The Chair, Cabinet

Government Response to the Royal Commission on Genetic Modification: Legislative changes for new organisms – Paper 2 Laboratory Research, Cloning, and Human Cell Lines

Proposal

1. This paper provides advice to Ministers on proposed amendments to the Hazardous Substances and New Organisms (HSNO) Act arising from the recommendations of the Royal Commission. It covers amendments relating to laboratory research, the importation of low risk genetically modified organisms (GMOs) into containment, the cloning of animals and genetic modification of human cell lines. The changes proposed simplify processes and lower compliance costs for low risk genetic modification research and address technical and regulatory gaps.

Executive Summary

2. "Low-risk" GMOs are organisms that are seen as presenting minimal risks to both people and to the environment **and** which are contained within a registered containment facility such as a laboratory or glasshouse. Approvals for low-risk research are usually made by Institutional Biological Safety Committees (IBSCs), under delegation from ERMA. The process and information requirements for approving laboratory research involving low-risk organisms are complex and time consuming given the low level of risk. Officials recommend that the approval process for this research be simplified by the removal of some of the information requirements that are currently required by the HSNO Act. The changes proposed would not change the type of research that can currently be approved by IBSCs.

3. While IBSCs can currently approve the development of low-risk organisms, they cannot be delegated the power to approve the importation of the same low-risk GMOs. As a consequence each application to import a low-risk GMO has to be considered and approved by ERMA – an expensive and time-consuming process. Officials recommend that the HSNO Act be amended to permit IBSCs to approve the importation of low-risk GMOs.

4. The advancement of new technologies, such as cloning, allows animals to be regenerated from tissue samples. The HSNO Act did not foresee the potential for this technology to enable the development of new species that were not already in New Zealand. Officials recommend that the HSNO Act be amended to close this potential gap, so that new organisms created in this way would be assessed under the HSNO framework. This would affect only new organisms, not the cloning of organisms already in New Zealand such as cows or sheep. The cloning of humans and other human reproductive technologies will be addressed separately in proposed human assisted reproductive technology legislation.

5. The genetic modification of human cell lines is currently unregulated in New Zealand because of exemptions in both the HSNO and Medicines Acts. The same modifications of animal cell lines are, however, assessed and regulated under the HSNO Act. Officials recommend that the genetic modification of human cell lines be subject to the provisions of the HSNO Act.

Comment

1 Approval process for the development of low-risk GMOs

Background to low-risk GM approvals

6. The Royal Commission recommended that applications to develop genetically modified organisms in PC1 and PC2 containment be assessed by the IBSCs on a project rather than organism basis.

7. Cabinet agreed (CAB Min (01) 34/13 refers) to accept the intent of the recommendation which is to simplify the assessment of low-risk laboratory research either by using defined criteria to assess organisms, or by providing for the approval of groups of organisms of similar types and risks, rather than requiring separate approvals for each organism.

Explanation of the issue

8. The Royal Commission heard considerable evidence from researchers that the approval procedures for frequently used genetic modification research techniques in laboratories using low-risk organisms were overly complex, impractical, costly and time consuming. The Royal Commission agreed that it was appropriate to streamline the approval processes for this type of GM research. Their recommended response was to permit the approval of low-risk organisms on a "project" basis. The intention was to streamline the approval process that is currently undertaken by IBSCs, without changing the type or risk of low-risk research in laboratories that IBSCs were already able to approve. IBSCs operate under delegated authority from ERMA.

9. "Low-Risk GMOs" are organisms that are seen as presenting minimal risks to both people and to the environment (by virtue of the nature of the host organism and the genetic modifications made to it) **and** which are contained within a registered containment facility such as a laboratory or glasshouse. GMOs that are able to infect and cause significant disease in humans, plants and animals are not low-risk organisms. Similarly, genetic modifications that increase the toxicity or risk of otherwise benign organisms are not low-risk. The field-testing or outdoor containment of GMOs is also not considered low risk under the regulations, as the activity is not carried out and contained within a registered containment facility.

10. Much of the research involving low risk GMOs uses genetic modification as a research tool to study genetic differences or the function of genes in bacteria, plants and animals. Many overseas regulatory agencies have simplified procedures to approve or notify research involving low-risk GMOs in line with those being proposed here.

11. There is currently no definition of low-risk GMO in the HSNO Act. The types of genetic modification that are considered to be low-risk and some of the features of low-risk organisms are, however, defined in the HSNO (Low-Risk Genetic Modification) Regulations.

12. ERMA has already taken some steps to streamline approvals of low-risk research within the current legislation by allowing applications for "group approvals" to be made to IBSCs. These group approvals provide for a range of organisms or modifications in a single application. Cabinet has also approved amendments to the HSNO low risk genetic modification regulations and these are currently being drafted. The effect of the changes to these regulations will be to more clearly and accurately define the scope of low-risk GMO developments in laboratory containment facilities. While these changes will correct some current anomalies in the regulations and allow some approvals to be grouped, they still leave a relatively complex approval process involving detailed organism descriptions and risk analyses for much of the routine research involving low-risk GMO developments.

Public consultation

13. Those submitters who are undertaking research involving genetic modification were strongly supportive of measures to streamline the approval process for low-risk GMO developments in containment. There was support for approval systems similar to those used overseas where general approvals or licences are given for specified types of low-risk research in containment.

14. Those submitters with concerns about research involving GMOs particularly noted the importance of provisions to ensure the effective containment of the organisms. Some submitters did not think that any genetic modifications could be considered "low risk" because of the potential for unanticipated effects.

15. Several organisations representing iwi indicated an opposition in principle to genetic modification, particularly when the transfer of genetic material from one species to another was involved. This concern was reflected in their views of whether such organisms could genuinely be considered low-risk. There was a desire to see a strongly precautionary approach taken to the approval of research involving low-risk organisms.

Officials' advice

16. Despite ERMA's use of "group" approvals and the proposed amendments to the HSNO low-risk regulations, the approval processes for low-risk GMO developments in laboratory containment remain time consuming, inflexible and costly given the nature of the genetic modifications, their containment regime and the low level of the risks they present.

17. Officials propose that the detailed and descriptive requirements of the current process for approving research involving low-risk GMOs in containment be reduced. Officials recommend that the current organism-by-organism detailed assessment be replaced by a prior notification, approval and reporting process for low-risk GMO developments. This procedure would apply to exactly the same type of low-risk research as that currently approved by IBSCs under delegation. i.e. the development of Category A and B low-risk GMOs in MAF-approved PC 1 and PC 2 laboratory containment facilities Where institutes do not have an IBSC with delegated powers from ERMA, the same requirements would apply except that ERMA would provide the approval. The proposal would not apply to outdoor developments or field tests.

18. The approval process proposed would reduce the time required to prepare applications (the key concern of researchers), but still provide IBSC and ERMA oversight and auditing of genetic modification research. ERMA has a policy requiring IBSCs to have Maori members. Many submitters (including those opposed to the use of GMOs outside laboratories) considered that containment of low-risk GMOs was the critical issue. Officials consider that reducing information requirements for research involving low risk GMOs in secure containment, while maintaining oversight by IBSCs or ERMA, will facilitate laboratory research without increasing the level of risk to human health or the environment.

19. The proposed streamlining would also fulfil the intent of the recommendation of the Royal Commission. The system proposed is as follows:

(i) Prior notification - Before a researcher undertakes any research involving the development of low-risk GMOs they would be required to inform their IBSC (or ERMA if their organisation did not have an IBSC) of the identity of the host organisms and a description of the project and the proposed range of genetic modifications. The current requirements for detailed descriptions and risk assessments of each GMO to be developed would no longer be necessary. The notification would provide an IBSC (or ERMA) with information that would enable them to confirm that the organisms and containment

provisions were appropriate for low-risk research, that the researcher had the necessary skills to undertake the research safely and that appropriate consultation had taken place. e.g. the current delegation to IBSCs prescribes consultation with Maori for research involving native flora and fauna, and informed consent for research involving copies of human genes.

(ii) Approval - The IBSC or ERMA would receive the notification and confirm that the research fulfilled low risk criteria and any other research requirements. The IBSC (or ERMA) would then inform the researcher whether the research could proceed or not proceed, and whether there were any other constraints or other requirements placed on the research.

(iii) Progress reporting – At the end of each year (or earlier if necessary) the researcher would be required to report to the IBSC or ERMA on progress in the research programme involving the low risk developments. This report would have sufficient information to inform the IBSC (and subsequently ERMA) about the range of organisms involved, the types of organisms retained and their location and any other relevant matters.

20. The overall effect of the proposed changes would be to reduce the complexity of the information required from researchers while maintaining the same IBSC/ERMA regulatory oversight of low risk research in laboratories including auditing of the research and the activities of the IBSC. The GMOs developed remain "approved new organisms in containment" under the Act.

21. Changes to the HSNO Act will be required to reduce the current information requirements from researchers. The HSNO Act requires ERMA to maintain a register of low risk approvals. The Act may need to be amended to provide for the changed information requirements from applicants.

22. However, other outcomes of the system proposed above can be achieved through amendments to ERMA's delegation of approvals to individual IBSCs and also through amendments to the ERMA guidelines on low-risk research that are followed by IBSCs.

23. It may also be useful to include a definition of low-risk GMOs in the Act. See next section on delegation of imports for further discussion of the definition.

2 Delegating the approval for the importation of low-risk GMOs to IBSCs

Background to importation of low-risk GMOs

24. The Royal Commission recommended that the HSNO Act be amended to allow for the efficient importation of low-risk genetically modified organisms, through delegation of the approval process to the IBSCs. Cabinet agreed to accept the recommendation (CAB Min (01) 34/13 refers).

Explanation of the issue

25. The current HSNO Act allows IBSCs to be given the delegated authority to approve the development of low-risk GMOs in containment. There is no comparable delegation for rapid assessment and approval for the importation of GMOs into containment. The importation of (possibly the same) low-risk GMO requires specific approval from ERMA. The HSNO Act does not currently allow this approval role to be delegated. The approval of imports of low-risk GMO routinely costs researchers more than $1,000 and can sometimes take three months or more. This

can result in substantial delays to even routine projects in the fast moving area of biotechnology research.

Public consultation

26. Feedback was sought from submitters on ways for IBSCs to be given authority to assess and approve imports of low-risk GMOs. Researchers supported the proposal to allow IBSCs to receive delegated authority from ERMA. They noted that the nature and effect of such organisms is largely predictable from knowing the host organism, the inserted DNA and the vector that transfers the DNA into the host. Researchers noted that it can be difficult to obtain information from a foreign supplier about the process used to develop an organism even when the organism itself is well characterised, but such information was not necessary to determine the risks if the nature of the introduced material was known.

27. Other submissions proposed a more cautious approach as they considered that the development of GMOs involved a significant risk because of potential unexpected consequences. Some submitters considered that IBSCs should not make decisions involving the approval of low-risk GMO imports into containment.

28. Those iwi submissions that stated a general opposition in principle to genetic modification sought the same precautionary approach to the import of low-risk GMOs as they proposed for the development of low-risk GMOs in New Zealand.

Officials' advice

29. The delegation to IBSCs of the approval to import low-risk GMOs into containment is desirable to provide more consistency with the assessment and approval process for the development of low-risk GMOs in New Zealand. However, these imports of low-risk GMOs will still require detailed descriptions of the organisms or groups of organisms to be made to enable a MAF import permit to be issued for their importation, and to demonstrate that they do meet the requirements of a low risk organism or development.

30. If the researcher is unable to obtain the necessary information about the host and new genetic material then the application could not be approved by the IBSC and would, by default, have to be considered by ERMA in the same way that applications are considered now. ERMA currently tests the description of the GMO to be imported against the provisions in the low risk regulations. Most of the low-risk organisms that would be imported under IBSC delegation are, however, expected to be well characterised and described with detailed information on the host and new genetic material.

31. This proposal maintains the organism-by-organism consideration of each proposed import of a low-risk GMO or group of GMOs and would be valid only for the institution which sought the approval. (IBSCs are local committees and do not have national responsibilities. Currently ERMA approvals to import GMOs are valid nationally. The proposed change will result in a more restricted approval, the same as for approvals of developments by IBSCs. However, for researchers their main concern was the time and cost of obtaining an approval to import, and with a more rapid approval process, the effect of a local import approval is likely to be unimportant. IBSCs would also be required to notify ERMA of any approval they made to import low-risk GMOs as they would be operating under powers delegated by ERMA. As with development of low risk GMOs, there may need to be changes to the information recorded in the ERMA register.

32. The addition of a definition of a "low-risk" organism will also assist the approval process by clarifying the identification requirements for low risk organisms being imported. Currently a low-risk **development** is an organism developed by the process described by the HSNO (Low-Risk Genetic Modification) Regulations. The organisms developed by these processes all present

minimal risks to both people and the environment and are contained in approved laboratories. A low-risk **organism**, however, is not defined in the Act. The inclusion of a definition of a low-risk organism in the HSNO Act would make it easier for researchers to show that the particular organisms they wish to import meet the low risk criteria. Officials consider that the characteristics of the new organism and the containment system are the key factors in determining risk.

33. Officials recommend that a "low-risk" organism be defined in the Act. The definition should be expressed in terms of being: an organism that presents minimal risks to both people and the environment **and** which has characteristics described in the Low-Risk Regulations **and** which is, or will be, contained within registered containment laboratories. The containment provisions and minimal risk requirements are already implicit in the low-risk regulations, but it may be useful to include these characteristics in the definition for clarity.

3 New organisms regenerated from tissues

Background to the regeneration of new organisms from tissues

34. The Royal Commission recommended that the HSNO Act be amended to cover procedures used in mammalian cloning such as nuclear transfer or cell fusion. Cabinet agreed (CAB Min (01) 34/13 refers) to accept the intent of the recommendation, to the extent that it ensures that new species of mammals (or other animals) cannot be imported as tissues and subsequently regenerated by cloning and released without an appropriate HSNO Act approval.

Explanation of the issue

35. The issue raised by the Royal Commission with respect to cloning relates to the potential for new technologies, such as cloning, to create new organisms that could potentially be utilised or released into New Zealand. For example, it may now be possible to legally import small tissue samples of animals that are new organisms under the Act, and using cloning technology, to regenerate a whole animal. The HSNO Act did not foresee this possibility and consequently there is a potential to develop some new organisms without appropriate consideration and approval by ERMA. Release of such animals from containment is, however, covered by the HSNO Act.

36. The HSNO Act does not presently cover the reproductive cloning of animals from tissues, as the definition of "develop" only involves genetic modification. Most animal tissue samples and cell cultures cannot spontaneously regenerate into whole organisms. The cloning process produces near identical copies of animals. If the original animal or its cells or tissues are not genetically modified then the cloned animals produced will also not be genetically modified. They therefore fall outside the definition of "develop" and are consequently not subject to the HSNO Act.

Public consultation

37. Submissions were sought on ways to ensure that animals that were regenerated from tissues by cloning, and were themselves new organisms, could be subject to the HSNO Act.

38. Submitters, including one iwi authority, generally agreed that this potential gap in HSNO coverage should be addressed. While some wanted the cloning of animals banned because of animal welfare concerns, others noted that the technology was not relevant in assessing the environmental effects of an organism.

Officials' advice

39. Although the Royal Commission made its recommendation in respect to the cloning of mammals, the potential gap in HSNO coverage applies equally to most animals that are new organisms. This issue is not as relevant to plants, since many plants are routinely cloned by taking and growing cuttings or other vegetative material and so the ability of plant material to be regenerated into an organism is usually considered when it is imported. Although the process of cloning is the technology that currently provides a challenge for the HSNO Act coverage, other technologies may become available in the future to regenerate animals from cells or tissues. Consequently any amendment should not limit the technology that is used to produce a new organism.

40. The most straightforward way of ensuring that new organisms arising from the regeneration of tissues are covered by the HSNO Act appears to be to amend the definition of "develop" in the Act. Currently to "develop" an organism means to genetically modify an organism but it could be extended to encompass means of regenerating a new organism from tissues, cells or other genetic material. The proposed change would have no effect on the cloning or regeneration from tissue, using in vitro techniques, of species or varieties of organisms that are currently in New Zealand or the natural regeneration of some species from their tissues or cells.

4 Genetic modification of human cell lines

Background to the genetic modification of human cell lines

41. The Royal Commission recommended that the HSNO Act be amended to clarify that research involving genetic modification of human cell lines or tissue cultures is covered by the Act. Cabinet agreed (CAB Min (01) 34/13 refers) to accept the intention of the recommendation, which is to ensure that the genetic modification of human cell lines and tissue cultures is subject to appropriate regulation.

Explanation of the issue

42. Human cell lines and tissue cultures are groups of cells initially derived from human tissue, but which are being grown in a culture medium in a container. Genetic modification of these cells allows detailed study of the functions of particular cell types and genes and their role in cell metabolism and disease. A wide range of human cell lines is available commercially and these are the cell lines most often used in research.

43. Currently the HSNO Act definition of "organism" excludes humans, human tissues and cells. The effect of this is that a HSNO approval is not required to import GM human cell lines or to genetically modify human cell lines in New Zealand. This creates an anomaly, as HSNO approval is required to import GM animal cell lines or genetically modify animal cell lines. The Medicines Act covers activities such as clinical trials of new medicines and other medical activities and procedures involving people but also excludes research using human cell lines if human subjects are not involved.

44. There is consequently a regulatory gap for the genetic modification of human cell lines and tissue cultures and there are two options available to ensure appropriate regulation of this technology. The first is to provide coverage under the HSNO Act. The second is to provide coverage under the Ministry of Health review of all aspects of collection, storage, use and disposal of human bodies, organs, tissues and tissue samples and related research.

Public consultation

45. Information was sought from submitters about the options available for bringing genetically modified human cell lines and tissues under appropriate regulatory control and the implications of the options. There was broad agreement that the current anomaly with respect to human cell lines should be addressed.

46. A range of views was expressed about the best mechanism for this. Those groups that utilise both animal and human cell lines in their research point out that the types of genetic modifications made to human and animal cell lines are often identical. It therefore makes sense for approvals to be made through the same regulatory system – the HSNO Act. They also note that most of the cell lines used in research are commercially available lines that are widely utilised internationally. Furthermore the HSNO low-risk GMO regulations already list human cell lines as approved hosts for genetic modification.

47. A number of submitters opposed any genetic modification of human cells. Some of these were concerned that this could involve, or lead to, the germ-line genetic modification of people. This involves genetic modifications to people that are passed on to subsequent generations through their children.

48. One iwi authority expressed their total opposition to the genetic modification of human cell lines and another supported the regulation of these activities.

Officials' advice

49. The current anomaly between the regulation of the genetic modification of animal and human cell lines and tissue cultures needs to be addressed. The simplest mechanism for this is to extend HSNO coverage to include human cell lines and tissue cultures by amending the HSNO Act so that human beings are exempt but non-reproductive human cells are not. This would allow a single regulatory process for researchers who are often undertaking the same sort of research on both animal and human cells. While this involves a change in policy to include coverage of human cells under the HSNO Act, human cell lines are already listed as hosts under the low-risk regulations and they are specifically excluded from coverage under the Medicines Act.

50. There is a clear distinction between the approval of research involving human cell lines and any subsequent use of those cells for human therapy. Approval of research involving GM human cells under the HSNO Act would only apply to cells in culture – i.e. in the test tube. Any approval for the use of the cells in human therapy would still require quite separate consideration and approval through health ethics committees and health legislation.

51. The issue of individuals giving their consent for the use of their tissues, including the derivation and genetic modification of cell lines, is also best dealt with under the informed consent procedures currently required by health approval processes. It should be noted, however, that nearly all-current research in New Zealand involving genetic modification of human cell lines uses commercially available cell lines that are widely used and extensively studied. While documentation of informed consent is not always available, ERMA currently requires that imports of such cell lines be from reputable researchers or companies that can give an assurance of where the samples are derived from.

52. The well-founded concerns about germ-line genetic modification of humans are not relevant in the context of the regulation of the genetic modification of human cell lines. Germ-line genetic modification of humans is currently controlled in the interim in New Zealand under Section 7A of the Medicines Act. It will be further addressed in the proposed human assisted reproductive technology legislation. Proposals for this legislation are expected to be presented to Cabinet in the first half of this year.

53. In summary when the GM cells are being developed in the test tube or being imported they will be subject to the HSNO Act. When the GM cells are to be used for therapeutic purposes involving a person, approval processes under the Medicines Act will also apply. If the GM cells are to be used for reproductive purposes then this activity will also be subject to the provisions of the proposed human assisted reproductive technology (HART) legislation. (Note that germ-line genetic modification is currently controlled by Section 7A of the Medicines Act). If it is proposed to obtain a stem cell line from an embryo and to genetically modify these cells then the derivation of the stem cells will similarly be regulated by the HART legislation.

54. Officials recommend that the HSNO Act be amended to regulate the genetic modification of human cell lines and tissue cultures.

Timetable implications

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

Financial implications

56. There are no financial implications associated with the recommendations of this paper.

Human rights

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

Legislative implications

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

Regulatory impact and compliance cost statement

59. A Regulatory Impact and Business Compliance Cost Statement is attached to this paper in Annex 1 and complies with the requirements of Cabinet Office Circulars CO(98) 5 and CO(01)2.

60. The businesses potentially affected by these proposed amendments will be researchers and ERMA. The key compliance cost issues associated with this paper are time and cost associated with preparing and processing applications. The proposed amendments are intended to decrease compliance costs (for development and importation of low risk GMOs) or fill in regulatory gaps with little change in compliance costs (for regeneration of new organisms from tissues and the genetic modification of human cell lines).

61. Based on the information provided in the attached RIS/BCCS, the Business Compliance Costs Unit considers that the disclosure of information is adequate, and the level of analysis is appropriate given the likely impacts of the proposal.

Gender implications

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

Disability perspective

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

Publicity

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

Consultation

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

Recommendations

66. It is recommended that Ministers:

Group approvals for the development of low-risk GMOs

a) **Note** that approval of research involving the development of low-risk GMOs under the HSNO Act currently requires the specific identification and risk assessment of individual organisms or groups of organisms

b) **Note** that the approval to develop low-risk GMOs is routinely delegated by ERMA to Institutional Biological Safety Committees (IBSCs)

c) **Agree** that the sections of the HSNO Act that provide for the approval of the development of low-risk GMOs in an approved containment facility, be amended to provide for a formal approval process involving:

- a requirement for the researcher to provide information about the identity of the organisms and a description of the project and proposed genetic modifications
- approval of the proposal by the IBSC or ERMA
- progress reports as specified by the IBSC or ERMA

d) **Note** that the proposed amendment to the existing approval process will simplify the approval process for low-risk developments currently undertaken by IBSCs, but will not change the range of low-risk developments that can currently be approved by IBSCs

Delegating approval of the importation of low-risk GMOs to IBSCs

e) **Note** that while IBSCs can currently approve the development of low-risk GMOs in New Zealand, there is no comparable delegation for the rapid assessment and approval for the import of low-risk GMOs into containment

f) **Note** that the definition of "low risk organism" will assist in the identification of low risk organisms being imported

g) **Agree** to define a "low-risk organism" in terms of being an organism that presents minimal risks to both people and the environment **and** which has characteristics described in regulations under the HSNO Act that relate to low-risk genetically modified organisms or developments **and** which is, or will be, contained within registered containment facilities

h) **Agree** that the HSNO Act be amended to allow IBSCs, under delegated authority, to consider and approve the import of low-risk GMOs into containment on a case-by-case basis, and that the approval only be valid for the institution or agency that the IBSC represents

New organisms regenerated from tissues

i) **Note** that the current HSNO Act did not foresee the potential to clone animals from tissue samples with the potential to develop new organisms in New Zealand without appropriate oversight by ERMA

j) **Agree** that the HSNO Act be amended to ensure that it covers means of regenerating an organism from tissues, cells or other genetic material, when that organism would be a new organism to New Zealand

Genetic modification of human cell lines

k) **Note** that there is currently no regulatory oversight of the genetic modification of human cell lines as these are excluded from consideration under the Medicines and HSNO Acts

l) **Agree** that the HSNO Act be amended to enable applications to import genetically modified human cell lines or to genetically modify human cell lines or tissue cultures, to be considered and, if appropriate, approved pursuant to the provisions of the Act

m) **Note** that the proposed changes would apply only to human cells in culture, and that any use of these cells for therapeutic procedures involving people would require additional consideration and approval through health ethics committees and other appropriate human health regulatory or legislative procedures

n) **Note** that the germ-line genetic modification of humans is currently controlled by Section 7A of the medicines Act, and that the proposed amendments relating to the genetic modification of cell lines affects only samples of human cells in laboratories and does not involve any procedures involving the genetic modification of people, and that such procedures will be addressed by the proposed human assisted reproductive technology legislation

Hon Marian L Hobbs
Minister for the Environment

Annex 1

Regulatory Impact Statement

Statement of the Problem and the Need for Action

There are four issues associated with amendments to the HSNO Act involving laboratory research that arise from recommendations from the Royal Commission on Genetic Modification:

1. Approval process for development of "low risk" GMOs

The approval process for development of "low risk" genetically modified organisms (GMOs) is seen to be unnecessarily complex, with applications being costly and time consuming for applicants. Such costs have the potential to inhibit areas of research, contribute to recruitment and retention of experienced staff, or to encourage non-compliance.

2. Import of low risk GMOs

While Institutional Biological Safety Committees (IBSCs) to approve developments of low-risk GMOs in containment, they are not able to similarly approve the importation of the same organisms. Imports of GMOs must be submitted to ERMA for approval. Consequently, compared with the process for GMO developments the current approval process for imports of GMOs can involve much greater time and cost impediments to research. Such costs have the potential to inhibit areas of research, contribute to recruitment and retention of experienced staff, or to encourage non-compliance.

3. New Organisms regenerated from tissues

The HSNO Act did not foresee the possibility of technological advances enabling new organisms to be regenerated from cells or tissues (such as in animal cloning) and so there is the potential to develop some new organisms without assessment and approval by the Environmental Risk Management Authority (ERMA). While new organisms do not appear to be currently being developed by this method there is a regulatory gap. Given the pace of the technology it is advisable to close this gap to ensure development of all new organisms is covered.

4. Human cell lines

The genetic modification of human cell lines does not currently require regulatory approval under the HSNO or other Acts. This creates an anomaly, as HSNO approval is required to genetically modify animal cell lines. Many researchers routinely develop or use genetically modified human cell lines along with genetically modified animal cell lines for research into gene function. The Medicines Act covers activities such as clinical trials of new medicines and other medical activities and procedures involving people but excludes research using human cell lines if human subjects are not involved. Consequently, there is a regulatory gap that enables some GMOs to be developed or imported without undergoing an assessment and approval process. Such a lack of assessment may mean that risks to human health and the environment are not adequately managed.

Statement of Public Policy Objective

The objective of the proposed amendments on these four issues is to simplify assessment and approval processes involving development or import of those GMOs considered to present

low risk to the environment and human health, and to ensure that all new organisms are subject to an assessment process.

Statement of Options for Achieving the Desired Objectives – Net benefit of this proposal

1. Approval process for development of "low risk" GMOs

The status quo requires a detailed description and risk assessment of low risk GMOs. The option of retaining the current process was rejected because of the high information requirements are viewed as impediments to the research. One option is to reduce the information requirements, while another option is to not require a formal approval process for low risk GMOs. Officials propose that the approval process for development of low risk GMOs be simplified by reducing some of the information requirements for development of GMOs that meet the criteria for low risk in laboratory containment. Simplifying the process rather than exempting low risk GMOs is preferred because in some cases consultation with Maori may be necessary. A formal (but simplified) approval process will ensure that such requirements are met, while reducing the time involved in making applications. The alternative of having no formal approval means that such oversight may be lost, and so this option is not preferred.

Lower information requirements will result in researchers (in industry and government research agencies) spending less time on application preparation and provide an assessment process commensurate with the risks, so encourage compliance and research that may be of societal and/or economic benefit. Quantitative information on the time spent preparing applications is not available, but anecdotal information indicates that the current process may take several days (depending on the nature of the application), while the preferred option is anticipated to reduce time to just a few hours. No significant costs to society have been identified since this only affects contained laboratory research.

2. Import of low risk GMOs

The status quo requires that approvals to import GMOs can only be given by ERMA, in contrast to the approval process for the development of the same GMOs in New Zealand. The status quo option was rejected because of high costs and time and because it was not aligned with the approval process for similar developments. The other option is to treat import and development of GMOs similarly. One alternative in this option is to remove the delegated powers of IBSCs so that development approvals are only issued by ERMA, but this is rejected because it is not consistent with the Government's response to recommendations in the report by the Royal Commission on Genetic Modification. Officials propose that the HSNO Act be amended to give IBSCs with delegated powers of approval from ERMA the ability to approve imports into laboratory containment of GMOs that meet the criteria for low risk.

Reduced time and costs for obtaining an import approval, which may result in encouraging research that leads to societal and or economic benefits. Currently, an application to import a low risk GMO can take several months, and cost more that $1000, compared with a much quicker (approval within a month, if IBSCs meet monthly) and low cost (applicants time spent preparing the application) approval process for development of the same GMO in containment (This process only applies to institutions that have an IBSC with delegated decision-making powers). This amendment will make the processes and costs for development and import of low risk GMOs consistent. No significant costs to society have been identified since this only affects contained laboratory research.

3. New Organisms regenerated from tissues

Currently "developing" a new organism only relates to genetic modification of an organism, but other methods are available to create a new organism. The status quo would retain the regulatory gap resulting from new technologies, and is not preferred since it means some new organisms would not undergo a risk assessment. Officials propose that the HSNO Act be amended to ensure that regeneration of new organisms from cells or other genetic material is regulated. This would ensure that all new organisms are regulated similarly.

The benefit of this proposal is to close a regulatory gap, and so ensure that development of new organisms using new technologies is subject to the same assessment process as for organisms developed by genetic modification. New technologies are not currently being used to develop new organisms so that the impact on researchers and industry is minimal, but making an application will involve application preparation time and processing costs. No significant costs to society or the economy have been identified since this only affects contained laboratory research.

4. Human cell lines

Currently, human cells and tissues are not considered organisms under the HSNO Act, and genetic modification of them are not covered by the HSNO or other Acts. Officials propose that the HSNO Act be amended to regulate the genetic modification of human cell lines in laboratories. An alternative option to have the issue addressed under a Ministry of Health review was rejected because covering human cells under the HSNO Act will be a simpler mechanism and enable the regulation of genetic modification of human and animal cell lines (which are often used in the same experiments) to be covered by the same legislation. The status quo would retain the regulatory gap resulting from exclusion of human cells and tissues, and is not preferred since it means some new organisms would not undergo a risk assessment.

The benefit of this proposal is to close a regulatory gap, and so ensure that genetic modification of human cell lines undergo a formal risk assessment process as is currently required for animal cell lines. Such an assessment will reduce the potential for environmental, health and economic risks associated with genetic modification of human cell lines. Applicants generally include human cell lines in their applications already so no significant additional compliance costs are expected. No significant costs to society or the economy have been identified since this only affects contained laboratory research.

Statement of consultation undertaken

Government agencies consulted or involved in these proposals were Consumers Affairs, DoC, DPMC, ERMA, MAF, MED, MedSafe, MFAT, MfE, and Treasury. No major concerns with the proposals were expressed. No other agencies or individuals were consulted, although the recommendations are similar to those proposed in submissions to MfE in their 2002 discussion document on changes to the HSNO Act.

Business Compliance Cost Statement

The four issues in this paper are:

1. Approval process for development of "low risk" GMOs
2. Import of low risk GMOs
3. New Organisms regenerated from tissues
4. Human cell lines (since this issue only involves incremental compliance costs it is not included below)

Sources of compliance costs

ERMA operates on a cost-recovery basis so that businesses with applications processed by ERMA incur compliance costs. There are also compliance costs associated with the time spent preparing applications. Businesses will have costs associated with identifying and understanding the new requirements.

Parties likely to be affected

Universities, CRIs, and some private companies (eg Genesis R&D, Carter Holt Harvey) conducted genetic research will be affected. Only about four private companies appear to be currently involved in such work in New Zealand, with staff numbers ranging from about 10 to 200 researchers.

Estimated compliance costs of the proposal

For Issue 1 compliance costs are likely to decrease due to reduced application preparation time. The decrease cannot be fully quantified since it will vary from application to application, but may result in hours rather than days being spent on application preparation. For Issue 2, compliance costs are likely to decrease substantially through reduction in the time and cost required to obtain an approval through ERMA (Approvals for low risk GMOs processed by ERMA can take from 10 to more than 30 working days, and cost over $1000 depending on staff time). For Issue 3 compliance costs will increase since this issue does not need regulatory approval at the moment (but there is no indication that this means of developing new organisms is currently used in New Zealand). Hours or days will be required to prepare an application, and the application will need to be processed by ERMA. Costs would be comparable to those associated with developing GMOs, taking from 10 to 30 working days and requiring a $3000 (plus GST deposit).

Longer term implications of the compliance costs

The costs are likely to be on going.

Level of confidence of compliance cost estimates

Based on the nature of the changes and ERMA's records of costs, there is a high level of confidence in the compliance cost estimates, but as noted costs depend on the nature of individual applications.

Key compliance cost issues identified in consultation

No compliance cost issues were identified in consultation.

Overlapping compliance requirements

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

Steps taken to minimise compliance costs

ERMA will disseminate information on the revised approval processes through its information sheets, User Guides, workshops, etc.