregation and traceability schemes would serve to reinforce ERMA's existing statutory discretion to require relevant information to be provided in applications for the conditional release of GM crops. The mandatory requirement to provide this information will signal clearly to all parties that ERMA will specifically consider controls relating to segregation and traceability during consideration of applications to conditionally release GMOs. ERMA would then impose suitable controls if they were deemed necessary to prevent or manage any risks of the conditionally released GMO.

ALTERNATIVE OPTIONS

Non-statutory guidance

Provision of additional non-statutory guidance is an alternative means to meet the objective of increasing transparency in decision-making.

ERMA provides non-statutory guidance to prospective applicants on information required to be submitted with applications.

ERMA could develop specific advice on the information relating to segregation and traceability schemes that should be provided with GMO conditional release applications.

Should this regulation be enacted, officials intend to develop such guidance to facilitate implementation of the regulations (see 'Implementation' below). ERMA would publish guidance on its website and provide information directly to prospective applicants and other interested parties on request.

However, ERMA would still retain its current discretion to decide whether segregation and traceability matters were relevant to specific GMO conditional release applications and whether they might require controls to be placed on approvals.

Consequently, development of additional non-statutory guidance alone would not meet the objective of increasing certainty that ERMA would consider segregation and traceability conditions as controls for conditionally released GMOs.

Industry self-regulation

Voluntary industry self-regulation would be an alternative to the proposed new regulations.

During consultation some submitters noted market imperatives exist for developers of GM crops to maximise the value of those crops by ensuring the GM characteristics are restricted to their crops. They noted also that New Zealand primary producers already proactively develop "codes of practice" to meet consumer expectations that would be needed to meet the consumer surety objectives of the proposal. Consideration of the need for segregation would therefore be inherent in addressing such concerns and informing the information requirements of section 38A(2)(h) of the HSNO Act (the controls that the applicant proposes the organism would be subject to on its release).

This group generally saw value in segregation and traceability schemes but considered they should be market driven rather than prescribed by regulations. They considered it would be more effective for regulators to work with industry to achieve voluntary, cooperative segregation of GMOs and non-GMOs, via industry self-regulation.

The Ministry of Agriculture and Forestry is currently consulting on a generic code of practice "template" for the seed crop industry, based on the principles and best practice for segregation. It is anticipated the template will provide a basis to develop crop-specific codes of practice for the segregation of GM crops. Industry could adhere to such crop-specific codes of practice on a voluntary basis, or ERMA could require them to be followed as a mandatory condition on an approval.

If such a code of practice was available ERMA would be likely to require adherence as a way to manage potential risks posed by a conditional release. However, under current legislation, ERMA would treat each application on a case-by-case basis, taking into consideration the existing provisions of section 38D (1)(c) that provide that ERMA may impose an obligation on approval holders to comply with relevant codes of practice or standards.

A change to the HSNO Act would be needed if compliance with any specific codes of practice for GM crop management were to be mandatory controls for ERMA GM conditional release approvals.

Nonetheless, such information is integral to enabling ERMA to make decisions on controls (conditions) that it deems appropriate for ensuring an appropriate level of segregation and traceability of a conditionally released GMO. Controls imposed could directly facilitate coexistence between GM and non-GM production systems - an approach government confirmed after consideration of the Royal Commission on Genetic Modification's 2001 report.

The scope of the new regulations reflects the requirements of the current draft code of practice template for the seed crop industry [CBC (08) 20/24 recommendation 6 refers].

Amending the Methodology Order

This proposal addresses Cabinet Business Committee's invitation on 14 July 2008 (confirmed by Cabinet on 21 July 2008) to the Minister for the Environment

> *to submit to the Legislation Committee, by 31 August 2008, draft Regulations under the Hazardous Substances and New Organisms (HSNO) Act 1996 and/or proposals for amending the Methodology Order to prescribe requirements for segregation and traceability schemes, that the Environmental Risk Management Authority (the Authority) would have particular regard to imposing as controls when considering GMO conditional release applications.*

Section 9 of the HSNO Act authorises the Governor-General to make an Order in Council to establish a Methodology for ERMA when making decisions under Part 5 (Assessments). This section also requires ERMA to consistently apply this Methodology when making such decisions.

The Hazardous Substances and New Organisms (Methodology) Order 1998 describes the process and procedure for ERMA's decision-making in terms of the assessment of risks, costs and benefits. Consideration was given to whether changing this Methodology Order might be a preferable means of meeting the policy objective.

The Methodology Order is, however, limited as to its scope by its empowering authority in the HSNO Act. In the absence of legislative amendment or development of new regulations, any changes to the Methodology Order relating to substantive matters may extend the scope of the Order beyond what section 9 of the HSNO Act allows. This would be risky as those provisions could be challenged as ultra vires section 9 of the HSNO Act, or possibly be the subject of a complaint to the Regulations Review Committee for consideration under standing order 315 [CBC Min (08) 20/24 refers].

As with the proposed regulations, an amendment to the Methodology Order would not overcome ERMA's statutory discretion and case-by-case approach. The HSNO Act already provides for the proposed regulations to be given statutory weighting without amending the Methodology, through ERMA's case-by-case decision-making.

Amending the statute (the HSNO Act)

In 2001 the government accepted the Royal Commission on Genetic Modification's overall recommended strategy of "preserving opportunities". The government noted, however, that in most cases the tools needed to implement this approach in practice applied generally to all new organisms.

The resulting law changes reflected that reality and, for the most part, applied equally to non-GM as well as GMOs. This was considered appropriate on the basis that ERMA's case-by-case assessments will be the most appropriate means to identify controls needed to manage potential risks posed by release of a particular GMO.

As noted above, section 38D of the Act gives ERMA a wide discretion to impose controls on approvals. While an approval holder would be obliged to comply with any such control, ERMA would not itself be under an obligation to impose such a control in the first instance. ERMA has discretion to impose whatever controls it considers are appropriate and necessary to manage risk.

The nature of information to be provided by the applicant in relation to segregation and traceability should the GMO be approved for conditional release, is not currently prescribed by either regulation or non-statutory guidance.

Section 38D(1) of the HSNO Act provides a non-exhaustive list of possible controls that ERMA may impose on a conditional release approval, while section 38D(2) stresses that these are not limiting.

The Act could be amended to prescribe requirements for "segregation and traceability schemes that ERMA would have particular regard to imposing as controls when considering applications to conditionally release a GMO, particularly any GM crop". However, this would have no practical effect over and above the regulations unless they were prescribed under the Act as mandatory conditions for approvals.

Since the Act was amended in 2003, there has been no decision to change this policy of case-by-case decision-making or to mandate in statute specific controls that ERMA must place on approvals. Policy approval has not been granted for such a fundamental change to the way the HSNO Act operates. However, further advice on any amendments to the HSNO Act required to implement requirements for segregation and traceability schemes as mandatory controls is scheduled for Cabinet consideration by 1 December 2008 [recommendation 10, CBC Min (08) 20/24 refers].

PREFERRED OPTION

Key Features

Supports the government's policy of "preserving opportunities"

The framework for conditional release provided for through the 2003 amendments to the HSNO Act was intended to maximise positive effects while minimizing adverse effects, including environmental, social and economic effects.

The regulations aim to ensure that non-GM growers have a heightened level of assurance about the integrity and marketability of their product, while still allowing GM crops to be approved by ERMA subject to their standard assessment practices based around associated risks and benefits.

Consistency with case-by-case decision-making

In developing the 2003 amendments to the HSNO Act, government also considered criteria for conditions and level of prescription for the new conditional release provisions of the Act. The submission to Cabinet advised that the framework for conditional release "needs to recognise that management of new organisms is complex and requires expert judgement". It was therefore considered "critical that the framework is sufficiently flexible that ERMA can set appropriate case-specific conditions as it considers necessary".

A key feature of the proposed regulations is that it does not undermine case-by-case decision-making (an approach strongly supported by the Royal Commission on Genetic Modification in its 2001 report).

Cabinet noted that ERMA remains subject to the decision-making provisions specified in Part 2 of the HSNO Act when imposing conditions on conditionally released new organisms. Cabinet agreed that ERMA be given broad discretion to impose appropriate conditions on a new organism which it approves for conditional release. It agreed further that the conditions imposed may include, but are not limited to "the possible obligation to comply with relevant codes of practice or standards (e.g. to meet particular coexistence requirements)". However, it did not consider that particular controls would be required for all conditionally released GMOs, but that each organism would pose different risks dependant on its unique characteristics and intended use.

Consequently, ERMA does not have to impose prescribed conditions on any conditional release approval but has discretion under the HSNO Act to impose controls on a case-by-case basis.

Scope

In accordance with Cabinet's directives [CBC Min (08) 20/24 and CAB Min (08) 28/1C refer], the regulations prescribe information on proposed segregation and traceability schemes that ERMA would have particular regard to imposing as controls when considering applications to conditionally release a GMO, particularly any GM crop.

Cabinet considered that references to "GM crops" in its decisions should apply also to other GMOs, including veterinary and human medicines that are, or contain, GMOs, where that is practicable.

Without knowing what kinds of GMOs may be applied for under the conditional release provisions of the Act, or the use intended for those organisms, regulations with highly prescriptive information requirements would not be practicable or they may not be pertinent to some GMOs. However, the regulations do need to be specific enough to provide a clear indication to applicants (and others) of the type of segregation and traceability information of relevance.

During consultation on the proposed regulations, ERMA specifically asked for comment on whether the management of types of GMOs other than crops (for example, GM animals and vaccines) might benefit from the application of segregation and traceability schemes. Few submitters provided comment in this regard; most that did simply indicated they considered the scope of GMOs covered by the regulations should not be unduly limited nor so broad as to impact negatively on previous work to streamline decision-making and reduce compliance costs.

Cabinet also determined that the scope of the new regulations should reflect the requirements of the current draft code of practice template for the seed crop industry [CBC (08) 20/24 refers].

Consultation on the draft code of practice template is underway, but the final details of any generic or specific codes will not be decided for some time. Nonetheless, key characteristics of the draft code that will likely be applicable for most types of GMO conditional release applications have been included in the regulations. Furthermore, the regulations specifically refer to provision of information on codes of practice that may be relevant.

Consequently, the proposed regulation includes the following key provisions:

- the date the regulations will come into force;
- a requirement that applicants to ERMA for conditional release approval for GMOs provide information on how they propose to segregate their GMO and how that GMO could be traced after release with controls;
- specification of the effectiveness the applicant expects the proposed measures would provide; and
- specification of information on any codes of practice or standards the applicant considers relevant to the proposed release with controls.

Some GMOs not covered by the regulations

Cabinet has agreed that the regulations will apply not only to GM crops but to other GMOs, including veterinary and human medicines that are, or contain, GMOs, where that is practicable.

In 2003, as part of the government's response to the Royal Commission on Genetic Modification, Cabinet approved amendments to the HSNO Act to improve the approval process for medicines that are or contain new organisms [CAB Min (03) 4/1B refers].

The amendments specifically streamlined the evaluation process for animal and human medicines that are or contain a new organism (termed a "qualifying organism" under the HSNO Act), including human medicines containing GMOs (termed "qualifying medicines" under the Act) or veterinary medicines containing GMOs (termed "qualifying veterinary medicines" under the Act).

The amendments introduced a scheme to allow regulatory agencies to quickly assess and approve (through "rapid assessment") agricultural compounds and medicines. The changes to the HSNO Act, Medicines Act 1981 and Agricultural Compounds and Veterinary Medicines Act 1996 removed a regulatory barrier which delayed access to agricultural compounds or medicines required urgently to manage emergencies but also reduced the compliance costs associated with applications to market animal and human medicines that are or contain new organisms.

A consequence of these amendments was that human or veterinary medicines that are or contain a new organism (including some GMOs) meeting low risk criteria (defined in the HSNO Act) are not subject to full ERMA assessment[4] and public consultation inherent in conditional release assessments.

The proposed regulations relate specifically and exclusively to segregation and traceability information required to be submitted with applications for conditional release approval of GMOs. Such applications are submitted under section 38A of the HSNO Act (Application for approval to import or release new organism with controls).

Applications for "qualifying medicines" and "qualifying veterinary medicines" are submitted under section 34 of the Act (Application for approval to import or release). They are assessed under section 38I of the Act (Assessment for applications for release of qualifying organisms). Furthermore, any organism defined as a "qualifying medicine" or "qualifying veterinary medicine" by meeting the rapid approval criteria would, by definition, be considered to present a low risk to the environment and the health and safety of people and communities.

For these reasons, "qualifying medicines" and "qualifying veterinary medicines" are not covered by the proposed new regulations. However, any application for conditional release of a "qualifying organism" that did not meet the criteria needed to be considered a "qualifying medicine" or "qualifying veterinary medicine" and that was submitted under either section 38A or 34 (and considered as a conditional release by agreement with the applicant) would be covered.

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[4] ERMA may (but has not as yet) delegate decision-making and approval for "low risk" qualifying medicines and qualifying veterinary medicines 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.

Impacts

Impacts on industry and the public sector

Without knowing the types of GMOs that may be applied for under conditional release and in the absence of a history of decision-making in this context (with only two conditional applications submitted to ERMA since the provisions were enacted in 2003), it is not possible to assess the likely impacts of the proposed regulations.

The regulations will directly affect researchers and the wider primary production community. This will likely include members of the agricultural, horticultural, viticultural, forestry and pastoral, meat and wool production sectors.

The ERMA application fee for conditional release of a GMO will remain constant. Additional costs may be incurred in providing specific information prescribed by the regulations. Additional costs will be likely as organisations will need to familiarise themselves with the new requirements. However, as ERMA may already request such information, additional costs arising directly from compliance with the regulations are not likely to be significant.

Industry and research applicants seeking conditional release approval of a GMO will directly fund the costs of providing the necessary information to support any application covered by the regulations. Some application preparation costs may be reduced through provision of greater clarity on the information requirements (both through the regulations themselves and through non-statutory guidance provided by ERMA to support the new regulations).

Costs to society in general, including interested parties wishing to lodge submissions on notified applications to ERMA, may be reduced through increased clarification of the regulatory requirements and ERMA's decision-making processes.

Implications for government agencies

There will be financial implications for government agencies associated with implementing the proposed regulations. However, these would be met under existing baselines. In particular, ERMA will incur costs through measures taken to publicise the new regulations and in providing non-statutory guidance to prospective applicants.

The costs of providing information with any application will be funded directly by the applicant so no additional costs fall to government in this regard.

Clarifying the information requirements for GMO conditional release applications is likely to reduce the costs associated with ERMA's pre-application engagement with prospective applicants. Ultimately, specifying the information required to support and inform ERMA's GMO conditional release decision-making may reduce the costs associated with considering applications.

Increased clarity around ERMA's decision-making will also reduce the likelihood of unnecessary judicial appeal on decisions and the associated costs for all parties.

No enforcement costs are relevant. Should an applicant not comply with the information requirements of the regulations, the application would simply not be approved.

Risks

Time period available for submissions

ERMA carried out a two-week public consultation, commencing on Thursday 31 July and ending on Friday 15 August (refer "Consultation" below).

The Minister for the Environment acknowledged at that time that the short time available for consultation on the proposals was less than optimal and did not sit well with ERMA's customary six week consultation 'best practice' model.

However, it was stressed that the time allowed for consultation was, by necessity, shorter than normal to allow sufficient time for the submissions to be assessed and regulations to be drafted within the timeframe directed through Cabinet's decisions on this matter.

One group of submitters, including most individual submitters and those submitting form submissions who were of the view that New Zealand should be GE-free regardless of any proposed regulations, did not express concern over the consultation timeframe.

However, most industry, research and primary production sector organisations and biotechnology advocacy groups commented that, given the importance and high potential impact of the issue, they viewed the time period available for making a submission as inadequate for due consideration.

Lack of due consideration

The "unrealistic haste" was considered by many submitters insufficient to enable them or their organisations to provide a meaningful response on the proposed regulatory changes. Several also claimed it contravened the normal conventions that apply in a sound democracy by preventing organisations wishing to submit on the proposals from undertaking the democratic process of consultation with their members. Some noted that member organisations were unable to provide submissions at all, meaning "the information collated could not fully represent stakeholders' view on the proposals".

In this regard, some submitters noted the two week consultation reduced the transparency the regulations were intended to support. This in turn was considered to reduce confidence in the intent and outcome of the proposals with potential to impact negatively on the quality of the resulting regulations. Many criticised the fact that a full economic impact assessment had not been done. Others commented that the short consultation time did not enable potentially affected parties to be properly informed of the nature and impact of the proposals and therefore the consultation does not meet section 141 of the HSNO Act. Section 141 specifies, inter alia, that persons who may be affected by a proposed Order in Council should be given a reasonable opportunity to make submissions.

As a consequence of the limited time available to consider the proposals (and perhaps also as a reflection of the complexity of the matters addressed under the consultation and the preceding Cabinet papers) many submissions did not focus specifically or in any detail on the proposed regulations. Instead they provided comment on the range of proposals canvassed in the submission to the Cabinet Business Committee and on the range of measures decided by Cabinet. Others seemed not to appreciate that the proposed regulations would apply only to applications for conditional release of GMOs and provided detailed comment on other application types. Others discussed the presence or use of GMOs in New Zealand generally, without referring specifically to the proposed regulations.

The proposal is considered too lax

During consultation, many submitters who favoured regulations prescribing information requirements stated they considered it would help to ensure that New Zealand GE-free production can be maintained. However, many supporting such a policy direction opposed the proposed regulations. The fact that the regulations would not prevent consideration of GM conditional release applications or restrict ERMA's case-by-case decision-making discretion indicated there might one day be a conditional release of a GM crop - a possibility inconsistent with their personal preference for an outright ban on all GMO releases.

Negative impacts on innovation

In the submission to Cabinet giving rise to this paper [CAB (08) 334 refers], several government departments expressed concern that the proposal (and the others contained in that submission) would "effectively change the balance of government's overall strategy of proceeding with caution while preserving opportunities". These departments stressed the importance of striking a balance between risk management and innovation and feared that some of the proposals could be perceived by innovators and investors as reducing the perceived independence of ERMA and increasing the costs and uncertainty of GM-related innovation, without managing any significant risk.

Such negative impacts are not the intended outcome. The submission stressed that the range of options presented aimed at providing a greater level of transparency, increased accountability and greater public openness of GM crop management. Nonetheless, similar concerns to those noted by officials were reflected in many of the substantive submissions received during consultation on the proposed regulations.

Negative impacts on case-by-case assessment

Many of those submitters who did comment specifically on the new regulations supported the proposal as responsible practice. In doing so, some submitters stressed the importance of all parties involved sharing responsibility for segregation and traceability schemes if they are to be successful. Many noted they supported the underlying objective of increasing transparency and accountability in management of GMOs and saw the proposed regulations as a means to advance this objective.

Others, however, submitted that the proposed regulations would go beyond achieving a "heightened level of assurance" for non-GM growers. They considered that the proposed regulations would effectively undermine public confidence in ERMA's independence by reducing ERMA's ability to assess GMOs case-by-case and make independent, evidential decisions based on real risks, costs and benefits. It was specifically suggested that prescriptive regulations could adversely impact ERMA's reputation as an impartial and independent regulator. In this regard, many such submitters preferred self-regulation by industry and therefore opposed new, prescriptive information requirements.

Good governance and transparency

Many from the wider industry sector regarded the proposed regulations (and their development) as contrary to good governance and transparency. The regulation was described as having no scientific, legal or financial basis. Some submitters considered it effectively runs counter to both the letter and the spirit of the recommendations of the Royal Commission on Genetic Modification by impacting negatively on New Zealand's ability to 'proceed with caution'.

It was also suggested that the proposed regulations could be subject to [legal] challenge on the basis that the rationale for the proposal, namely to give effect to an agreement between political parties, was not a valid purpose of the HSNO Act (namely, to address environmental risks associated with GMOs) so was an irrelevant issue in such considerations.

The regulations would ultimately be impracticable

It was noted by several submitters that the proposed regulations would, in time, be ineffective. It was suggested that any such regulations regarding traceability, particularly those dependent on genetic testing for monitoring or auditing purposes, would be unenforceable in time.

In support of this position submitters proposed that the most likely GM candidates for conditional release in the near future would contain no 'foreign' DNA (namely, no identifiable genetic material sourced from a different organism). Such 'cisgenic' and 'intragenic' organisms cannot be identified and tracked by current molecular technologies.

IMPLEMENTATION AND REVIEW

Implementation

Interested parties and the public will be made aware of the new regulations through the *New Zealand Gazette* in accordance with the 28-day rule.

A communication strategy will be developed to inform applicants of the legislative changes and their potential obligations under the new regulations. As part of this communications strategy, ERMA will advise interested parties of the new requirements by means of seminars, information sheets, web-publishing, ERMA's newsletter (The Bulletin) and individual attention.

In terms of managing the information requirements at the time of application, ERMA already provides significant support to applicants for conditional release and this will apply to any future applicants. Support is in the form of documentation such as application guides outlining information requirements and technical guides on risk identification and assessment. All of these initiatives serve to educate and inform applicants so that compliance costs in preparing applications are minimised. Specific guides will be prepared to provide potential applicants with information to assist in preparation of the information required under the new regulations.

Consideration has been given to the concerns expressed during consultation. It is noted that many of the concerns expressed relate to problems that might arise from perceptions that New Zealand's already stringent regulatory system for GMOs would be seen as unduly restrictive of innovation and development. To remedy these concerns, where possible, effort will be made through the proposed communications strategy to clarify for both the research community and production sector the scope of the regulation so as to alleviate any unwarranted concerns over perceived but unrealised adverse impacts for their sectors.

Monitoring and review

Without knowledge of the types of GMOs that may be subject to the regulations, and in the absence of a history of decision-making for conditionally release GMOs, it is not possible to assess the likely efficacy of the proposed regulations.

ERMA's powers, functions, and duties as specified in section 11 of the HSNO Act, include:

- providing advice to the Minister for the Environment on the extent to which persons are complying with the provisions of the Act [section 11(1)(a)(i)]
- monitoring and review of the extent to which the Act reduces adverse effects on the environment or people from new organisms [section 11(1)(b)(i)].

Section 97A of the HSNO Act prescribes the Ministry of Agriculture and Forestry as the government agency responsible for enforcement in respect of conditions imposed on any conditionally released new organism. Furthermore, as well as having administrative oversight of the HSNO Act, section 31(c)(i) of the Environment Act 1986 specifically provides for the Ministry for the Environment to provide the government, its agencies, and other public authorities with advice on the application, operation, and effectiveness of (inter alia) the HSNO Act.

In the absence of knowledge of the number and range of conditional release GMO applications ERMA will receive, a formal schedule for such review can not be practicably determined in advance.

However, ERMA and the Ministries for the Environment and of Agriculture and Forestry will work together, as and when potential GM conditional release applicants engage in the HSNO process, to assess the efficacy of the new regulations and the administrative provisions undertaken to implement them.

Should ERMA receive applications for GMO conditional release, the efficacy of the regulations and its implementation will be assessed and options for improvement identified should this be considered necessary.

CONSULTATION

Public consultation

On 30 July 2008, in accordance with the requirements of section 141(1) of the HSNO Act, the Minister for the Environment asked ERMA to conduct a public consultation on the proposed Order in Council to be made under section 140(1) of the Act.

ERMA was asked to do everything reasonably practicable on its part to advise all persons who or which in its opinion may be affected, of the proposed terms of the Order in Council; and to give such persons a reasonable opportunity to make submissions on them.

ERMA posted a consultation document on its website, outlining the terms of the proposed new regulations and provided a link to the Cabinet paper and Minute of decision giving rise to the proposal (published on the Ministry for the Environment website). ERMA also directly notified a wide range of potentially affected parties of the consultation.

The consultation document included a series of prompting questions designed to generate information on which the proposal could be assessed and to inform development of the regulations. In calling for submissions, ERMA asked specifically for comment on the range of GMOs the regulations should apply to and whether the term "GM Crop" needed to be defined in the regulations.

ERMA noted that the regulations could potentially require the applicant to provide information on:

- a completed template code of practice with information specific to the proposed crop species and location;
- specification of the level of segregation that would be achieved by adherence to this code of practice;
- proposed traceability mechanisms that would be employed over the life of the organism; and
- the details and results of any consultation conducted with potentially affected parties.

ERMA also requested comment on the practicality, equity, efficiency and workability of the proposed regulations and on the potential financial or non-financial benefits or costs of implementing the proposal.

Despite the short time provided for consultation (noted above), ERMA received a total of 635 submissions during the two-week submission period.

General comments on submissions

The two main groups of submitters, those in favour of more regulation regarding segregation and traceability of GMOs and those opposed to new regulatory requirements for segregation and traceability of GMOs, had some common concerns. Although looking for a different outcome - with one group seeking adoption of beneficial GM technologies while the other promotes organic or conventional non-GM production - both groups:

- noted the importance of maintaining a choice between GM, non-GM conventional and non-GM organic for producers and consumers;
- expressed desire for there to be consistent regulatory oversight to ensure that no group is unfairly disadvantaged economically;
- stressed the importance of New Zealand remaining competitive in the international market place; and
- referred to the importance of New Zealand adhering to the recommendations of the Royal Commission on Genetic Modification to “take a precautionary approach”, to “preserve opportunities” and “to encourage the coexistence of all forms of agriculture” in support of their views.

Support for retaining the status quo

Many submitters commented that the current case-by-case risk-based assessment is appropriate and adequate to manage the potential risks posed by the conditional release of GMOS, including GM crops. As ERMA can already require applicants to provide relevant information on segregation and traceability and can impose controls to address any such matters as it deems necessary to manage risks, new regulations are unnecessary.

Further, some submitters also noted that, given the high investment in developing GM crops and the need for developers and those commercialising GMOs to earn return on their investments, developers are likely to proactively address any segregation and traceability matters to be covered by the proposed regulations.

Some submitters noted further that legislation to provide balance between different interests has been developed over a considerable period. They submitted that the legislative and regulatory changes following from the recommendations of the Royal Commission have yet to be fully tested. In the absence of any conditional release applications for GM crops, the current regime has not been found wanting. The proposal was considered unnecessary, constituting "another regulatory impost on organisations attempting to contribute to government goals of economic transformation and environmental sustainability with no demonstrable diminution of risk or other advantage to the country". They considered there was no justification for regulatory change.

Opponents of genetic modification (in food and the environment)

The majority of submissions from individuals and the organics industry group (464 of 635) were based in part or all on a form submission template circulated through an 'information resource' website promoting support for "New Zealand being GE-Free in food and the environment" (www.giantexperiment.co.nz). Few such submissions provided substantive comment on the desirability or likely impacts of the proposed regulation itself, but rather provided more generic comment on the range of proposals considered by Cabinet or on the regulation of all GMOs (and not specifically conditionally released ones).

In summary, these 'form' submissions supported development of regulations to maintain the ability of New Zealand farmers to produce non-GM food, with the expectation that any new regulations should provide 100% assurance that non-GM production will not be contaminated with GM. Some of these submitters were concerned that the proposed regulations would not be robust enough to achieve this level of assurance. Many such submitters were also generally united in their stance that any release of GMOs should be prohibited if there is any risk of contamination.

Key statements of support for the proposed regulations considered it would:

- facilitate systems for segregating GM production from immediately surrounding production (especially like non-GM crops and other potentially affected crops);
- promote equable distribution of costs;
- encourage companies to comply with best-practice systems;
- provide systems for identifiable and segregation during harvesting, transport, storage and packing, and disposal of byproducts of GM crops, animals and vaccines; and
- provide a framework for innovation and ethical use of gene science that does not involve release of GMOs that would maintain the integrity and commercial value of the "clean green New Zealand Brand".

A small number of individual submitters were opposed to the proposed regulations because they perceived them to be a 'step towards full acceptance' of GMOs in New Zealand, something they vehemently opposed.

Proponents of the use of genetic modification technology

Over a quarter of submissions received were from groups with stakeholder interests in the development or use of GM technology in New Zealand. These included professional bodies representing farmers, Crown Research Institutes, biotechnology companies, and other industry bodies and scientific organisations from within New Zealand and from Australia.

In summary, these submitters were predominantly concerned that the proposed regulations (and in many cases any additional regulation of GMOs over that currently in force) would have significant (and financially costly) impacts on innovation and economic development. By and large, these submitters considered that the proposed regulations would unduly restrict technological advancement of agriculture in New Zealand with consequent negative impacts on the economy, the environment and on society generally. Recurring sentiments focussed particularly on the following areas.

Adding costs without benefits

Requiring generic information to be submitted with initial proposals that may not be necessary for the purposes of mitigating and managing risk for that situation was regarded as imposing costs and barriers to producers and researchers (and their farmer clients) for uncertain benefits in such a way as to "seriously threaten industry" and potentially render New Zealand's largest industry sector uncompetitive.

Increasing uncertainty

Rather than promoting increased transparency and certainty, many submitters considered the regulations would add unwarranted complexity and uncertainty. The proposal was considered to adversely impact on understandings of the New Zealand regulatory regime, notably with respect to providing for the clear pathways to market required for New Zealand agriculture to remain competitive. It was held that this increased uncertainty would significantly delay the release of potential new cultivars in New Zealand and reduce the competitiveness of New Zealand's agriculture in a manner prejudicial to the government goals of economic transformation and environmental sustainability.

Stifle innovation

It was suggested the proposed new regulations would damage New Zealand's biotechnology capabilities by reducing the attractiveness of New Zealand as a location for investment by biotechnology companies and thereby risk the potential intellectual and economic advantages to New Zealand of engaging in world leading research.

Reduce competitiveness

Many submitters considered the proposal would prevent GM producing countries from exporting to New Zealand. They considered new regulations would put domestic research and development of biotech crop production systems and commercialisation of new 'products' (e.g. biomaterials derived from renewable resources and (potentially) medical biotechnology developments) at an extreme economic disadvantage. They considered such negative impacts would diminish New Zealand's future ability to have a strong economy based on agriculture and forestry in the face of global competition.

Damage New Zealand's scientific skill base

Increased regulation was considered likely to impact negatively on recruitment and retention of New Zealand's scientific skill base by proving a disincentive to student enrolments and adversely effecting employment opportunities for science graduates. This in turn could force New Zealand developed technology overseas to the detriment of the economy and society and acting as a significant deterrent to ongoing research and its commercialisation.

Departmental views

The following departments were consulted in the preparation of this regulatory impact analysis and their views are reflected in the submission:

The Ministry of Agriculture and Forestry; the Ministry of Economic Development; the Ministry of Research Science and Technology; the Ministry of Foreign Affairs and Trade; the Ministry of Consumer Affairs; the Ministry of Justice; the Department of Conservation.

The Environmental Risk Management Authority; the New Zealand Food Safety Authority; New Zealand Customs; Treasury and Te Puni Kokiri were also consulted.

The Department of the Prime Minister and Cabinet was informed.

The prevailing view among officials was that the current provisions of the HSNO Act, in particular ERMA's ability to require any information needed to inform its decision-making, provides adequately for consideration of segregation and traceability concerns without the need to impose new regulation.

Departments voiced support for the use of traceability and segregation schemes, where practicable. However, they stressed that given the varying nature of GMOs ERMA should continue to have the ability to determine what controls may be appropriate for any given GMO on a case-by-case basis. As did submitters, departments also commented that the limited time available for consideration of the proposal did not provide for in depth analysis.