Office of the Minister for the Environment

The Chair
Cabinet Policy Committee

**THE GOVERNMENT'S RESPONSE TO THE REPORT OF THE ROYAL COMMISSION ON GENETIC MODIFICATION**
**PAPER 2: RESEARCH AND CONTROLS IN CONTAINMENT**

## PROPOSAL

1. This paper provides advice to Ministers on the response to those recommendations of the Royal Commission on Genetic Modification that relate to research and controls on genetically modified organisms (GMOs) in laboratory containment.

## EXECUTIVE SUMMARY

2. This paper reports on 12 of the 49 recommendations of the Commission. Officials are advising Cabinet to accept the recommendations or their intent in all cases.

3. In four of the recommendations no further action is required as the issues identified are already being addressed.

4. In six of the recommendations various amendments to the Hazardous Substance and New Organisms Act 1996 (HSNO Act) or its regulations are required. Officials are proposing to undertake further policy analysis of the issues and to report back to Cabinet by the end of February 2002 with the details of the changes to the legislation required. Recommendations relating to further proposed amendments to the HSNO Act are discussed in other papers in this series.

5. In two recommendations, the intent is accepted but officials are recommending the issues be addressed by mechanisms proposed in response to other Commission recommendations.

## BACKGROUND

6. This is the second of a suite of six papers that provide advice from officials on the 49 recommendations of the Commission. This paper provides advice on 12 of the recommendations that relate to research and controls on GM organisms in laboratory or glasshouse containment.

## COMMENT

***The Commission's recommendations considered in this paper***

7. This paper responds to a package of 12 recommendations related to the costs of research and the controls on GM organisms in laboratory containment.

8. The 12 recommendations fall into three broad groups. These relate to:

- Simplifying approval processes for laboratory GM research;
- Gaps in the Hazardous Substances and New Organisms (HSNO) Act coverage; and
- Ethical and cultural issues related to research.

9. This paper discusses the broader issues arising from these three groups of recommendations and then addresses each of the Commission's recommendations separately. Officials have provided specific advice to Ministers on whether each recommendation should be accepted or rejected, and what actions, if any, are required. In some cases the intent of the Commission's recommendation was not clear from its wording and officials have referred to the text of the report and sometimes to the contributing submissions to clarify the intent. As a consequence officials have for those recommendations advised that Ministers accept the intent of the recommendation, rather than the specific wording.

10. The three groups of recommendations addressed in this paper are:

| **Simplifying approval processes for laboratory GM research** | |
|---|---|
| 6.1 | Assessment of low risk applications for research on a project basis |
| 6.2 | Review of approval forms, standards and regulations for GMOs |
| 6.3 | New form for low-risk applications to IBSCs |
| 6.4 | Amend the HSNO Act to allow IBSCs to approve imports of low-risk GMOs |
| 6.5 | ERMA approvals of GMOs to cover holding and breeding |
| 6.7 | Delegate development of GM animal cell lines to IBSCs |
| 6.11 | Fund research portfolios to include HSNO application costs |

| **Gaps in HSNO Act coverage** | |
|---|---|
| 6.6 | Amend the HSNO Act to cover GM of human cell lines or tissue culture |
| 6.9 | Amend the HSNO Act to cover procedures used in mammalian cloning |

| **Ethical and cultural issues related to GM** | |
|---|---|
| 6.10 | Include at least one Maori member on IBSCs |
| 7.5 | Use non-food animals as bioreactors to produce human proteins |
| 7.6 | Use of alternatives to human genes in transgenic mammals |

## SIMPLIFYING APPROVAL PROCESSES FOR LABORATORY GM RESEARCH

11. The Commission heard from many researchers that the processes required by the Environmental Risk Management Authority (ERMA) to approve laboratory based low-risk research involving GM organisms are unnecessarily complex, costly and time consuming for the level of risk involved. The reasons for these problems arise from:
    - Highly prescriptive HSNO regulations that have lists of approved organisms that cannot be easily updated to incorporate new knowledge and techniques;
    - The fast changing technology and the nature of research which is to progressively build on the knowledge gained from previous experiments;
    - Inconsistencies in the HSNO Act that mean that different approval processes can apply to the same organism in different circumstances.

12. Both the Ministry for the Environment (MfE) and the ERMA have been aware of many of the problems and have taken steps to resolve them. The HSNO Amendment Act 2000

gives the ERMA the authority to update forms that were previously prescribed in legislation. A review of the HSNO (Low Risk Genetic Modification) Regulations 1998 (low risk regulations) identified changes that would simplify the approval process for low-risk GM organisms. These amendments would not change either the types of organisms that could be developed under low-risk approvals, or the level of risk of the research.

13. During 2000 MfE prepared a package of amendments to the low-risk regulations for consideration by Cabinet. Cabinet delayed consideration of this package until after the Commission reported (CAB Min (01) 8/7 refers). The amendments proposed in the package now need to be reviewed in light of the Commission's recommendations. As a consequence, officials recommend that the package of amendments to the low-risk regulations be reviewed and reported back to Cabinet in association with related matters from the Commission's recommendations, by the end of February 2002.

***Recommendation 6.1: "that applications to develop genetically modified organisms in PC1 and PC2 containment be assessed by the Institutional Biological Safety Committees (IBSCs) on a project rather than organism basis."***

14. PC1 and PC2 are levels of containment for low risk organisms that are unlikely to survive outside the laboratory or would have minimal environmental impact in the event of escape. Currently the low risk regulations of the HSNO Act require each new organism developed in a laboratory to be assessed and approved individually. This results in a complex and time-consuming approval process for organisms generated during research, even when they are very similar to each other.

15. The proposal would allow researchers to make applications for groups of organisms of similar types and risks, rather than requiring separate approvals for each organism. The overall effect would be to reduce the time and cost of making applications without changing the types of organisms that could be developed under low-risk approvals.

16. The ERMA and MfE have already done much of the policy work associated with this recommendation. Some further analysis is needed to confirm the best way to group organisms in these applications to ensure compliance with the HSNO Act. Officials support the intent of this recommendation and note that it would require an amendment of the low risk regulations.

***Recommendation 6.2: "that all approval forms, standards and regulations relating to the development of genetically modified organisms in containment be reviewed and updated."***

17. Rapid developments are being made in GM technology and this recommendation proposes that relevant HSNO regulations and standards, and associated documentation covering GM research in laboratories are kept up to date with, and are appropriate to, the technology. The HSNO Amendment Act 2000 now allows the ERMA to amend forms formerly prescribed by regulation.

18. Amendments to some forms and standards, such as the Ministry of Agriculture and Forestry/ERMA micro-organism standards, are already underway or complete, and other recommendations of the Royal Commission propose changes to HSNO regulations. Officials support the recommendation and note that the proposed reviews will be ongoing

and that they will report back to Cabinet on any remaining actions by the end of February 2002.

***Recommendation 6.3: "that a separate, simplified form be developed for low-risk (Categories A and B) applications to IBSCs"***

19. Currently there is a single form for all high and low-risk laboratory developments in containment. This results in unnecessary information being required from researchers for approvals to carry out research with low-risk organisms in the laboratory.

20. The format of these application forms was formerly prescribed by HSNO regulations but since the passing of the HSNO Amendment Act 2000, the ERMA is now able to modify these application forms directly. The ERMA intends to update the application forms identified by the Royal Commission during 2001. Officials support the recommendation, but note that no further action is required to implement it.

***Recommendation 6.4: "that the Hazardous Substances and New Organisms Act 1996 (HSNO) be amended to allow for the efficient importation of low-risk genetically modified organisms, through delegation of the approval process to the IBSCs."***

21. Currently the HSNO Act requires that all low-risk GM organisms imported into containment in New Zealand must be specifically approved by the ERMA, while approval to develop exactly the same organisms in containment in New Zealand can be delegated to IBSCs.

22. This recommendation proposes the removal of this anomaly to ensure that the approval of research involving low-risk organisms is based on risk, rather than whether they are imported or not. Implementation of the recommendation would mean that New Zealand researchers could more easily take advantage of the advances in international research and collaborate with colleagues overseas.

23. Officials support the recommendation. Implementation of the recommendation would require an amendment to s 42 of the HSNO Act, which allows for the rapid assessment of GMOs.

***Recommendation 6.5: "that approvals to develop or import genetically modified organisms be deemed to cover their holding and breeding"***

24. This recommendation seeks to clarify the issue of the holding and breeding of new GM organisms in containment. The issue relating to the **holding** of GM organisms such as mice is of relevance only to the GM organisms that were developed before the HSNO Act came into effect. The majority of these were deemed approved during 2000 by Order of Council under s 257 of the Act, but some were unintentionally omitted. This issue has now largely been cleared up. The ERMA is currently in the process of bringing the remaining developments into compliance with the HSNO Act.

25. The issue of **breeding** GM animals relates to the question of whether the breeding of subsequent generations of an organism is covered by the original HSNO Act approval, or whether a new approval is required. Such breeding is a normal part of development approvals and is already covered by both the ERMA's policy and the HSNO legislation.

26. Officials support the intent of the recommendation, which is to ensure that low-risk GM organisms are all held with appropriate legal approvals, and note the intent of the recommendation has been implemented.

***Recommendation 6.7: "that approval for development of genetically modified animal cell lines be delegated to the Institutional Biological Safety Committees."***

27. Approval for the development of GM animal cell lines that are specifically identified in a prescribed list in the HSNO Act low risk regulations and meet certain criteria can currently be delegated to an IBSC for approval through the "rapid assessment" process. Animal cell lines that are not on the prescribed list but have similar characteristics must go through the full ERMA process.

28. Officials support the intent of the recommendation. The proposed amendment to the HSNO Act low-risk regulations discussed in the response to relation to Recommendation 6.1 would resolve this issue by replacing the prescriptive list with low-risk criteria.

***Recommendation 6.11: "that the funders of research portfolios be resourced to include the costs of compliance with HSNO."***

29. The Commission noted that the current ERMA processes result in unnecessary and burdensome compliance costs for making applications for low risk areas of research, and that the approval process ought to more clearly reflect the different risk profiles of research. This recommendation proposes that the funders of the research should meet the costs of making applications to the ERMA.

30. In fact all the government agencies that fund research portfolios (The Foundation for Research, Science & Technology, The Health Research Council, and The Royal Society of New Zealand) presently operate with policies to "fully fund" the costs of research. This includes the costs of HSNO Act applications and any other regulatory requirements for the research.

31. The funding agencies are able to monitor the costs of compliance with the ERMA processes and consider these when allocating funding to research portfolios.

32. In the current situation, however, where funding levels are stable and HSNO Act compliance costs have risen, the consequence is that less research can be done within the available budget. The impact of this shortfall in research is greater with field test applications than for laboratory developments as field test applications tend to be more costly.

33. Officials support the intent of this recommendation, which is to ensure that research is not unnecessarily constrained by compliance costs. The implementation of other Commission recommendations in this group will also assist in reducing the costs of approvals for low-risk laboratory based research.

## GAPS IN THE HSNO ACT'S COVERAGE

34. The Commission recommended two amendments to the HSNO Act that relate directly to laboratory-based research. One of these identifies a gap in the regulatory oversight of research involving GM of human cells, and the other a gap arising from developments in cloning technology that have arisen since the Act and regulations came into force. In both cases officials agree that there is a gap in the regulatory oversight but further policy analysis is required to determine the best way to resolve the issues.

***Recommendation 6.6: "that HSNO be amended to clarify that research involving genetic modification of human cell lines or tissue cultures is covered by the Act."***

35. The genetic modification of animal cells in the laboratory currently requires approval under the HSNO Act. The same modification of human cell lines or samples of tissues as part of a research programme does not require comparable approval, as humans and human tissues are specifically exempt from coverage under the HSNO Act. The Medicines Act covers research involving people, but this too excludes human cells or tissues outside the body. The recommendation is not intended to address the issue of genetic modification of people. It is solely concerned with laboratory research that involves the genetic modification of small human cells lines or samples of tissues for medical research.

36. As a consequence of the exemptions from the two Acts, there appears to be a gap in the regulatory oversight of research involving genetic modification of human cell lines and tissues. While the issue could be resolved by an amendment to the definition of "organism" in the HSNO Act, officials need to ensure that such action is consistent with other legislation such as the Medicines Act, the proposed Assisted Human Reproduction legislation and with other regulatory and ethical committees that oversee human research activities.

37. Officials support the intent of the recommendation, which is to ensure that there is appropriate regulatory oversight of research involving genetic modification of human cell lines or tissue cultures in the laboratory. Further policy analysis will confirm the best mechanism to achieve it. Officials will be reporting to Cabinet on the detail of the best mechanism by the end of February 2002.

***Recommendation 6.9: "that HSNO be amended to cover procedures used in mammalian cloning, such as nuclear transfer or cell fusion."***

38. Cloning technology has progressed significantly since the HSNO Act and associated regulations came into force, and it is now possible to clone whole animals from tissues or cell cultures. In New Zealand for example, the last surviving Enderby Island cow was infertile, so was cloned to prevent the extinction of the breed. In this case the cloned offspring are not new organisms and no genetic modification is involved, so no ERMA approval is needed.

39. An issue may arise, however, if samples of tissue from animals not presently in New Zealand are imported and whole animals are cloned from these. The wording of the HSNO (Organisms not Genetically Modified) Regulations 1998 did not foresee this eventuality. Although it appears that while GM animals cloned in this way **would** require an ERMA approval, new species of non-GM animals might not. This cloning technology might therefore allow a new organism to bypass the HSNO Act.

40. Officials agree that all new organisms, whether GM or not, should be subject to appropriate HSNO oversight and support this aspect of the recommendation. Implementation of this would require a review of the HSNO (Organisms Not Genetically Modified) Regulations. HSNO Act coverage should not, however, be extended to cover the cloning of conventional animals already present in New Zealand as this cloning does not result in the introduction of new organisms.

## ETHICAL AND CULTURAL ISSUES RELATED TO GENETIC MODIFICATION

41. This group of three recommendations relates to the need to be more responsive to different cultural and ethical perspectives of GM technologies. The Commission heard widely divergent views on the ethics of this area of research. Scientists outlined the medical opportunities arising from animals that are able to produce human proteins that can be used to provide better treatments for human diseases. Opponents of GM considered that the use of human genes in animals was unethical and interfered with the very nature of what it is to be human.

42. The Commission has proposed the establishment of Toi te Taiao: the Bioethics Council (Recommendation 14.2). This Council would be an appropriate forum for the discussion of the varied ethical issues that arise from GM technology.

***Recommendation 6.10: "that IBSCs include at least one Maori member, appointed on the nomination of the hapu or iwi with manawhenua in the locality affected by an application."***

43. This recommendation addresses the issue of appropriate and timely consultation with Maori about applications for low risk research that is approved by IBSCs. The Commission indicated that the current system generally falls short in ensuring Maori are consulted over GM research involving human genes and native flora and fauna. In particular the Commission noted that it was the responsibility of IBSCs to advise researchers when consultation is required and that Maori memberships would enable this.

44. Existing ERMA policy already requires that in defined circumstances, such as when experiments involve DNA from humans and native flora and fauna, IBSCs must have either a Maori member who is mandated to speak on behalf of the most affected hapu or iwi, or must consult fully with involved hapu or iwi in respect of the application. Currently 11 out of 19 IBSCs have at least one Maori member and the ERMA is working with science institutions to complete the coverage.

45. Officials support the intent of the recommendation, but consider that the representation proposed by the Commission may not provide the best means for consultation and advice to IBSCs when considering applications of interest to Maori. In responding to the Commission's Recommendation 11.1 (which recommends giving effect to the principles of the Treaty - Paper 6) officials are proposing a review of ERMA processes, particularly those involving consultation with Maori. Further consideration of Maori representation on IBSCs should take place as part of this review.

***Recommendation 7.5: "that, wherever possible, non-food animals, or animals less likely to find their way into the food chain, be used as bioreactors rather than animals that are a common source of food."***

46. GM animals can now be used to produce products such as new proteins for pharmaceutical use. These are known as animal bioreactors, and if they contain copies of human genes they can produce human proteins in their milk. These proteins are extracted and purified for therapeutic purposes. The Commission wanted to ensure that these animals did not unintentionally enter the food chain.

47. The reasons were twofold. First, some people would not wish to eat animals that contain copies of human genes, and second, these animals would not have been approved as safe to eat by the Australia and New Zealand Food Authority (ANZFA). Animals such as cows and sheep are commonly used as bioreactors since they are easy to manage, are well researched and produce significant quantities of milk.

48. The current legislative and regulatory regimes under the HSNO Act, Food Act, and Animal Products Act ensure we eat safe and approved foods. The regime would prevent bioreactor animals from entering the food chain unintentionally.

49. Officials support the intent of the recommendation to prevent GM animals and their products from unintentionally entering the food chain, but consider that this is best achieved through the current and proposed regulatory regimes. If adopted by Government, the new "conditional release" category proposed in Recommendation 6.8 would also allow controls to be placed on the use of any animals, which could include animal bioreactors, and their products that were approved under this category.

***Recommendation 7.6: "that, wherever possible, synthetic genes or mammalian homologues of human genes be used in transgenic animals to avoid the use of genes derived directly from humans."***

50. In making this recommendation the Commission assumes that the ethical concerns about the use of copies of human genes in animals would be reduced if synthetic or closely related genes from other mammals were used instead.

51. In fact, when transgenic animals are developed novel genes are not transferred directly from the source to an animal. The gene that codes for the desired protein must first be isolated from all the other source genes and copied (and sometimes altered) before being inserted into the DNA of the animal. Identical copies of desired genes can also be synthetically made in the laboratory.

52. Copies of genes coding for the desired novel protein can also be obtained from other mammals. While these can be very similar to human genes (mammalian homologues) they produce proteins that are not identical to human proteins. These proteins are often not as useful for research or human therapeutic purposes.

53. Officials consider it unlikely that the ethical concerns of people who are opposed to aspects of gene technology would be ameliorated by the subtleties of how genetic modification is done. Some aspects of their concerns may be reduced if a related animal gene was used but they would still be unlikely to support this approach. Officials

therefore advise that the issues associated with this recommendation are best addressed by the proposed Toi te Taiao: the Bioethics Council (Recommendation 14.2).

## CONSULTATION

54. The following agencies were consulted in the preparation of this paper: Ministry for the Environment, Ministry of Agriculture and Forestry, Department of Conservation, The Treasury, Te Puni Kokiri, Customs, Ministry of Foreign Affairs and Trade, Ministry of Justice, Ministry of Health, the ERMA New Zealand, and The Foundation for Research, Science and Technology. Amendments were made to this paper at the direction of the office of the Minister for the Environment, by the Ministry for the Environment in consultation with some other agencies. These amendments were required as some matters previously referred to in this paper were considered in Paper 1 at Cabinet on 29 October 2001.

## FINANCIAL RECOMMENDATIONS

55. There are no direct financial implications arising from the recommendations in this paper at this stage. Paper 1 identifies the financial implications within Vote Environment for policy advice to amend the HSNO Act and associated regulations. These costs will be confirmed as part of the detailed report-backs on the proposed changes.

## HUMAN RIGHTS ACT

56. There are no human rights implications arising from the recommendations of this paper.

## LEGISLATIVE IMPLICATIONS

57. A number of the recommendations in this paper have legislative implications, principally amendments to the HSNO Act. Officials will be reporting back to Cabinet by the end of February 2002 on the suite of proposed HSNO Act amendments arising from this and other papers responding to the Commission's recommendations.

## REGULATORY IMPACT AND COST COMPLIANCE STATEMENT

58. Several of the recommendations in this paper may result in amendments to various HSNO Act regulations. While the general purpose of the changes will be to simplify the process for making applications to ERMA for laboratory based research, the number and form of these amendments will only be known once further policy analysis has been completed. Officials will be reporting to Cabinet on the detail of the proposed changes in by the end of February 2002 and the necessary regulatory impact statement will be prepared at that time.

## TREATY OF WAITANGI IMPLICATIONS

59. The recommendations in this paper include one relating to the Maori input to IBSCs. Discussion of broader Treaty issues related to the Commission's report is found in Paper 6 of this series.

## PUBLICITY

60. A separate communications strategy is being developed for the whole package of Government decisions on the Royal Commission's report.

## RECOMMENDATIONS

61. It is recommended that Cabinet Policy Committee:

### Simplifying approval processes for laboratory GM research

1. **Note** consideration of a proposed consultation process on suggested amendments to the Hazardous Substances and New Organisms (HSNO) (Low Risk Genetic Modification) Regulations 1998 was deferred until the Government had received the report of the Royal Commission on Genetic Modification and that the Minister for the Environment was invited to report to the Cabinet Finance, Infrastructure and Environment Committee in July 2001 (refer CAB (01) 49; FIN Min (01) 1/9);

2. **Agree** this issue be considered as part of the report back to Cabinet by February 2002 on the actions required to implement the Royal Commission's recommendations consider in this paper;

3. **Note** the Royal Commission's Recommendations 6.1-6.5, 6.7 and 6.11 comprise a suite of seven recommendations that aim to simplify the approval process for low-risk laboratory based GM research, without changing the scope of the low-risk research that can be permitted;

4. **Note** some of the policy analysis related to the simplifying of low risk research in the laboratory has already been undertaken by MfE and ERMA, and that implementing the intent of the recommendations would probably involve some minor amendments to the HSNO Act and associated regulations.

   ***Recommendation 6.1: "that applications to develop genetically modified organisms in PC1 and PC2 containment be assessed by the Institutional Biological Safety Committees (IBSCs) on a project rather than organism basis."***

5. **Note** implementing the intent of this recommendation would involve an amendment to the low risk regulations of the HSNO Act;

6. **Agree** to accept the intent of Recommendation 6.1, which is to simplify the assessment of low-risk laboratory GM 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;

7. **Direct** officials to report back to Cabinet by the end of February 2002 on the actions required to implement the intent of this recommendation.

   ***Recommendation 6.2: "that all approval forms, standards and regulations relating to the development of genetically modified organisms in containment be reviewed and updated."***

8. **Note** the HSNO Amendment Act 2000 now allows the ERMA to amend the forms formerly prescribed by the HSNO (New Organisms Forms and Information Requirements) Regulations, and that work is currently underway to update the forms;

9. **Note** that various standards are reviewed as needed, and that the various regulations relating to GM research have been, or are currently being, reviewed;

10. **Agree** to accept the intent of Recommendation 6.2 which is to ensure that administrative and regulatory processes are kept up to date, are appropriate, and are able to respond to new developments in GM technology;

11. **Direct** officials to report back to Cabinet by the end of February 2002 on any remaining actions required to implement this recommendation.

***Recommendation 6.3: "that a separate, simplified form be developed for low-risk (Categories A and B) applications to IBSCs."***

12. **Note** there is currently one application form for all applications to undertake research in containment and that the intent of this recommendation is to have application forms that are more closely linked to the ERMA's information needs for the type of application;

13. **Note** the HSNO Amendment Act 2000 gives ERMA the authority to amend these forms which were formerly prescribed by regulation;

14. **Note** the ERMA is currently reviewing the format and information requirements in the application form for low risk laboratory developments and that the review will be complete by the end of November 2001;

15. **Agree** to accept Recommendation 6.3, and that no further action is required.

***Recommendation 6.4: "that the Hazardous Substances and New Organisms (HSNO) Act 1996 be amended to allow for the efficient importation of low-risk genetically modified organisms, through delegation of the approval process to the IBSCs."***

16. **Note** that all low-risk GMOs imported into containment in New Zealand must be specifically approved by ERMA, while approval to develop exactly the same organisms in containment in New Zealand can be delegated to IBSCs.

17. **Note** that to resolve this anomaly there would need to be an amendment of the HSNO Act to make provision for the approval of imports of low-risk GMOs to be delegated to IBSCs;

18. **Agree** to accept Recommendation 6.4;

19. **Direct** officials to report back to Cabinet by the end of February 2002 on the actions required to implement this recommendation.

***Recommendation 6.5: "that approvals to develop or import genetically modified organisms be deemed to cover their holding and breeding."***

20. **Note** that the issue of the "holding" of GM organisms relates to pre-HSNO Act developments which had not had their status confirmed by a deemed approval under

the HSNO legislation, but that the ERMA is currently in the process of bringing these into compliance with the HSNO Act;

21. **Note** that "breeding" of GMOs is a normal part of development approvals and that the HSNO Act already provides for approvals to cover subsequent breeding of the organism;

22. **Agree** to accept the intent of Recommendation 6.5, which is to ensure that low risk GMOs are all held with appropriate legal approvals, and that no action is required, as remaining issues are being resolved by the ERMA.

***Recommendation 6.7: "that approval for development of genetically modified animal cell lines be delegated to the IBSCs."***

23. **Note** that GM animal cell lines that are identified in a prescribed list in the HSNO (Low Risk Genetic Modification) Regulations 1998, and meet certain criteria can currently be delegated to an IBSC for approval through the "rapid assessment" process but that similar cell lines, that are not on the prescribed list must go through the full ERMA process;

*24.* **Agree** to accept the intent of Recommendation 6.7, which is to delegate authority to IBSCs for appropriate low risk developments involving animal cell lines, and that this issue will be addressed in the amendment to the low-risk regulations proposed in the response to Recommendation 6.1.

***Recommendation 6.11: "that the funders of research portfolios be resourced to include the costs of compliance with HSNO."***

25. **Note** that the agencies that fund public good research portfolios all operate with a policy to "fully fund" the costs of research, i.e. that compliance costs are already built into the funding of research portfolios;

26. **Note** that as the costs of making applications increases the amount of research that can be undertaken decreases correspondingly;

27. **Note** that the implementation of Recommendations 6.1 - 6.5 will also assist to reduce the costs of making applications for low risk laboratory research;

28. **Agree** to accept the intent of Recommendation 6.11, which is to ensure that research is not unnecessarily constrained by compliance costs.

## Gaps in HSNO Act coverage

29. **Note** that the Royal Commission's recommendations 6.6 and 6.9 address gaps in the coverage and regulatory oversight relating to new organisms;

30. **Note** that further policy work is required to clarify the extent of these gaps, and to determine the most appropriate mechanisms to resolve them;

***Recommendation 6.6: "that HSNO be amended to clarify that research involving genetic modification of human cell lines or tissue cultures is covered by the Act."***

31. **Note** that the GM of animal cells in the laboratory currently requires a HSNO Act approval, while the same modification of human cells or tissue cultures does not require comparable approval;

32. **Note** further policy work is needed to determine the most appropriate mechanism to resolve the current gap in regulation of GM cell lines and tissue cultures;

33. **Agree** to accept the intent of Recommendation 6.6 which is to ensure that the GM of human cell lines and tissue cultures is subject to appropriate regulation;

34. **Direct** officials to report back to Cabinet by the end of February 2002 on the actions required to implement the intent of the recommendation.

***Recommendation 6.9: "that HSNO be amended to cover procedures used in mammalian cloning, such as nuclear transfer or cell fusion."***

35. **Note** that it is now possible to clone whole animals from tissues or cell cultures and that this technology has progressed significantly since the HSNO Act and associated regulations came into force;

36. **Note** that the HSNO (Organisms not Genetically Modified) Regulations 1998 lack clarity with respect to the cloning of non-GM new organisms (i.e. organisms not currently in New Zealand) and that implementing the intent of the Commission's recommendation would require a review of these regulations

37. **Agree** to accept the intent of Recommendation 6.9, 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;

38. **Direct** officials to report back to Cabinet by the end of February 2002 on the actions required to implement the intent of the recommendation.

## Ethical and cultural issues related to GM

39. **Note** that the Royal Commission's Recommendations 6.10, 7.5 and 7.6 are a group of recommendations that relate to ethical and cultural issues around the approval for research and the types of genes and organisms used in GM;

40. **Note** that officials consider that no action is required for Recommendation 7.5 and that the other two recommendations (6.10 and 7.6) are better addressed through alternative mechanisms identified in the response to other Royal Commission recommendations.

***Recommendation 6.10: "that IBSCs include at least one Maori member, appointed on the nomination of the hapu or iwi with manawhenua in the locality affected by an application."***

41. **Note** existing ERMA policy already requires that in defined circumstances, such as when experiments involve DNA from humans, native flora and fauna, IBSCs must have either a Maori member who is mandated to speak on behalf of the most affected hapu or iwi, or must consult fully with involved hapu or iwi in respect of the application;

42. **Note** that 11 out of 19 IBSCs already have at least one Maori member and that the ERMA is working with science institutions to complete the coverage;

43. **Agree** to accept Recommendation 6.10 which is to ensure appropriate Maori input into the decisions made by IBSCs, and that any further action can be considered as part of the review proposed by officials in response to Recommendation 11.1 (giving effect to the principles of the Treaty).

***Recommendation 7.5: "that, wherever possible, non-food animals, or animals less likely to find their way into the food chain, be used as bioreactors rather than animals that are a common source of food."***

44. **Note** that the reason that animals such as cows and sheep are used as bioreactors to produce human proteins in their milk, is because they are easily managed, well researched and produce significant quantities of milk;

45. **Note** that the current legislative and regulatory regimes under the HSNO Act, Food Act and Animal Products Act give a high level of security to prevent bioreactor animals and their products entering the food chain, and that this level of security is applied to all animals and their products, whether or not they contain human genes;

46. **Note** that the proposed "conditional release" category (Recommendation 6.8) would allow controls to be placed on the disposal of bioreactor animals and their products approved under this category;

47. **Agree** to accept the intent of Recommendation 7.5, which is to ensure that GM animals and animal products do not enter the food chain unintentionally and that no further action is required.

***Recommendation 7.6: "that, wherever possible, synthetic genes or mammalian homologues of human genes be used in transgenic animals to avoid the use of genes derived directly from humans."***

48. **Note** that in making this recommendation the Royal Commission was primarily addressing the issue of the ethics of using "human" genes in animals;

49. **Note** that any "human" genes transferred to another organism are copies of a gene from human DNA, rather than genes taken directly from a person;

50. **Note** that genes from other mammals that are very similar to human genes (mammalian homologues) produce proteins that are not identical to human proteins and are often not as useful for research or human therapeutic purposes;

51. **Note** that the use in animals, of entirely synthetic human genes, or of closely related animal genes rather than "copies" of genes from human cells, would be unlikely to ameliorate the ethical concerns of people who are opposed in principle to the use of transgenic animals in research or human therapy;

52. **Agree** to accept the intent of Recommendation 7.6 and that the proposed Toi te Taiao: the Bioethics Council (Recommendation 14.2) could address the ethical issues raised by this recommendation.

Hon Marian L Hobbs
**MINISTER FOR THE ENVIRONMENT**