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 4: FOOD AND MEDICAL

PROPOSAL

1. This paper provides advice to Ministers in response to the recommendations of the Royal Commission on Genetic Modification (the Commission) that relate to food and medical uses of genetic modification (GM).

EXECUTIVE SUMMARY

2. This paper proposes a Government response for a subset of the recommendations of the Royal Commission on Genetic Modification relating to food and medicine.

3. The Commission recommended improving the availability of information on GM food and its regulation, including facilitating a voluntary 'GM-free' label; and that the proposed Food Safety Authority monitor studies on stock feed. Officials advise that the Government agree to accept these recommendations, subject to funding.

4. The Commission recommended, with respect to the food/medicines interface, that products be clearly defined in legislation. Officials advise that the Government accept the principle of the recommendation, but not the specific terminology used to describe products on the foods/medicines interface, as they are not recognised terms.

5. The Commission recommended simplifying the approval process for medicines containing genetically modified organisms (GMOs), while maintaining appropriate regulatory control. Officials advise that the Government accept these recommendations in principle, but engage further analysis with respect to scope. It is noted that obtaining approval of medicines in advance, as recommended by the Commission, will not necessarily reduce the risks of infectious disease in certain emergency circumstances.

6. The Commission recommended ensuring that medical ethics concerns are properly considered. Officials advise that the Government accept these recommendations in principle; but require further analysis to identify the interfaces between regulators, and follow a broader interpretation than the Commission has provided for the development of ethical guidelines.

BACKGROUND

7. This is one of a suite of six papers that provide advice from officials on the 49 recommendations of the Royal Commission on Genetic Modification. Cabinet considered the first paper on 29 October 2001. This paper provides advice on 10 of the recommendations.

COMMENT

8. The 10 recommendations in chapters eight (food) and nine (medicine) of the report of the Royal Commission (the Report) fall into four main groups:

   A - Food and consumer information

   B - Food/medicine interface issues

   C - Medicines approvals

   D - Medical ethics.

A - Food and Consumer Information

9. The Commission supported the existing mandatory pre-market safety assessment of GM foods, and the new labelling requirements that come into force on 7 December 2001 (the amended GM Food Standard). The theme of the Report's recommendations on GM food is primarily about improving the availability of information about GM food. However, Recommendation 8.1 suggests that the Government also monitor information on the implications for human health of supplying GM feed to animals (and act if the collected information indicates such a need).

Recommendation 8.1	*that the Food Administration Authority monitor research studies on stock feed and act on any that indicate a need for stock feed to be assessed in relation to human health.*

Officials' advice: Accept, subject to adequate resourcing.

Conclusions of analysis

- Contract a programme to monitor research into stock feed for indications of human health effects.
- More work is required to determine an appropriate response should any studies indicate that action is required.

Analysis

10. The Commission heard evidence of potential pathways through which stock being fed GM feed could harm human health (in particular, horizontal gene transfer). As there was no evidence of actual harm to human health, the Commission did not consider that a mandatory safety assessment on stock feed should be imposed.

11. A monitoring programme of research into the health implications of GM stock feed is expected to be straightforward to set up. This could be modelled on a programme commissioned by the Ministry of Health, which monitors literature about GM food for human consumption and costs $69,000 per annum.

12. Because evidence to date has disclosed no threat to human health from the consumption of animals fed genetically modified stock feed, there are no mechanisms in current legislation for preventing or managing potential risks. If research disclosed actual risks, a legislative change would be required to establish appropriate risk management programmes. Additional funding would be required to meet the costs of implementing programmes to establish the nature of the risk to human health and appropriate risk avoidance measures.

Recommendation 8.2	*That Government facilitate the development of a voluntary label indicating a food has not been genetically modified, contains no genetically modified ingredients and has not been manufactured using a process involving genetic modification.*

Officials' advice: Accept the recommendation but note that the Ministry of Consumer Affairs and other involved departments may require additional resources.

Conclusions of analysis

- This initiative raises technical difficulties and could fail.
- Consumers and industry support the recommendation.

Analysis

13. The Royal Commission supported the amended GM Food Standard. However, it recommended an additional and complementary voluntary labelling system to assist consumers who wished to avoid food produced using genetic modification even where there is no detectable GM presence in the final food.

14. The amended GM Food Standard gives no guidance on the use of negative claims ('GM-free' labelling). When considering options for mandatory labelling of GM food, Ministers avoided prescribing the form of negative claims, as it would have been unworkable and costly to implement.

15. For the label to be successful it must be readily recognisable, understood and trusted. Although there is a risk that a 'GM-free' labelling system would not be widely adopted, recent informal stakeholder consultation suggests that there is consumer and industry support for such a label.

16. There are technical and cost issues that may pose barriers to the development and use of the label. It is difficult to detect GM ingredients in highly refined foods, and to establish with certainty that the food does not result from a GM process. These issues will have a bearing on the willingness, and the ability, of suppliers in the market to make a standardised 'GM-free' claim. Choosing whether to use the voluntary 'GM-free' label would be a commercial decision by food suppliers.

17. It should also be noted that although the Commerce Commission has the role of enforcing the Fair Trading Act, there might be an overlap with the role of the Food Safety Authority in testing the validity of claims made by manufacturers using the 'GM-free' label.

18. Scoping of the project would be met out of the Ministry of Consumer Affairs baseline. However, should the scoping identify that the proposed facilitation exercise requires significant government support, the Ministry of Consumer Affairs and other involved departments may require additional funding.

Recommendation 8.3	*that, as a matter of priority, the Food Administration Authority disseminates information on the labelling regime for genetically modified foods and consumer rights in relation to foods made available for consumption at restaurants and take-away bars.*

Officials' advice: implement a limited term communications exercise and an on-going audit programme as soon as practicable.

Conclusions of analysis

- A communications exercise is required to disseminate the information on the labelling regime together with an enforcement strategy to complement the communications exercise.
- The communications and audit programmes are essentially part of implementing the relevant Food Standard.
- Strategy A set out below is the most cost effective option for achieving the desired communications outcome. Details of these costs and of the audit programme costs are set out below.

Analysis

19. The Commission believed that information about the amended GM Food Standard should be readily accessible to consumers and would need to be produced "as a matter of priority" to successfully raise awareness before the requirements come into force on 7 December 2001. Should Cabinet accept Recommendation 8.3 and approve additional funding, the Ministry of Health proposes to act as soon as practicable.

20. Although it was not reflected in Recommendation 8.3, the Commission asserted that the GM food Standard should be proactively enforced and the public given the assurance that the safety of GM food is closely monitored.

21. Officials believe that the intent of the Commission's recommendation is an effective implementation of the GM Food Standard, which includes both ensuring compliance, and the communications exercise of Recommendation 8.3. Proposed communications and enforcement strategies, with estimated costs are outlined below.

22. The Ministry of Health is currently responsible for administering domestic food standards and would initiate both the communications and enforcement aspects of the implementation strategy. Responsibility and relevant funding for the implementation strategy will transfer to the new Food Safety Authority once it is established [CAB Min (01) 22/29 refers].

Strategy A

23. For the communications part of this implementation exercise, officials propose Strategy A. It is a cost-effective strategy incorporating a mixture of no-cost promotions such as media statements, and radio and television interviews; low cost newspaper advertisements and pamphlets for food retailers; a mail drop (to 1.3 million households); and a small amount of paid iwi/local radio time.

Strategy B

24. A low-cost option (Strategy B) was considered as an alternative to Strategy A. Strategy B excludes the mail drop of Strategy A (a cost effective means of reaching a wide audience). This removes approximately $120,000 from the cost. Such a strategy is still likely be effective, albeit less so than Strategy A.

Strategy C

25. Strategy C is a higher-cost alternative, based on Strategy A, but including the more effective television advertising. It is also significantly more expensive. The Ministry of Health believes that such a high profile and costly campaign could attract criticism, given other health priorities, and that Recommendation 8.3 may not warrant such expense. The indicative costs of the three communications strategies are as follows:

Strategy A (officials preferred)	0.75 FTE Food Analyst 0.2 FTE Communications Advisor Advertising, printing and other costs	[*Deleted under section S9(2)(f)(iv) of the Official Information Act*].
Strategy B	0.75 FTE Food Analyst 0.2 FTE Communications Advisor Advertising, printing and other costs (excluding mail drop)	[*Deleted under section S9(2)(f)(iv) of the Official Information Act*].
Strategy C	0.75 FTE Food Analyst 0.2 FTE Communications Advisor Advertising, printing and other costs Television advertising	[*Deleted under section S9(2)(f)(iv) of the Official Information Act*].

Two year audit and enforcement project

26. For the enforcement part of the implementation strategy, officials propose a discrete two-year audit project based on risk management principles embodied in current food safety initiatives.

27. It is estimated that there are approximately 30,000 food businesses in New Zealand. Of these, approximately 3,000-4,000 are at risk of non-compliance with the amended GM Food Standard because of the types of food they produce.[1] It is proposed that a food business auditor be engaged to assess approximately 10% of 'risk' businesses in the first year, in co-ordination with enforcement officers around the country. The exercise would be communicated to the food industry and public in advance through media releases and in targeted consultation with food business associations.

28. The audit project would run for 2 years to cover the transition to the new Food Safety Authority and transitional provisions for the new GM food labelling requirements. [*Deleted under section S9(2)(f)(iv) of the Official Information Act*].

[1] New Zealand Yearbook 1997 and 1998.

29. Costs of the joint audit and communications projects are estimated to be $0.665 million over three years but options costing up to $1.535 million have been considered. The projects will not provide health gains, and will transfer to the new Food Safety Authority once it is established. Existing functions to be transferred from the Ministry of Health to the new Authority have already been identified [EXG Min (01) 7/3 refers] and do not include these activities. A bid for funding these activities in 2001/02 and 2002/03 from outside the Vote: Health funding cap is made in this paper. Extra funding of approximately $0.200 million per annum will be sought for the on-going enforcement of the GM food Standard in a business case for the new Food Safety Authority.

Recommendation 8.4	*that the Food Administration Authority produce and distribute consumer information on the use of gene technology in the production of food.*

Officials' advice: Accept the recommendation.

Conclusions of analysis

- The objective could be achieved by updating the existing web-based GM food fact sheets produced by Ministries of Health and Agriculture and Forestry.

Analysis

30. The Government has already identified a need for the public to be informed about developments in genetic modification in order to participate in debate, and to make informed choices about purchasing GM food, (and set up the Independent Biotechnology Advisory Council to help fill a similar role in the broader biotechnology context). The Ministries of Health and Agriculture and Forestry have produced web-based consumer information material in the past that could be updated to fulfil this Recommendation without further funding. [*Deleted under section S9(2)(f)(iv) of the Official Information Act*].

31. It is proposed that the broader issue of the need and appropriate mechanisms for the provision of education and information on biotechnology be developed further as part of the biotechnology strategy.

B - Food/Medicine Interface Issues

Recommendation 9.3	*that products be clearly defined in legislation as medicines, pharmaco foods, functional foods or dietary supplements.*

Officials' advice: Accept the principle of the recommendation, that the regulation of products on the foods/medicines interface should be clarified.

Conclusions of analysis

- Reject the specific terminology of the Commission.
- Work to clarify the foods/medicines interface is already underway.
- Problems identified by the Commission will be addressed as part of the Trans-Tasman Therapeutic Goods Project.

- Products not covered by the proposed new therapeutics legislation will be covered by a new food standard being considered by Australia New Zealand Food Authority (ANZFA).

Analysis

32. The Commission perceived that there was a problem with inconsistent and incomplete regulation of the foods and medicines interface. Increasingly foods, and products intended for a therapeutic purpose, are being sold as dietary supplements to avoid the stringent requirements to prove safety and efficacy under the Medicines Act 1981. Unlike therapeutic products, dietary supplements are not evaluated to determine quality and safety before entry onto the New Zealand market.

33. Regulation is inconsistent with Australia. Whereas 'pills and capsules' dietary supplements are regulated as foods in New Zealand, in Australia they are regulated under the Therapeutic Goods Act 1989. This causes significant problems as foods may move freely between the two countries under the Trans-Tasman Mutual Recognition Arrangement but medicines may not.

34. The New Zealand dietary supplements industry acknowledged before the Royal Commission that some 'pills and capsules' type dietary supplements are derived from GMOs. However, although these products are regulated under the Food Act 1981, they are not foods for the purpose of the Australia New Zealand Food Standards Code. This means that, unlike other GM foods, 'pills and capsules' dietary supplements require no pre-market safety assessment and are not subject to GM labelling requirements.

35. A long-term project is already underway on options to establish a joint Trans-Tasman Therapeutic Goods Regulatory Authority. This project, and a proposed 'functional foods' standard to be developed by ANZFA, is expected to achieve the Royal Commission's objective. However, the estimated commencement time of a new therapeutics agency is 2004/05. The ANZFA standard may be developed within 2 years.

C - Medicines Approvals

36. The theme of these recommendations is the prevention of unnecessary hurdles, while ensuring appropriate regulatory control.

Recommendation 9.4	*that imported medicines and pharmaco foods that include live genetically modified organisms be approved for use by Medsafe without a requirement for additional approval from ERMA*

Officials' advice: Accept in principle on proviso of further analysis with respect to scope, and determining the appropriate environmental risk assessment process.

Conclusions of analysis

- Would require amendment of regulations under the Hazardous Substances and New Organisms (HSNO) Act and the Medicines Act.
- May require a contractual arrangement between Medsafe and the Ministry for the Environment.

Analysis

37. The Commission identified the need to reduce regulatory compliance costs and confusion. Currently, medicines containing new living organisms (including GMOs) require a dual assessment: by Medsafe for safety and efficacy to standards required by international regulatory guidelines, and by the Environmental Risk Management Authority (ERMA) for environmental impact.

38. Dual assessment requirements are costly and may deny New Zealanders access to new medicines. Medicines were recently made exempt from the hazardous substances part of the HSNO Act. The Commission's recommendation that medicines containing genetically modified organisms should be exempt from the new organisms part of the HSNO Act is consistent with the precedent set for finished dose forms of new chemical medicines. Medicines would still be subject to environmental risk assessment. Further analysis is required to determine the appropriate agency for carrying out the environmental risk assessment.

39. The Commission's recommendation does not treat domestic and imported products the same. Imported medical products are required to be assessed by Medsafe only, but products developed or grown in New Zealand would still require ERMA approval. The Commission gives no explanation for this difference. Environmental risks could exist for both imported and domestically developed medical products that contain GMOs. Setting New Zealand specific standards raises the regulatory barrier and may prevent research and product development in New Zealand.

40. This recommendation requires further analysis with respect to the scope and size of the minimum environmental data set required for evaluation by Medsafe, and the issue of New Zealand-specific standards under the proposed trans-Tasman regulatory agency.

Recommendation 9.5	*that, in respect of applications for approval as Animal Remedies of genetically modified organisms or products manufactured by processes using genetic modification techniques, the specified information which the Director-General of Agriculture and Forestry requires to be contained in applications under the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM) include full information on the efficacy and the form of the genetic modification used in manufacture; and that such information be included as one of the categories of relevant risks and benefits under section 19 of the Act.*

Officials' advice: Accept the recommendation.

Conclusions of analysis

- Either rely on existing operational arrangements under the ACVM and HSNO Acts, or prescribe in the ACVM Act.

Analysis

41. The Commission considered that full information relating to GMOs or their products used as animal remedies should be required as part of the application for registration. (No GMOs are currently used in veterinary medicine.)

42. Recommendation 9.5 is consistent with existing assessment criteria for veterinary medicine product efficacy. The potential environmental impact of live GMOs will be covered in the HSNO Act approval that would be required for any live GMO in a veterinary medicine product.

43. The combined ACVM Act and HSNO Act approval processes already provide the means to achieve the Commission's objectives. These objectives could be achieved for animal remedies which are GMOs by ensuring that information provided to ERMA on the form of the genetic modification is also provided to the Director-General of Agriculture and Forestry. To obtain information on the type of genetic modification used in the manufacture of any other animal remedy would require a simple alteration of the operational arrangements under the ACVM Act.

Recommendation 9.6	*that, as protocols identify useful therapeutics for serious disease control, approvals through ERMA and Medsafe be sought in advance for the importation of live genetically modified organisms in the form of vaccines.*

Officials' advice: Accept the concerns of the Commission but note that obtaining medicines approvals in advance will not necessarily reduce the risk of infectious diseases in certain emergency circumstances (including bioterrorism).

Conclusions of analysis

- Agree to explore the possibility of implementing a risk management strategy to manage the risk of epidemics of animal or human infectious diseases.

Analysis

44. The Commission has identified a risk that in the case of an outbreak of disease in humans or animals, rapid importation of vaccines or medicines containing live GMOs may not be possible. This risk would also apply in cases of bioterrorism. Officials advise that constraints on the availability of appropriate medicines may be both legislative (obtaining approvals) and logistical (obtaining adequate stocks in emergency situations).

45. The HSNO Act allows prior application for approval of a GMO for use in foreseeable emergencies. This allows, for instance, for vaccines containing live GMOs to be available for use in an emergency. The Health and Biosecurity Acts also have wide-ranging emergency powers. However, the Medicines Act contains no emergency power, and all applications to import and use medicines in an emergency would still require Ministerial approval.

46. Because of possible constraints on obtaining medicines in emergencies, neither emergency nor advance approvals will ensure their availability should the need arise. Officials support the intent of the recommendations, which is to be prepared for infectious disease emergencies. However, developing and implementing a risk-management strategy requires more work.

D - Medical Ethics

47. The theme of these recommendations is to ensure ethical concerns are properly considered. There are relationships between the proposed Bioethics Council (considered by Cabinet on 29 October 2001) and existing ethical and technical advisory bodies.

Recommendation 9.1	*that all gene therapy, whether in the public or the private sectors, require formal medical ethical oversight.*

Officials' advice: Accept the underlying intention of the recommendation, that new medical technologies involving genetic modification should only be introduced into a clear legislative and ethical framework.

Conclusions of analysis

- Germ-line and somatic cell gene therapy will need to be treated differently.
- Changes to the Medicines Act, the HSNO Act and the proposed Human Assisted Reproductive Technology Bill may be required to accommodate the proposed framework.
- Much work is required to identify the interfaces between the different regulators and to develop an appropriate regulatory framework.

48. The Commission noted that gene therapy exists in two forms:

- Somatic cell gene therapy – where an attempt is made to replace the DNA coding for a particular enzyme, or chemical, in the target cells of a patient suffering from a particular medical condition; and
- Germ cell line gene therapy – where an attempt is made to modify the genome of an embryo that carries the gene for a particular hereditary condition.

Analysis

49. The Royal Commission expressed concern that somatic cell gene therapies developed entirely overseas could be introduced into New Zealand without ethical consideration.

50. The Commission also expressed concern that germ cell line gene therapy (in some respects similar to cloning technology), is not specifically regulated, other than by professional obligation and that it could be introduced in private hospital facilities without ethical or regulatory approval.

51. While the Commission has not identified any particular public health risks associated with the current lack of ethical approval over somatic cell gene therapy, an underlying principle in the report appears to be that new technologies should only be introduced following ethical discussion and social acceptance. Consequently, the Commission has proposed that all somatic cell gene therapy products be examined and approved by an ethics committee on a case-by-case basis before being used in New Zealand. However, no gene therapy is likely to be available for a minimum of 5 to 7 years, and any use prior to that time will almost certainly take place within tightly controlled clinical trials which have been subject to ethical review and approval.

52. Somatic cell gene therapy would be considered to be a medicine under the current legislation. Therefore, all clinical trials would need to be approved by both Medsafe and an institutional ethics committee. Following clinical trials the sponsor of the somatic cell gene therapy product would require the approval of the Minister of Health before the product could be commercially distributed. Officials agree with the Commission that new

somatic cell gene therapy proposals from private non-institution based medical practitioners should undergo similar ethical scrutiny.

53. The technology used in germ cell line gene therapy requires manipulation of DNA in fertilised eggs. The technology used, and ethical issues raised by germ cell line gene therapy are closer to those associated with cloning than to somatic cell germ therapy. As a method of treatment, germ cell line gene therapy is not expressly covered by legislation. However, the Human Assisted Reproductive Technology Bill will cover genetic manipulation of embryos and include the requirement that new and innovative approaches to reproductive technology must be assessed and approved by a national ethics committee prior to the introduction of the technology.

54. The following proposals would achieve the Commission's objectives:

- In consultation with technical and scientific advisory bodies the Bioethics Council, or some other national expert/ethics committee, will consider the ethics of somatic and germ cell line gene therapy prior to its introduction as a mainline medical therapy;
- Research into creating genetically modified human cell lines, tissues or organs will be subject to legislation;
- Germ cell line gene therapy will be subject to regulation under either the Human Assisted Reproductive Technology or Medicines legislation;
- Each request to conduct germ cell line genetic manipulation will be subject to both an ethical and technical review of its safety, quality and efficacy;
- Clinical trials in humans of somatic cell gene therapy products will continue to be permitted as these studies are already subject to oversight by the Gene Technology Advisory Committee (a sub-committee of the Health Research Council) and Institutional Ethics Committees. All new proposals to use somatic cell gene therapy on individual patients outside of a clinical trial must also be referred for ethics scrutiny.

55. Further work on the proposed Human Assisted Reproductive Technology legislation is required. Implementation of either the Commission's original recommendation or the Government's modified proposal will require consultation with stakeholders including the pharmaceutical industry, the Health Research Council and the wider community.

Recommendation 9.2	*that Toi te Taiao: the Bioethics Council develop ethical guidelines for xenotransplantation involving genetic modification technology.*

Officials' advice: accept a broader interpretation of the recommendation that covers transplantation of genetically modified human tissue and all forms of xenotranplantation involving humans (including xenotransplantation *not* involving genetic modification).

Conclusions of analysis

- The introduction of xenotransplantation technology into humans, should not proceed until the Bioethics Council (or some other national expert/ethics committee with Maori representation), in consultation with expert technical advisory bodies, has considered:

- Xenotransplantation (transplantation of tissue between species) of tissues or organs to humans, irrespective of whether it utilises genetically modified animals or not;
- Allotransplantation (transplantation of tissue within a species) of genetically modified tissue or organs;

- A change to the Medicines Act 1981 is required to allow the Minister of Health to prohibit an activity (such as xenotransplantation).
- Implementation of Recommendation 9.2 is dependent on a Cabinet decision to establish the Bioethics Council.

Analysis

56. The Commission expressed concerns about the safety of xenotransplantation, (the transplantation of tissues or organs from one species to another, e.g. animal to human). There are risks of transmission of retrovirus infection to transplant recipients and the wider community. The Ministry of Health shares these concerns but believes the risks associated with xenotransplantation exist irrespective of the nature of the source animal. Recommendation 9.2 should cover xenotransplantation in general, rather than only that which involves genetically modified animals.

57. Given the current uncertainty about the risks associated with xenotransplantation the Commission indicated that it should not be considered as a serious treatment option until further research occurs. The Ministry of Health believes that the risks of xenotransplantation are not well defined enough to allow clinical trials involving humans to proceed at this point in time. Research involving xenotransplantation between non-human animals species is required to adequately define the risk of transmission of retroviruses to humans. The Commission also stated that: "when eventually the issue arises as a practical question… the issue will first need to be considered by the Bioethics Council".

58. Recommendation 9.2 is consistent with the Ministry of Health position that public consultation on the introduction of xenotransplantation technology is required before research involving humans as xenotransplant recipients could proceed in New Zealand.

59. Restrictions on xenotransplantation are strongly supported by Maori and some community sectors but would not be supported by a New Zealand biotechnology company that is developing a xenotransplantation product.

CONSULTATION

60. The following departments were involved in the preparation of this paper: Ministry for the Environment, Ministry of Agriculture and Forestry, Ministry of Consumer Affairs, 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, State Services Commission, Te Puni Kokiri, and the Treasury. 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 IMPLICATIONS

61. Recommendations 8.1 - 8.4, 9.1, 9.2, and 9.4 have fiscal implications. Indicative costs of implementing the recommendations are outlined below. An overview of the overall fiscal implications is contained in Paper 1 of this suite (which was considered by Cabinet on 29 October 2001).

	2001/02	2002/03	Out years	Other fiscal implications
8.1				
8.2				
8.3				
8.4				
9.1 & 9.2				
9.4				

HUMAN RIGHTS AND TREATY OF WAITANGI IMPLICATIONS

62. There are no human rights implications of these recommendations. Treaty of Waitangi implications are discussed in Paper 6.

LEGISLATIVE IMPLICATIONS

63. A number of the recommendations in this paper have legislative implications, principally changes to the HSNO Act and the Medicines Act. Combined with legislative changes recommended in other papers in this suite, these will likely form part of a wider HSNO Amendment Bill during 2002. The detail of these legislative implications will be discussed in more detail when officials report back on the specific legislative changes required.

REGULATORY IMPACT AND COMPLIANCE COST STATEMENT

64. Implementation of Recommendations 9.1, 9.2, 9.4, and 9.5 may involve legislative change and will require regulatory impact assessments.

65. Recommendations 9.1 and 9.2 may add an extra dimension to the ethical approval required for innovative treatments and clinical trials: with additional associated costs to applicants.

66. Recommendation 9.4 would reduce compliance costs, as applications for approval of medicines containing live GMOs would no longer require approval by two agencies. The reduction in compliance costs would be very dependant on future decisions about the size of the environmental risk assessment. Officials will be reporting to Cabinet on the detail of the proposed changes by the end of April 2002 and the necessary regulatory impact statement will be prepared at that time.

67. Recommendation 9.5 would create a marginal increase in compliance costs for applications to approve veterinary medicines. Further information would be required from applicants, however this information is usually already included in applications.

PUBLICITY

68. A separate communications strategy is being developed for the whole package of Government decisions on the Commission's report. Recommendations 8.3 and 8.4 will require the provision of consumer information.

RECOMMENDATIONS

69. It is recommended that Cabinet Policy Committee:

Food and Consumer Information

1. **Note** that Recommendation 8.1 of the Royal Commission recommended:

   that the Food Administration Authority monitor research studies on stock feed and act on any that indicate a need for stock feed to be assessed in relation to human health.

2. **Direct** the Ministry of Agriculture and Forestry to plan a programme to monitor research into the health aspects of GM stock feeds, subject to resourcing, similar to that currently being carried out by the Ministry of Health in respect of the effects of genetically modified food on human health; to assess what action might be required in the future and to assess the costs of such action, should the monitoring programme indicate negative health effects; and to determine what legislative tools and risk management strategies would be necessary in order to act on such findings.

3. **Note** there are no legislative mechanisms in the Agricultural Compounds and Veterinary Medicines Act for preventing or managing risks to human health from stock feeds. A legislative change to the Act would be required to put in place the necessary risk management programmes. Implementation of these programmes would require additional human and financial resources.

4. **Note** that Recommendation 8.2 of the Royal Commission recommended:

   that Government facilitate the development of a voluntary label indicating a food has not been genetically modified, contains no genetically modified ingredients and has not been manufactured using a process involving genetic modification.

5. **Note** the proposed voluntary label is additional and complementary to the mandatory labelling system (coming into force on 7 December 2001); it is intended to assist those consumers who wish to avoid foods that contain any GM ingredients or result from a GM process.

6. **Note** despite consumer and industry support for such a voluntary label, there may be barriers to its use, including:

   - the cost and difficulty of detecting GM material in processed foods;

- the ability of identity preservation systems to verify food's origin; and
- the willingness and ability of suppliers to standardise 'GM-free' claims.

7. **Direct** the Ministry of Consumer Affairs to scope what would be required for an interdepartmental working group to facilitate the development of a voluntary 'GM free' labelling system, and to proceed with the facilitation if it can be resourced from within baselines.

8. **Note** that the Ministry of Consumer Affairs and other involved departments may require additional funding should the scoping phase identify the need for significant government support.

9. **Note** that Recommendation 8.3 of the Commission recommended

   that as a matter of priority, the Food Administration Authority [the Ministry of Health until such an agency is established] disseminate information on the labelling regime for genetically modified foods and consumer rights in relation to foods made available for consumption at restaurants and take-away bars.

10. **Note** that the intent of the Commission is the effective implementation of the GM Food Standard, which includes both ensuring compliance, and Recommendation 8.3's communications exercise.

11. **Agree** to the communications Strategy A, subject to funding approval in Paper 1, which would give effect to Recommendation 8.3.

Strategy A (officials preferred)	media statements, radio and television interviews; newspaper advertisements and pamphlets; mail drop; iwi/local radio.	[*Deleted under section S9(2)(f)(iv) of the Official Information Act*].
Strategy B	Advertising, printing and other costs (excluding mail drop)	[*Deleted under section S9(2)(f)(iv) of the Official Information Act*].
Strategy C	Advertising, printing and other costs Television advertising	[*Deleted under section S9(2)(f)(iv) of the Official Information Act*].

12. **Agree** to accept a 2-year audit project, subject to funding approval in Paper 1 of this series [*Deleted under section S9(2)(f)(iv) of the Official Information Act*] which would give effect to the informal recommendations of the Commission that the amended Standard should be enforced in a proactive manner to ensure compliance.

13. **Agree** that funding for 2003/04 and outyears will be considered as part of the wider funding business case for the Food Safety Authority.

14. **Note** that Recommendation 8.4 of the Commission recommended:

    that the Food Administration Authority produce and distribute consumer information on the use of gene technology in the production of food.

15. **Note** that this recommendation could be achieved within Ministry of Health and Ministry of Agriculture and Forestry baselines if it is limited to revising existing web-based material; additional and extensive communications work including print-based material would require further funding.

16. **Direct** the Ministry of Health and the Ministry of Agriculture and Forestry and the Food Safety Authority, once it is established, to update existing web-based information for consumers on the use of gene technology in the production of food.

17. **Note** the provision of broader information on biotechnology is proposed to be developed further as part of the biotechnology strategy (considered by Cabinet on Monday 29 October 2001).

Food/Medicine Interface Issues

18. **Note** that Recommendation 9.3 of the Commission recommended:

    that products be clearly defined in legislation as medicines, pharmaco foods, functional foods or dietary supplements.

19. **Note** that the Commission developed the term 'pharmaco food' and there are no internationally recognised definitions of "pharmaco foods", "functional foods" and "dietary supplements".

20. **Agree** with the intent of Recommendation 9.3, which is to ensure clear and consistent regulation of the foods and medicines interface.

21. **Agree** that the clarification of the foods/medicines regulatory interface be progressed through the existing Trans-Tasman Therapeutic Goods Project (estimated completion date: 2004/05) and the planned development of a 'functional foods' standard by the Australia New Zealand Food Authority (estimated completion date: 2003).

Medicines Approvals

22. **Note** that Recommendation 9.4 of the Commission recommended:

    that imported medicines and pharmaco foods that include live genetically modified organisms be approved for use by Medsafe without a requirement for additional approval from ERMA.

23. **Note** that the recommendation is consistent with the precedent set for finished dose forms of medicines, which are exempt from the hazardous substances part of the Hazardous Substances and New Organisms (HSNO) Act 1996.

24. **Agree** in principle that medicines that are or contain GMOs should be exempted from the new organisms part of the HSNO Act, provided an appropriate environmental assessment is performed by an appropriate agency, which is yet to be determined.

25. **Direct** officials (Ministry for the Environment lead) to determine the scope of the necessary environmental assessment and to include domestically developed GMO medicines in the exemption, and to report back to Cabinet by April 2002 as part of a proposal for a HSNO amendment bill.

26. **Note** that Recommendation 9.5 of the Commission recommended:

    that, in respect of applications for approval as Animal Remedies of genetically modified organisms or products manufactured by processes using genetic modification techniques, the specified information which the Director-General of Agriculture and Forestry requires to be contained in applications under the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM) include full information on the efficacy and the form of the genetic modification used in manufacture; and that such information be included as one of the categories of relevant risks and benefits under section 19 of the Act.

27. **Note** that the Commission considered that full information relating to GMOs used as animal remedies should be required in the application for registration.

28. **Note** that the Director-General of Agriculture and Forestry could readily achieve the Commission's intent by requiring information on the efficacy and form of genetic modification under existing provisions of the ACVM Act.

29. **Direct** officials to alter the operational arrangements issued under the ACVM Act to reflect the intent of Recommendation 9.5.

30. **Note** that Recommendation 9.6 of the Commission recommended:

    that, as protocols identify useful therapeutics for serious disease control, approvals through ERMA and Medsafe be sought in advance for the importation of live genetically modified organisms in the form of vaccines.

31. **Note** the concerns of the Commission that New Zealand may be at risk in certain emergency circumstances; and that there are no protocols for identifying useful therapeutics for serious disease control.

32. **Note** that concerns about the availability of medicines in emergency situations apply equally to medicines that are not produced using genetic modification.

33. **Agree** with the intent of Recommendation 9.6, which is to minimise the risk in case of serious disease outbreak.

34. **Direct** officials to explore the possibility of implementing a risk management strategy for epidemics of animal or human infectious diseases, and to report to Cabinet by the middle of 2003.

Medical Ethics

35. **Note** that Recommendation 9.1 of the Commission recommended:

    that all gene therapy, whether in the public or the private sectors, require formal medical ethical oversight.

36. **Note** that 'somatic' cell gene therapy and germ cell line gene therapy raise different ethical issues and would be considered differently.

37. **Agree** to accept the intent of Recommendation 9.1 that new medical technologies involving genetic modification should only be introduced into a clear legislative and ethical framework that is sound and based on current risk management methodologies.

38. **Agree** to accept that the introduction of a new somatic cell gene therapy product should be referred an appropriate ethics body.

39. **Agree** that clinical trials in humans of somatic cell gene therapy products will continue to be permitted as these studies are already subject to oversight by the Gene Technology Advisory Committee and Institutional Ethics Committees.

40. **Agree** that each application to conduct germ cell line genetic manipulation should be referred to an appropriate ethics body, in addition to a safety and efficacy evaluation by an appropriate technical committee.

41. **Note** that much work is required to implement this recommendation and officials will report back to Cabinet by April 2002 as part of the Bioethics Council project discussed in Paper 1 (considered by Cabinet on Monday 29 October 2001).

42. **Note** that Recommendation 9.2 of the Commission recommended:

    that Toi te Taiao: the Bioethics Council develop ethical guidelines for xenotransplantation involving genetic modification technology.

43. **Note** that xenotransplantation (transplantation of cells and tissue between species) should not be considered as a serious treatment option until further research occurs, given the current uncertainty about the associated risks, which apply equally to xenotransplantation *not* involving genetic modification.

44. **Note** that Recommendation 9.2 is consistent with the Ministry of Health position that, when the safety of xenotransplantation is better defined, public consultation on the introduction of xenotransplantation technology will still be required before human research can proceed in New Zealand.

45. **Agree** to accept and broaden Recommendation 9.2 such that prior to the application of xenotransplantation technology to humans the Bioethics Council, or some other national expert/ethics committee with Maori representation, in consultation with expert technical advisory bodies, is required to consider:

    - Xenotransplantation of tissues or organs to humans, irrespective of whether it utilises genetically modified animals or not;

    - Transplantation of genetically modified tissue or organs within a species.

Hon Marian L Hobbs
MINISTER FOR THE ENVIRONMENT