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 6: Ministerial Call-In and Confidential Supporting Information

Proposal

1. This paper proposes amendments to the Hazardous Substances and New Organisms (HSNO) Act 1996 in relation to confidential supporting information (CSI) associated with applications and the grounds for Ministerial Call-in. Amendments relating to confidential supporting information will also affect the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.

Executive summary

2. In relation to Ministerial Call-in, this paper seeks to amend s68 of the HSNO Act to allow the Minister to call-in applications with significant cultural or spiritual or ethical effects. Approval is also being sought to extend the timeframe for call-in to the end of the public submission period to allow the Minister more time to seek advice and consider matters of significance

3. In relation to commercially sensitive information contained in the confidential supporting information (CSI) supplied with applications for HSNO approvals to ERMA, the issues considered were reasonableness, notification and extending special protection. The paper proposes:

- **not** to amend the Act to include grounds for deciding on the "reasonableness"
- with respect to "notification", amendments to s.57(4) of the HSNO Act and to s12(4) of the Agricultural Compounds and Veterinary Medicines (ACVM) Act to ensure authorities make all reasonable efforts to contact the person who provided information regarded as CSI and that, in the event of a non-response, information should not be released, except in accordance with section 9 of the OIA
- with respect to extending "special protection", s.55 of the HSNO Act be amended so as to ensure special protection for confidential supporting information in applications to the ERMA for approvals that are also the subject of innovative agricultural compounds or medicines application, whether these are applications for hazardous substances or new organisms

4. The scope of the proposed amendments for Ministerial Call-in covers both hazardous substances and new organisms. The scope of the proposed amendments for confidential supporting information covers new organisms and some hazardous substances. Although the scope of consultation has been focused on GMOs, there appear to be no problems with the proposed amendments applying to hazardous substances and new organisms in general.

5. This paper is written in two sections and addresses proposed amendments regarding Ministerial Call-In and CSI separately.

Section One: Ministerial Call-in

Background

6. The Royal Commission on Genetic Modification (RCGM) recommended that the call-in section of the HSNO Act (section 68) be extended to include significant cultural, ethical and spiritual issues as grounds for the Minister's call-in powers. Spiritual and ethical matters are not referred to in the HSNO Act. Cultural matters are referred to in various sections, however 'cultural' is not defined.

7. The Government responded to this recommendation by agreeing to amend section 68 of the HSNO Act 1996 to include significant cultural, ethical and spiritual effects as grounds for Ministerial call-in of an application (CAB Min (01) 34/16 refers).

8. The Royal Commission recommendation was made as a result of the discussion on values and ethical decision-making. The Commission also recommended establishing a Bioethics Council – which the government agreed be an expert and independent body to promote and participate in public dialogue on the cultural, ethical and spiritual issues associated with biotechnology.

Issues identification

9. The government sought public submissions on the proposed changes to legislation set out in the public discussion document *Improving the operation of the HSNO Act for new organisms.* Chapter 7 of the document dealt with the grounds for Ministerial call-in.

10. The two key messages from the submitters that supported the extension of the call-in powers, and were a feature of the form submissions, were:

- *Appropriate consideration of cultural, spiritual and ethical issues*
- *Role of the Bioethics Council*

Appropriate consideration of cultural, spiritual and ethical issues

11. Most submissions in favour of changing the call-in section wanted wider consideration of cultural, spiritual and ethical matters in decision-making processes.

12. A recurring theme in the Royal Commission's consultations also was that ethical, cultural and spiritual dimensions of GM were not being adequately addressed. To address these concerns the Royal Commission recommended the establishment of the Bioethics Council.

13. The Royal Commission was of the opinion that dealing with cultural, spiritual and ethical issues, while appropriate matters for consideration, are almost impossible to deal with in the course of the case-by-case decisions that are the responsibility of the ERMA. The Commission also suggested the Bioethics Council be included as an additional body to which the Minister might refer issues when exercising power under section 68.

14. Ministerial call-in is a backstop tool to allow the Minister to make decisions on applications that have unusual or significant features. It is not a method to include cultural, spiritual and ethical matters in decision-making on specific applications.

15. Special targeted consultation was undertaken with Maori groups. Some important themes from these meetings relating to Ministerial call-in were related to who decides the meaning of the terms and the significance for Maori. Views from one meeting were that Maori wanted to be active and effective partners in HSNO processes and not just reactive to ERMA decision-making. A cautious case-by-case approach was supported by participants at one meeting. Another meeting wanted definitions clarified to relate directly to cultural groups recognised in existing legislation. The impression is that changes to s68 are supported bearing in mind the above points.

16. Officials have developed options in order to provide advice on the appropriate consideration of cultural, spiritual and ethical issues:

Amending call-in and further defining terms

17. As suggested in the discussion document, cultural, spiritual and ethical could be included in the call-in section and further defined in the interpretation section of the Act (Section 2). This would make explicit that applications with significant cultural, spiritual and ethical effects can be called in for Ministerial decision.

18. A review of New Zealand legislation shows that while cultural, spiritual and ethical are referred to, they are not further defined. There is also considerable international debate on the meaning of these terms. For further detail, see Annex 1.

Amending call-in without further defining terms

19. The reason to include cultural, spiritual and ethical effects is to allow the Minister to call-in applications of an unusual or significant nature and defining the terms may unhelpfully limit the Ministers discretion.

20. Furthermore, defining cultural in section 2 to include ethical and/or spiritual would impact on the principles relevant to the purpose of the Act (section 5). Including a definition of the terms would mean the ERMA would be legally required to recognise and provide for the spiritual and ethical issues of GM in their day to day consideration of applications – a responsibility the RCGM believes is almost impossible for the ERMA to carry out and a responsibility that goes beyond the scope of the Royal Commission recommendation to amend section 68. The Bioethics Council will consider these issues.

21. Including cultural, spiritual and ethical effects in s68 without further defining the terms would address the inability of the Minister to call-in applications on these grounds without altering the decision-making criteria in the Act.

22. Officials recommend this option.

Major rewrite of the call-in section

23. The section could be rewritten to allow the Minister to call-in applications when there were any nationally significant effects that warranted it. For example, the RMA has broader call-in provisions.

24. The advantage of this is that it does not presume what type of effect will be significant and allows flexibility to meet future needs. Spiritual and ethical matters may need to be referenced elsewhere in the Act to meet current expectations. However, this option goes

further than both the Royal Commission recommendation and the Government decision to amend section 68.

25. In addition, this option may result in a loss of transparency. A prescriptive list provides submitters and the public with certainty and assurance of the range of significant issues that could be grounds for call-in.

Role of the Bioethics Council

26. Many submitters to the HSNO discussion document suggested a more formal role for the Bioethics Council. This would require a major change to the Terms of Reference of the Council and the decision-making process in the HSNO Act.

27. The government agreed (CAB Min (02) 15/4) that the role of the Bioethics Council is to advise, provide guidelines and promote dialogue on the cultural, ethical and spiritual issues associated with biotechnology and, together with the functions of education and future-watch, encompass the existing functions of the Independent Biotechnology Advisory Council (IBAC).

28. The Bioethics Council was not established to consider individual applications received by the ERMA, nor would it be appropriate for the Council to do so as it was established to consider broader issues rather than specific applications.

Timeframe for Ministerial Call-in

29. The ERMA also raised an issue in relation to the timeframe of call-in.

30. The time available for the Minister to consider call-in is too short. Currently, the Minister only has 15 working days post receipt of the application to call it in. This may not allow the Minister enough time to reach an appropriately informed decision on applications she chooses to consider.

31. The Resource Management Act 91 (RMA) has a similar call-in mechanism to the HSNO Act. The Minister has the power to call-in an application under the RMA up to 5 days before a hearing.

32. Officials recommend that there be an extension to the time for call-in to 30 days after public notification (the time specified in s 59(1)(c)). This would give the Minister the same opportunity as others to assess the application. The costs to the applicant will be the same regardless of the time limit.

Section Two: Confidential Supporting Information

Background

33. The Royal Commission recommended the Hazardous Substances and New Organisms Act 1996 and the Agricultural Compounds and Veterinary Medicines Act 1997 be amended to give appropriate protection to all commercially sensitive or confidential supporting information provided with applications for approval.

34. The Government responded to this recommendation by noting that the HSNO Act does not provide such protection for confidential supporting information and directing officials to undertake consultation with key stakeholders to determine what level of protection

is appropriate with a view to amending the two Acts as recommended by the Royal Commission (CAB Min (01) 34/15 refers).

35. No specific comments were received from Maori groups on the 3 issues raised in this part of the paper during hui held as part of the consultation programme. In written comment to the public discussion paper, comment was made that traditional biodiversity related knowledge is often not recognised as intellectual property and that the term "confidential information" itself, has always excluded Maori and their processes.

36. While there were a number of other issues identified by the Royal Commission and by submitters to the public discussion paper, officials have advised that only the following three issues in relation to confidential supporting information need Cabinet's consideration:

- ***Reasonableness***

  When applying to the ERMA for an approval, the applicant identifies "confidential supporting information" [CSI]. There is argument in the discussion paper about what is or is not CSI, what information it is *"reasonable"* to release, and whether there should be a formal process in the HSNO Act to identify CSI.

- ***Notification***

  In the event that a third party makes an Official Information Act (OIA) request to the ERMA for information after an application has been lodged, the original applicant will be notified. There is argument that clarification is needed in the law about what happens in the event of non-response by the original applicant.

- ***Extending Special Protection***

  The special protection (SP) afforded under s.55 of the HSNO Act to confidential supporting information (CSI) is available only for *hazardous substances* applications that are also the subject of innovative agricultural compound or medicine applications under the ACVM and Medicines Acts, respectively. All other applications, including GMO applications, do not have special protection, and the protection of CSI relies on ERMA's application of the OIA.

Reasonableness

37. Neither "commercially sensitive" nor "confidential supporting information" is defined in the HSNO Act but the relevant provisions of ACVM and Medicines Act apply in some circumstances. While the RCGM did not consider this issue, the discussion paper raised the possibility that these provisions may be interpreted broadly thereby limiting the amount of information that is disclosed. It was suggested inclusion of a reasonableness standard in the legislation might be perceived as providing greater objectivity to the decision making process so that decisions to withhold information on the basis of its commercial sensitivity are seen as fair and more robust.

38. Submitters have said:

> Defining "reasonableness" would have the effect of encouraging an open dialogue between the applicant and (potential) opponents.
> An NGO suggested adopting criteria listed in the "Aarhus Convention" (which New Zealand has not signed) and also supports having a formal identification process.

Industry and CRI submitters are generally opposed to defining "reasonableness" and are divided on the need for a formal process to determine confidential information.

39. Notwithstanding arguments advanced by submitters for criteria in the HSNO Act, Officials recommend that a "reasonableness" test in legislation would add little value and may create additional uncertainty. It is more appropriate that administrative steps be taken by the ERMA, in consultation with the public, to clarify criteria for defining CSI and protocols for its release. Such steps could result in amendment or replacement of ERMA Information Sheet Number 12 (see Annex 2).

Notification

40. The HSNO and ACVM Acts both afford two stages of protection for CSI provided to regulatory authorities. For HSNO, information provided to ERMA prior to an actual application for approval is exempt from the OIA until an application is received or 5 years has lapsed. Once an application is received, information is subject to the OIA. The OIA in turn specifically provides for the withholding of trade secrets and information likely to unreasonably prejudice the commercial position of the information provider.

41. In addition to the above, New Zealand has international obligations in respect of CSI under the World Trade Organisation's Agreement on Trade-Related Aspects of Intellectual Property (the TRIPS Agreement). The TRIPS Agreement requires WTO Members to protect, against "unfair commercial use", the information provided to regulatory authorities by companies wishing to obtain regulatory approval to market pharmaceutical or agricultural chemical products that utilise new chemical entities.

42. Notwithstanding our obligation to protect CSI against "unfair commercial use", information included in approvals may be released by ERMA as a result of the Official Information Act. When an OIA request is made in relation to information supplied pursuant to the HSNO and the ACVM Acts, the Authority is required to "notify" the person who originally supplied the information. HSNO provides that after 10 days the ERMA may release the information if the person fails to respond. Whether or not the person responds within the 10-day period, ERMA's final decision is a balancing exercise between the public and private interest as required by the OIA.

43. Submitters have said:

- an NGO said the status quo is acceptable and that the balance is already in favour of industry as opposed to the public interest
- industry and CRIs tend to support amendment of the HSNO Act to clarify what is meant by "notification" with the aim of ensuring a "positive" contact with the person who supplied the information
- there were no submissions in favour of deleting the current notification requirement entirely

44. In light of the international obligation New Zealand has to protect CSI under the TRIPS Agreement and the concerns expressed by industry, officials are of the view that s57 of HSNO and s12 of ACVM should be amended to clarify the notification obligations on the Authority and to further reduce any risk of inadvertent release of CSI under the OIA. Officials suggest that s57(4) HSNO and s12(4) ACVM be amended;

(a) to require the authority to make all reasonable efforts to contact the person who provided the information regarded as CSI
(b) to clarify that in the event of a non-response, information should not be released except following an assessment of the appropriateness of releasing the information in accordance with section 9 of the OIA

45. These amendments would strengthen the notification procedures provided for in s57 of HSNO and s12 of ACVM, as well as ensuring that we continue to be able to comply with our TRIPS obligations in relation to confidential information. While there have been no problems to date in this area, the amount of information provided to ERMA is likely to increase and it will therefore be important to ensure clarity on this issue.

Extending special protection

46. The RCGM recommended the HSNO and ACVM Acts be amended to give appropriate protection to all commercially sensitive information or confidential supporting information provided with applications for approval. The RCGM's report discussed two areas of concern in relation to the scope of protection accorded to CSI under HSNO.

47. First, the RCGM noted that the release of data for the purposes of approvals to experiment with, or market, new compounds and organisms under HSNO and the ACVM could have an adverse impact on the future patentability of products, especially where approval is required at an early stage. This concern is being addressed in the context of the review of the Patents Act 1953. Cabinet has already approved the amendment of the Patents Act to provide that the novelty of an invention is not destroyed if details of the invention are released (prior to the filing of a patent application) by way of a breach of confidence.

48. The second issue identified by the RCGM was that amendments to HSNO relating to hazardous substances meant that CSI relating to genetically modified organisms submitted to ERMA would not have the protection under HSNO that was formerly provided. The RCGM commented that this protection should be restored so that New Zealand complies with its obligations under Article 39(3) of TRIPS.

49. The Special Protection (SP) afforded under the HSNO Act to CSI is currently available only for hazardous substances applications that are also the subject of innovative agricultural compound or medicine applications under the ACVM and Medicines Acts, and not to other applications, including those relating to GMOs. Under Article 39 of the TRIPS Agreement New Zealand is obliged to protect, against "unfair commercial use", CSI provided in applications for approval of all pharmaceutical or agricultural chemical products that utilise new chemical entities. The Act will require therefore amendment, as noted by the RCGM, to extend special protection for CSI in accordance with Article 39 of TRIPS.

50. In considering the recommendations of the RCGM, the question arises as to whether it would be appropriate to extend special protection to CSI other than that which falls within the scope of TRIPS. This matter is discussed further below**.**

51. Officials have considered three options for addressing the Royal Commission's recommendation, concerning the scope of SP in the HSNO Act.

- **Option 1:** Extend SP to all applications that are also innovative agricultural compounds or medicines, whether these are hazardous substances applications or otherwise
- **Option 2:** Include "genetically modified organisms" applications not picked up by Option 1 above

- **Option 3:** Extend SP for all CSI provided to the ERMA, whether this be in applications for regulatory approvals for hazardous substances or new organisms, information provided for reassessments, or in any other information - for instance, that provided for enforcement purposes

52. Submitters have said:

> There was general agreement that the Act should be amended consistent with the TRIPS Agreement.
>
> Some submissions from biotech companies and CRIs were concerned that the release of data for the purposes of obtaining approvals could have an adverse impact on the future patentability of products. As discussed above, this issue is being addressed in the review of the Patents Act 1953. Some also argued that SP under the HSNO Act should be extended to CSI provided in applications relating to genetically modified organisms.
>
> Some submissions also noted the need to balance protection of information with those of access to information in the public interest, including for the purposes of further research.

Analysis: Option 1

53. As pointed out in the public discussion paper, the scope of protection available now that HSNO is fully in force is more limited than previously. There are some "agricultural chemical products" that in other countries would have TRIPs-based protection but that do not have SP under HSNO because the scope of the section 55 is restricted to hazardous substances. The Act therefore requires amendment to extend the scope of protection to cover all applications that are also innovative agricultural compounds or medicines, whether these are hazardous substances applications or otherwise. This will ensure that our legislation complies with the TRIPs Agreement and is consistent with the observations of the RCGM's report.

Analysis: Option 2

54. The practical effect of Option 2 is to extend SP to CSI provided to the ERMA for approvals for GMO laboratory work in containment and/or field tests. Once a GMO-containing product has reached the point of having a commercial application, it could be assumed that the developer would make an innovative agricultural compound or medicine application. There is an issue as to whether it is necessary to amend HSNO to include "genetically modified organisms" applications not picked up by Option 1, in order to prevent data cross-referencing by the ERMA for GMO R&D applications.

55. In contrast to the ACVM situation where more than one application can be received for what is essentially the same compound, data cross-referencing tends **not** to be a significant issue under HSNO.

56. There are two reasons why extension of data protection to HSNO GMO R&D applications is unnecessary. The first is that even the concept of a "data package" may be irrelevant because often the purpose of the research is to gather data. Very little information provided with such an application would be a commercially sensitive nature. Secondly the information provided on one organism is often unique and irrelevant for other organisms because of the case-by-case approval process inherent in the HSNO Act. (An exception would

be a situation where the same commercially sensitive gene construct is used in different species).

57. The issue identified by the research community concerning the possible loss of competitive advantage if the type of organism being developed is disclosed to competitors is not a data cross-referencing issue but, rather, relates to trade secrets. ERMA has been able to deal with the confidentiality requirements of these types of applications adequately under the current provisions of HSNO and has not requested any change in the legislation in this regard.

58. Officials therefore reject Option 2 on the grounds that there is no need for legislative change.

Analysis: Option 3

59. This option is rejected as going well beyond the scope of the Government's response to the RCGM recommendations.

Timetable implications

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

Financial implications

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

Human rights

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

Legislative implications

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

Regulatory impact and compliance cost statement

64. A Regulatory Impact Statement (RIS) is attached to this paper in Annex 8 and complies with the requirements of Cabinet Office Circular CO (98) 5. The RIS excludes consideration of the issue of the extension to the timeframe for Ministerial Call-In in accordance with paragraphs 3.34 and 3.35 of the Cabinet Office Step by Step Guide – Exemptions for Proposals of a Minor or Machinery Nature.

65. A Business Compliance Cost Statement has not been prepared, as it is impossible to determine in advance what, if any, compliance costs there may be for businesses in respect to Ministerial Call-In, and none are anticipated in respect of the CSI proposals.

Gender implications

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

Disability perspective

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

Publicity

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

Consultation

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

Recommendations

70. It is recommended that Ministers:

Ministerial Call In

a) **Note** that cabinet agreed to amend section 68 to include significant cultural, ethical and spiritual effects as grounds for Ministerial Call-in of an application (Cab Min (01) 34/16 refers)

b) **Agree** that it is not necessary to define the terms significant 'cultural', 'spiritual' and 'ethical' for the purpose of Ministerial Call-in

c) **Note** that Toi te Taiao: the Bioethics Council was established to advise, provide guidelines and promote dialogue on the cultural, ethical and spiritual issues associated with biotechnology

d) **Agree** that the timeframe for call-in is extended to the end of the public submission period to allow the Minister more time to seek advice and consider matters of significance

Confidential Supporting Information

e) **Agree** that s57(4) HSNO and s12(4) ACVM be amended (a) to require the Authority to make all reasonable efforts to contact the person who provided information regarded as CSI and (b) to clarify that, in the event of a non-response, information should not be released, except in accordance with section 9 of the OIA

f) **Agree** that s.55 of the HSNO Act be amended so as to ensure special protection for confidential supporting information in applications to the ERMA for approvals that are also the subject of innovative agricultural compounds or medicines application, whether these are applications for hazardous substances or new organisms

Hon Marian L Hobbs
Minister for the Environment

Annex 1

Discussion of relevant terms and definitions

Ministerial call in

Issues vs. effects

The RCGM referred to cultural, spiritual or ethical 'issues' as criteria for call-in. The proposed amendment discussion document referred to effects in line with other usage in the Act and with the other matters in s68. Some submitters thought that 'effects' was too limited and issues should be used, however most seemed to find 'effects' acceptable. The definition of effects is broad enough to cover effects of an application. Issues may be more appropriately discussed at the Bioethics Council level.

Significant

The term 'significant' is not currently defined in the HSNO Act and is used in s68 to provide the 'check' on effects to determine whether they merit call-in. Even if significant, the Minister still has discretion to call-in an application. There is no compelling reason in this case to further define significant as this is likely to limit the Ministers ability to decide what is significant.

Cultural, spiritual and ethical

Cabinet asked for further work to define the grounds for call-in. A review of other legislation shows that while cultural, spiritual and ethical are referred to they are not further defined (annexed). There is also considerable international debate on the meaning of these terms. Some submitters wanted these terms defined. However, as the reason to include cultural, spiritual and ethical is to allow the Minister to call-in applications of an unusual or significant nature further definition may unhelpfully limit the Ministers discretion.

Commercially sensitive information

Reasonable

When applying to the ERMA for an approval, the applicant identifies "commercially sensitive information". There is argument about what is or is not commercially-sensitive (confidential) information, what is *"reasonable"*, and whether there is a need for a *formal process* in the HSNO Act to identify CSI. [Issue 1]

Non-response

In the event that a third party makes an Official Information Act request to the ERMA for information after an application has been lodged, the original applicant will be notified. There is argument that clarification is needed about what happens in the event of non-response to *notification*. [Issue 2]

Data Cross-Referencing

Consideration needs to be given to the situation where CSI provided as part of one application could be used (by the ERMA) in the assessment of another, for example one made by a competitor. This kind of use is called data *cross-referencing.* [Issue 3]

Protected Periods

The HSNO Act refers to the ACVM and the Medicines Acts with respect to the duration of the *protected period* for CSI. There is argument protected periods should be reviewed. [Issue 4].

Annex 2

ERMA NEW ZEALAND
INFORMATION SHEET

NUMBER 12
MAY 2001

Confidential Information

Introduction

To ensure proper consideration of the risks, costs and benefits associated with hazardous substances and new organisms, adequate information must be available. However, the innovative nature of many new organisms and hazardous substances considered by the Authority means that specific information about them is likely to be highly confidential because of commercial sensitivity.
The HSNO Act provides for public participation in the approval process. There is likely to be conflict between the commercial sensitivity of some information and the requirement to provide for effective public participation.
This information sheet describes how confidential information will be managed under the HSNO Act processes.

What is confidential information?

Generally, information which can be withheld under the Official Information Act 1982 (OIA) can be confidential information under HSNO. The most likely grounds for withholding information – specifically referred to in the HSNO Act – is spelled out in the OIA. It applies where withholding the information is necessary to 'protect information where the making available of the information would disclose a trade secret or would be likely unreasonably to prejudice the commercial position of the person who supplied or who is the subject of the information'. (OIA, s9 (2)(b)).

While ERMA New Zealand must make the decision whether information is released, we rely on the person providing such information to identify it as confidential, and to justify this position.

Protection of confidential information

Information supplied by a prospective applicant at the pre-application stage is held by ERMA New Zealand on behalf of that person and the Official Information Act does not apply to it.
This information will not be released without the permission of the provider and will be returned on request.

Confidential information is securely stored, and is not released when any application is publicly notified.

If we receive a request under the Official Information Act to release information identified as being confidential, we must advise the person who provided the information. The provider has ten working days to advise whether the information should be withheld under the OIA (and why) before ERMA New Zealand decides to release or withhold the information.

Any decision to withhold information under the OIA is subject to review by the Ombudsman.

Providing the action is in accordance with our statutory obligations, we will treat it as confidential for as long as is specified by the applicant or submitter. All information provided by an applicant or submitter classified as such by that person remains commercially confidential.

Where we believe that information identified as confidential by the person who supplied it does not fall within the statutory criteria for withholding such information, we will advise the person supplying the information. We will give them the opportunity to further justify why the information should be withheld.

If an evaluation and review report or a decision document includes confidential information, this will be contained in a confidential appendix not publicly available. Where confidential information is to be presented at a hearing, the hearing can go into closed session for this purpose. At the conclusion of the closed session, the Chairman will report back to the full hearing, in terms that do not disclose the matters canvassed in the closed session.

How to handle confidential information when making an application

Confidential information should be clearly identified as such. We urge applicants to separate out confidential information into an appendix to the application that we can then place in secure storage.

Applicants should include in their publicly accessible application enough information to enable submissions to be made on an informal basis and, more generally, for the Authority to be able to give reasons for its decisions. Thus, while confidential information should be excised into an appendix, this main application should include a non-confidential summary of the information.
This should make it clear what the application is about, likely risks, costs and benefits, and likely effects of the hazardous substance or new organism.

Please resist the temptation to identify whole documents as confidential where only certain information is truly commercially sensitive.

In some instances, submissions on notified applications may contain confidential information.
The above principles apply to such submissions.

Applications for innovative agricultural compounds and innovative medicines

Along with the general provision for confidential information, the HSNO Act also makes special provision for confidential supporting information. This affects applications which are also the subject of applications for approval as an innovative agricultural compound (under the Agricultural Compounds and Veterinary Medicine Act 1997) or an innovative medicines application (under the Medicines Act 1981).

Where such a substance is the subject of an application under HSNO and under either of these Acts, confidential supporting information cannot be disclosed (with certain limited exceptions). Neither can the information be used by the Authority to determine whether to approve another application.

Confidentiality of notifications submitted under the Toxic Substances Act

The processing of notifications under section 32 of the Toxic Substances Act was carried out by ERMA New Zealand, on behalf of the Ministry of Health. ERMA New Zealand is responsible for assessing these substances under the Transitional Provisions of the HSNO Act.

The confidentiality of the information provided through the notification process will be maintained by ERMA New Zealand under the same conditions applied by the Ministry of Health. There is no public access to the information supplied with notifications. Technically, requests for information can be made under the Official Information Act but there are provisions for withholding information that is considered commercially sensitive. No information would be released without first checking with the notifier.

Conclusion

Robust mechanisms are in place for protecting confidential information. For these mechanisms to operate within the public HSNO approvals process:

- confidential information should be clearly identified as such and be included in a separate document
- the public documents should include a non-confidential description of the information and its significance
- only information which is truly confidential should be classified as such.

If you have any queries, please contact one of our application officers.

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ERMA NEW ZEALAND INFORMATION SHEETS:

ERMA New Zealand publishes information sheets on a range of topics to provide background information on current issues or proposals being dealt with by the Authority.
Please feel free to photocopy this material. Acknowledgement of ERMA New Zealand would be appreciated.
The information sheets are available from
ERMA New Zealand, PO Box 131 Wellington. Phone: 64 4 473 8426. Fax: 64 4 473 8433. Email: info@ermanz.govt.nz
The information sheets can also be viewed and downloaded on our website at **www.ermanz.govt.nz**

Annex 3

Relevant RCGM recommendations

Recommendation 10.7

that the Hazardous Substances and New Organisms Act 1996 and the Agricultural Compounds and Veterinary Medicines Act 1997 be amended to give appropriate protection to all commercially sensitive or confidential supporting information provided with applications for approval.

Recommendation 14.1

that section 68 of the Hazardous Substances and New Organisms Act 1996 be extended to include significant cultural, ethical and spiritual issues as grounds for the Minister's call-in powers.

Annex 4

Relevant sections of the O.I.A

Official Information Act 1982, Commenced: 1 July 1983

I: Purposes and Criteria

Section 9: Other reasons for withholding official information

9. Other reasons for withholding official information---
(1) Where this section applies, good reason for withholding official information exists, for the purpose of section 5 of this Act, unless, in the circumstances of the particular case, the withholding of that information is outweighed by other considerations which render it desirable, in the public interest, to make that information available.

(2) Subject to sections 6, 7, . . . 10, and 18 of this Act, this section applies if, and only if, the withholding of the information is necessary to---

(a) Protect the privacy of natural persons, including that of deceased natural persons; or

[(b) Protect information where the making available of the information---

(i) Would disclose a trade secret; or
(ii) Would be likely unreasonably to prejudice the commercial position of the person who supplied or who is the subject of the information; or

(ba) Protect information which is subject to an obligation of confidence or which any person has been or could be compelled to provide under the authority of any enactment, where the making available of the information---

(i) Would be likely to prejudice the supply of similar information, or information from the same source, and it is in the public interest that such information should continue to be supplied; or
(ii) Would be likely otherwise to damage the public interest;**]** or

(c) Avoid prejudice to measures protecting the health or safety of members of the public; or

(d) Avoid prejudice to the substantial economic interests of New Zealand; or

(e) Avoid prejudice to measures that prevent or mitigate material loss to members of the public; or

(f) Maintain the constitutional conventions for the time being which protect---
(i) The confidentiality of communications by or with the Sovereign or her representative;

(ii) Collective and individual ministerial responsibility;
(iii) The political neutrality of officials;
(iv) The confidentiality of advice tendered by Ministers of the Crown and officials; or

(g) Maintain the effective conduct of public affairs through---

(i) The free and frank expression of opinions by or between or to Ministers of the Crown [or members of an organisation] or officers and employees of any Department or organisation in the course of their duty; or
(ii) The protection of such Ministers [, members of organisations], officers, and employees from improper pressure or harassment; or

(h) Maintain legal professional privilege; or

[(i) Enable a Minister of the Crown or any Department or organisation holding the information to carry out, without prejudice or disadvantage, commercial activities; or

(j) Enable a Minister of the Crown or any Department or organisation holding the information to carry on, without prejudice or disadvantage, negotiations (including commercial and industrial negotiations); or]

(k) Prevent the disclosure or use of official information for improper gain or improper advantage.
In subs. (2) the expression ``8 (1)" was omitted by s. 4 (2) of the Official Information Amendment Act 1987
In subs. (2); paras. (b) and (ba) were substituted for the original para. (b) by s. 5 (1) of that Act.
In subs. (2) (g) (i) and (ii) the words in square brackets were inserted by ss. 5 (2) And 5 (3) of that Act respectively.
In subs. (2), paras. (i) and (j) were substituted for the original paras. (i) and (j) by s. 5 (4) of that Act.

Prevent the disclosure or use of official information for improper gain or improper advantage.

Annex 5

Relevant sections of the HSNO Act

The Hazardous Substances and New Organisms Act 1996:

V: Assessment of Hazardous Substances and New Organisms
Procedure for Assessment

SECTION 55: INFORMATION HELD ON BEHALF OF APPLICANT

55. Information held on behalf of applicant---

(1) Where any person---

(a) Supplies any information to the Authority; and

(b) The information is likely to relate to an application for approval; and

(c) The relevant application has not yet been lodged with the Authority,---

the information shall be held by the Authority on behalf of that person; and the provisions of the Official Information Act 1982 shall not apply to that information until the relevant application has been received by the Authority.

(2) Where any information supplied under subsection (1) of this section is held by the Authority on behalf of any person, that information shall be returned upon request.

(3) Where---

(a) Any information is held by the Authority relating to any application made under section 28 or section 31 or section 47 of this Act in respect of a hazardous substance; and

(b) That substance is also the subject of an innovative medicine application as defined in section 23A of the Medicines Act 1981; and

(c) That information includes trade secrets or information that has commercial value that would be, or would be likely to be, diminished by disclosure,---

the provisions of sections 23A to 23C of the Medicines Act 1981, with the necessary modifications, shall apply to that information as if the information were confidential supporting information as defined in section 23A of that Act.

(4) The provisions of sections 23A to 23C of the Medicines Act 1981, with the necessary modifications, shall also apply to the Authority in respect of the information referred to in subsection (3) of this section as if the Authority were the Minister of Health, and as if references in those sections to applications were references to applications in respect of hazardous substances; but---

(a) The protected period (as defined in section 23A of the Medicines Act 1981) shall be the same period for which the information is protected under the Medicines Act 1981; and

(b) The Authority may disclose the information to any prescribed person or organisation or prescribed class of persons or organisations; and

(c) The Authority shall provide a summary of the effects of any substance in respect of which subsection (3) of this section applies where an application for approval is required to be publicly notified in accordance with section 53 of this Act.

(5) Where---

(a) Any information is held by the Authority relating to any application made under section 28 or section 31 or section 47 of this Act in respect of a hazardous substance; and

(b) That substance is also the subject of an innovative animal remedy application as defined in section 35A of the Animal Remedies Act 1967; and

(c) That information includes trade secrets or information that has commercial value that would be, or would be likely to be, diminished by disclosure,---

the provisions of sections 35A to 35C of the Animal Remedies Act 1967, with the necessary modifications, shall apply to that information as if the information were confidential supporting information as defined in section 35A of that Act.

(6) The provisions of sections 35A to 35C of the Animal Remedies Act 1967, with the necessary modifications, shall also apply to the Authority in respect of the information referred to in subsection (5) of this section as if the Authority were the Animal Remedies Board, and as if references in those sections to applications were references to applications in respect of hazardous substances; but---

(a) The protected period (as defined in section 35A of the Animal Remedies Act 1967) shall be the same period for which the information is protected under the Animal Remedies Act 1967; and

(b) The Authority may disclose the information to any prescribed person or organisation or prescribed class of persons or organisations; and

(c) The Authority shall provide a summary of the effects of any substance in respect of which subsection (5) of this section applies where an application for approval is required to be publicly notified in accordance with section 53 of this Act.

(7) The Governor-General may, from time to time, by Order in Council, make regulations prescribing persons or organisations or classes of persons or organisations for the purposes of subsections (4) (b) and (6) (b) of this section.

V: ASSESSMENT OF HAZARDOUS SUBSTANCES AND NEW ORGANISMS MINISTER'S CALL-IN POWERS

SECTION 68: MINISTER'S POWER TO CALL IN APPLICATIONS WITH SIGNIFICANT EFFECTS

68. Minister's power to call in applications with significant effects---

(1) Where the Minister considers that the decision on any application under this Act will have---

(a) Significant economic effects; or
(b) Significant environmental effects; or
(c) Significant international effects; or
(d) Significant health effects; or
(e) Significant effects in an area in which the Authority lacks sufficient knowledge or experience,---

the Minister may direct that the Minister will decide the application.

(2) The direction shall include the Minister's reasons for giving it.

(3) Where the application is for approval to release from containment any new organism, the Minister, in the Minister's discretion, may include in the direction given under subsection (1) of this section a statement specifying, in the circumstances of the particular case, what is or is not significant for the purposes of applying section 36 of this Act in respect of the application.

Annex 6

Summary of other legislation that makes reference to cultural, spiritual and ethical

None of the statutes in the references below include a definition of cultural, ethical or spiritual.

- A search has found 486 'cultural and spiritual beliefs' records in legislation (98.5% of which were the Ngai Tahu Settlement Act), but only the compulsory treatment included ethical as well. Often the legislation referred to cultural spiritual and emotional interests – such as the Crown Forests Assets Act 1989 which states section 18 - The terms of every protective covenant for the protection of archaeological sites, and sites **having historical or spiritual or emotional or cultural significance** and Waahi Tapu shall be determined by the responsible Ministers in consultation with such persons or Maori who, or organisations that, in the opinion of the responsible Ministers, have an interest, or, represent persons or Maori having an interest, in the proposed covenants.

- Subjects of a personal nature - The Mental Health (Compulsory Assessment and Treatment) Act 1992 - A court, tribunal, or person exercising a power or conducting proceedings under that Act in respect of a person and that power must be exercised, or the proceedings conducted,—

  (a) With proper recognition of the importance and significance to the person of the person's ties with his or her family, whanau, hapu, iwi, and family group; and

  (b) With proper recognition of the contribution those ties make to the person's wellbeing; and

  (c) With **proper respect for the person's cultural and ethnic identity, language, and religious or ethical beliefs**.]

- Transit New Zealand Act 1989 (repealed) – Maori interests to be considered - no project that affects or is likely to affect Maori land, land registered under the Waikato Raupatu Claims Settlement Act, or **Maori historical cultural or spiritual interests** shall be included in any district land transport programme….

- The National Parks Act 1980 section 30 - The Board having jurisdiction in respect of the Whanganui National Park shall, in carrying out its functions,—
  (a) Have regard to the **spiritual, historical, and cultural** significance of the Wanganui River to the Whanganui iwi; and …

- The Ngai Tahu Claims Settlement Act 1998 – has numerous examples most along the lines of "Pursuant to Section [ ] of the Settlement Legislation (clause 12.2.2 of the Deed of

Settlement), the Crown acknowledges Te Rünanga's statement of Ngäi Tahu's **cultural, spiritual, historic and/or traditional association to** Mahi Tïkumu as set out below."

- The Resource Management Act 1991 – 4th Schedule "Matters that should be considered when preparing an assessment of effects on the environment— Subject to the provisions of any policy statement or plan, any person preparing an assessment of the effects on the environment should consider the following matters:
    (a) Any effect on those in the neighbourhood and, where relevant, the wider community including any socio-economic and cultural effects:

    (b) Any physical effect on the locality, including any landscape and visual effects:

    (c) Any effect on ecosystems, including effects on plants or animals and any physical disturbance of habitats in the vicinity:

    (d) Any effect on natural and physical resources having aesthetic, recreational, scientific, historical, spiritual, or cultural, or other special value for present or future generations:

Annex 7

Relevant sections of TRIPS agreement

Section 7: Protection of undisclosed information

Article 39

1. In the course of ensuring effective protection against unfair competition as provided in Article 10*bis* of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.

2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices[10] so long as such information:

   (a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

   (b) has commercial value because it is secret; and

   (c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

[10] *For the purpose of this provision, "a manner contrary to honest commercial practices" shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.*

Annex 8

Regulatory Impact Statement

Nature and magnitude of problem and need for Government action

"Call-In" is a means to allow the Minister to decide certain applications rather than the ERMA. It is a backstop tool to allow the Minister to make decisions on applications that have unusual or significant features. There is an existing Call-In provision in the HSNO Act but it has never been used. There is wide agreement, including support from the Royal Commission, that the Minister *should* be able to call-in applications with significant cultural, spiritual and ethical effects but it is uncertain whether this existing provision enables this. The legislation needs to be clarified.

With respect to confidential supporting information, the issue is how the ERMA should respond to requests under the Official Information Act (OIA) for information contained in applications for approvals. Abnormal circumstances such as the Pacific Seeds inquiry excepted, the ERMA receives 15-20 OIA requests each year. Of this number, only 5 or less, relate to information contained in applications for approval.

Industry has argued that the relevant sections of the HSNO Act could result in inappropriate disclosure of information that is commercially sensitive. Environmental groups have argued the reverse and say that the current system that allows industry to identify in applications what it regards as commercially sensitive results in information being withheld that should be in the public arena. The Royal Commission was concerned about consistency between hazardous substances and new organisms applications, and New Zealand's alignment with the TRIPS Agreement.

Public policy objective

The objective is to improve the overall effectiveness of the operation of the HSNO Act by clarifying:

- that the Minister can call-in applications that have significant cultural, ethical and spiritual effects and
- how ERMA may respond to Official Information Act requests

Options for achieving objectives

Non-regulatory options

Government has indicated it considers regulatory approval of the GM technology to continue to be necessary. Officials have not developed or considered non-regulatory options.

Regulatory options – Ministerial Call-In

Three options were developed to best deal with cultural spiritual and ethical considerations in the HSNO legislation:

- **Option 1**: Amending call-in and further defining terms
  "Cultural, spiritual and ethical" could be included in the call-in section and further defined in the interpretation section of the Act. Defining the terms however, may unhelpfully limit the Ministers discretion and complicate matters in regard to the principles relevant to the purpose of the Act.
- **Option 2**: Amending call-in without further defining terms
  Option 2 overcomes the two problems identified for Option 1.
- **Option 3**: Major rewrite of the call-in section
  Another alternative is to rewrite the section to allow the Minister to call-in applications when there were any nationally significant effects that warranted it.

Compared to the status quo, all three options give clarity in the legislation. Officials preferred Option 2 because it was adequately addresses the recommendations of the Royal Commission without unnecessarily widening the scope of the policy debate.

Regulatory options – Confidential Supporting Information

The significant issue with respect to confidential supporting information is the extent of "special protection" (SP) for information provided with HSNO Act applications. Again, three options were developed:

- **Option 1:** Extend SP to all applications that are also innovative agricultural compounds or medicines, whether these are hazardous substances applications or otherwise.
- **Option 2:** Include "genetically modified organisms" applications not picked up by Option 1 above;
- **Option 3:** Extend SP for all CSI provided to the ERMA, whether this be in applications for regulatory approvals for hazardous substances or new organisms, information provided for reassessments, or in any other information - for instance, that provided for enforcement purposes.

In considering the three options, officials looked at the balance between the private benefits to business of increasing levels of special protection and the public benefit of increasing the public's access to information. Given the small number of OIA requests the ERMA actually receives, and the lack of criticism in submissions of ERMA's operational-level policy on information protection, the practical effect of any legislative change is likely to be small. The more important issue appears to be international perceptions about New Zealand's compliance with the TRIPS Agreement. Officials preferred Option 1 as significantly improving compliance with the TRIPS Agreement without unreasonably restricting the public's access to information.

Net benefit of the proposal

Ministerial Call-In

The options are cost-neutral from the point of view of the applicant for an ERMA approval. The preferred option (Option 2) will deliver the objective in a manner that is efficient and effective in legal terms. Some industry submitters perceive that if an application is called in, there is an increased likelihood that it will be turned down. In other words, that the options will not deliver the same policy outcome. Officials have not considered this argument in detail, or attempted to construct economic models for each option.

Confidential Supporting Information

Similarly the options are cost-neutral from the point of view of applicants to the ERMA for approvals and persons who seek information from the ERMA through making an OIA request. The preferred option (Option 1) will deliver the deliver the objective in a manner that is efficient and effective in legal terms

Compared to the status quo, the significant benefit associated with the preferred option is improved compliance with the TRIPS Agreement. No attempt was made to quantify this benefit in financial terms.

Consultative process undertaken

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.

With respect to Ministerial Call-In, many submitters wanted to see a formal decision-making role for the Bioethics Council. The Bioethics Council, however, was not established to advise on individual applications received by the ERMA.

The following government agencies were consulted in the preparation of this 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.

With respect to the Confidential Supporting Information, the Ministry of Foreign Affairs and Trade made significant comment on New Zealand's compliance with the TRIPS Agreement. The Ministry of Justice commented from the standpoint of the public's access to information.