chapter |

14.

The biotechnology century: three major proposals

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1. The 21st century has been dubbed the biotechnology century. Genetic modification is but one of many new technologies likely to become available. New Zealanders have always been quick to adopt and adapt new technologies, in whatever field they arise. Biotechnology will be no exception.

2. Adoption of the new, however, should not be done uncritically. While the Commission has recommended an openness to genetic modification, we have proposed appropriate safeguards to ensure the well-being of the community and the environment.

3. To provide for ongoing oversight of biotechnological developments, the Commission makes three further proposals: a bioethics council, a parliamentary commissioner on biotechnology, and a biotechnology strategy.

Toi te Taiao : the Bioethics Council

4. Ethical, cultural and spiritual concerns underlay much of what we heard about genetic modification and biotechnology.

5. The current system of regulation for genetic modification and associated technologies operates through a number of ministries and government departments, assisted by advisory bodies, which provide policy advice to the Government. Some, like the Ministries of Health, and Agriculture and Forestry, implement those policies. Other regulatory functions are carried out by separate bodies such as the Environmental Risk Management Authority (ERMA) and the Australia New Zealand Food Authority (ANZFA).

6. Under the Hazardous Substances and New Organisms Act 1996 (HSNO), ERMA and all other persons exercising powers or duties are directed to recognise and provide for "the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social, and cultural wellbeing and for the reasonably foreseeable needs of future generations" (section 5(b)). They are also directed to consider the relationship Maori have with their ancestral lands, waters, sites, wahi tapu, plants, animals and other taonga (section 6(d)).

7. While these are appropriate matters for consideration, the general view is that they are almost impossible to deal with in the course of the case-by-case decisions that are the responsibility of ERMA. A recurring theme in the Commission's consultations was that the ethical, cultural and spiritual dimensions of genetic modification were not being adequately addressed. Typical of submissions received were:

> Public education and consultation processes are needed, so that an informed community can also participate fully in the discussion. ... Some issues, especially cultural concerns, may be best dealt with at this principled level rather than being handled, as they currently are, on a case-by-case basis within the regulatory process. (New Zealand Catholic Bishops' Conference [IP38])[1]
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> Government should publish high level policy directives defining the risk boundaries and social acceptability of different GM categories. ERMA would then become the operational arm of the framework implementing the protocols and only calling for hearings for new or uncertain risks or where a better understanding of issues is needed. (Association of Crown Research Institutes [IP22])[2]
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> The Act does not provide a sufficient framework within which to address the concerns [about cultural and spiritual issues] elaborated by Ngati Wairere. ... A broader approach is required to provide a context in which the HSNO Act can operate. (ERMA [IP76])[3]
>
> Decisions on how potential environmental risks are to be managed should not be based purely on scientific understandings and rhetoric. Spiritual, cultural and theological considerations are a fundamental component of this field. (Teremoana Jones [Nga Puhi] at the national hui held at Ngaruawahia).[4]

8. To address these concerns, the Commission recommends the establishment of Toi te Taiao : the Bioethics Council. Toi te Taiao may be understood as "the sphere of the spiritual and natural worlds". From the perspective of Maori, bioethical decisions emerge at the point where the spiritual and natural worlds meet. From a Pakeha point of view, as noted in chapter 3, ethical decisions arise at the conjunction of values with the specifics of a particular situation.

9. In chapter 3, the question of transgenic animals was discussed as a working model of the ethical decision-making process. Values identified as pertinent to this case included Maori spiritual concerns, human well-being, and the sustainability of the ecosystem. Relevant situational information to be taken into account included the purpose of the project, the scientific data as to how it would work, and the potential risks and benefits to people and the environment.

10. A case of this kind would be typical of those we would see being referred to the Bioethics Council. The Council would be a vital forum where issues of national significance are addressed, and appropriate guidelines formulated

supporting practical outcomes. It would be an expert and independent body to promote and guide public debate on matters of principle, and to develop guidelines for ERMA and other bodies.

Referring matters to the Bioethics Council

11. Existing agencies dealing with biotechnology issues that include an ethical or cultural dimension should be able to refer such issues to the Council. There are a number of such bodies, and the Commission considers that a Bioethics Council would enable rationalisation. As Dr Joanne Dixon, a medical geneticist who appeared on behalf of the New Zealand Branch of the Human Genetic Society of Australasia [IP59] said, changes were needed to "clarify and enhance the roles and responsibilities of ERMA, Standing Committee on Therapeutic Trials (SCOTT), Genetic Technology Advisory Committee (GTAC) and the National Ethics Committees", which in her view were to "ensure safe and reliable application of genetic modification technology and to inform the Government."

12. Any of the bodies named by Dr Dixon might refer matters to the Bioethics Council, as might a variety of others such as ANZFA, and animal welfare, medical and research ethics committees.

13. It was suggested that a Bioethics Council would also be of assistance to the Commissioner of Patents, when considering whether a biotechnology patent application should be declined on the grounds of "public morality" under section 17 of the Patents Act 1953. The New Zealand Institute of Patent Attorneys [IP71] submitted that morality considerations should be removed completely from the Patents Act, as the Commissioner of Patents was not the appropriate person, nor did the Intellectual Property Office of New Zealand have the resources, to consider these matters in relation to patent applications for genetic modification processes or products. The Commission considered the provision should remain in the Patents Act but such matters should be within the scope of the Bioethics Council, as discussed in chapter 10 (Intellectual property).

14. The Minister of the Environment has the power under section 68 of HSNO to "call in" any application to ERMA with significant economic, environmental, international, or health effects, or significant effects in an area in which ERMA lacks sufficient knowledge or experience. The Minister may direct that she or he will decide the application, and ERMA is then required to investigate and report to the Minister.

15. The Commission recommends that the grounds for the exercise of the Minister's call-in powers be expanded to include significant social, ethical and cultural issues, and that the Bioethics Council be included as an additional body to

which the Minister might refer such issues. There may also be issues of significance that arise independently of an application to ERMA or other ethical committees. In such cases, the Minister might take the initiative to refer the matter to the Council. From time to time the Council might itself become aware of issues it should address.

Recommendation 14.1

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

16. Under section 16(3) of the New Zealand Public Health and Disability Act 2000, the Minister of Health may ask any of the ministerial committees established to advise him or her, or the ethics committee of the Health Research Council, for advice on specific ethical issues of national, regional or public significance in any health or disability matters. This would be another situation where the Bioethics Council would be available for advice.

17. The involvement of the public in the consideration of major ethical issues is also of vital importance. The Commission recommends that the Council be required to publicise matters before it, and to call for submissions from relevant bodies and the public at large.

Would the Council's guidelines be binding?

18. The Commission debated this question and found it difficult. On the one hand, matters of major ethical or cultural significance require more than a recommendation that could be ignored at will. On the other hand, to provide a binding ruling in every situation would override the facility of discretion that may be appropriate to individual situations. It would also turn the Council into a quasi-judicial body.

19. Balancing these factors, the Commission considers the Council's guidelines should not generally have a binding character. However, where the Council believes a particular matter is of such significance that a prescriptive response is called for, it could recommend to the Minister that the issue should be determined by legislation or statutory regulation.

20. The Commission considers the role it recommends for the Bioethics Council will promote consistency and minimise duplication between existing ethics advisory bodies. These recommendations should also assist in the better use of available expertise and resources.

Membership of Toi te Taiao : the Bioethics Council

21. The Bioethics Council should have a multidisciplinary membership reflecting a wide range of expertise. The Commission envisages a body of manageable size, not more than 12 members, but with the capacity to co-opt or consult as required. The membership should not be constructed on a "stakeholder" basis, but should be so selected as to ensure that the Council becomes known for its credibility, independence, expertise and broad-based representation.

22. As ethical decisions cannot be made in a vacuum, a range of experts would be required from areas that make up the context within which ethical decisions are made. Relevant areas of expertise would encompass science, medicine, environment, agriculture, economics, law and ethics. The Council would be deliberately pluralistic, and widely representative of the New Zealand community.

23. Effective Maori representation would be essential to the Council's work. While some who appeared before us would want to see equal numbers of Maori on such a body, the Commission's view is that the criterion should be a fully consultative approach to achieve an effective partnership. Nga Kaihautu Tikanga Taiao, ERMA's Maori advisory body, will still be needed for individual applications and to facilitate consultation with Maori.

24. The Council should have the flexibility to determine its own procedures and approach. But it must be adequately resourced to enable it to have the membership and access to expertise needed to achieve its purpose.

Recommendation 14.2

that Government establish Toi te Taiao : the Bioethics Council to:

- **act as an advisory body on ethical, social and cultural matters in the use of biotechnology in New Zealand**
- **assess and provide guidelines on biotechnological issues involving significant social, ethical and cultural dimensions**
- **provide an open and transparent consultation process to enable public participation in the Council's activities.**

Parliamentary Commissioner on Biotechnology

> I ask the ethical issue … who watches who? That is a key, Ko wai ma e ata tino titiro ki nga tangata, wahine e mahi ana nga mahi ara te ira tangata? (Who is examining the works of the people who are doing genetic modification?) Mahara Okeroa (Taranaki) MP at Waiwhetu Marae, Wellington regional hui.[5]
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> Sed quis custodiet ipsos custodes? (But who guards the guards?) Juvenal (AD 60-c130)

25. The Commission's second major proposal is the establishment of a Parliamentary Commissioner on Biotechnology with a threefold responsibility:

- to audit the bodies charged with making decisions about and guiding biotechnology and its applications in New Zealand
- to monitor and respond to emerging developments in biotechnology in terms of their implications in the New Zealand context
- to fulfil a widespread educational and consulting role with the public.

26. The Commission sees the Parliamentary Commissioner's job content as covering all the aspects of biotechnology discussed in the chapters on economics and strategy, environment and health, and ethical, cultural and spiritual matters.

27. The Commissioner would watch and report on the interaction between the new technologies and society, and follow the issue of biotechnology through all its applications in New Zealand. Questions to be addressed might include:

- Which uses of biotechnology will be of benefit to New Zealand?
- Is the balance between risks and benefits acceptable?
- Are the regulatory systems adequate?
- What are the market trends in relation to biotechnology?
- What are the international developments in the area?
- What are the public perceptions about the use of, and controls on, biotechnology?
- Is the monitoring and audit of biotechnology uses being done properly?
- Are health and safety being protected or compromised?

28. In exercising the audit role, the Commissioner would oversee appropriate biotechnological aspects of the work of:

- Ministry of Research Science and Technology
- ERMA
- Ministry for the Environment
- Ministry of Health

- Ministry of Agriculture and Forestry
- ANZFA
- the Bioethics Council.

29. The office or function is analogous to that performed by the Parliamentary Commissioner for the Environment. The Parliamentary Commissioner on Biotechnology will be the system's guardian, ensuring that the functions and responsibilities of all who administer and use the system are appropriately exercised. The Commissioner will have investigatory powers, collect and distribute information, and encourage preventive measures and remedial action.

30. With regard to the educational and consulting role, the Parliamentary Commissioner for the Environment [IP70] argued that practical mechanisms need to be developed that will provide:

> - systems for providing information to the public, tangata whenua and interested groups and sectors, and for actively encouraging the flow, exchange and building of information from a wide range of sources
> - systems for challenging and debating information and the various associated issues, values and concerns
> - systems for the wider general public to participate in the decision-making processes for any proposed use of these new technologies
> - systems for tangata whenua to participate, within the frameworks of tikanga, kawa and kaitiakitanga, and according to the articles and the principles of the Treaty of Waitangi, in the decision-making processes for any proposed use of these new technologies.[6]

31. Monsanto New Zealand [IP6] considered that it was:

> ... essential that the public should be well informed, by an appropriate organisation, resourced to present the issues – public education should not be left to the media, the companies involved in developing the products, or those groups opposed to the science. It should be in the hands of a credible, learned organisation resourced to enable it to present the real issues to the public, in a manner that is easily understood and takes account of all aspects of the issue.[7]

The company suggested that the Independent Biotechnology Advisory Committee (IBAC) of the Ministry of Research, Science and Technology (MoRST) could perform this role.

32. Although not agreeing with Monsanto's suggestion of the organisation to undertake this function, the Commission endorses the above concepts as a basis for this aspect of the Commissioner's role.

33. The Commission sees the office of the Parliamentary Commissioner on Biotechnology as an independent entity, separate from the executive branch of Government, and reporting directly and publicly to Parliament.

34. The successes of the Parliamentary Commission for the Environment and the Office of the Ombudsmen, which have similar independence and functions, have convinced us that these offices are understood and accepted by, and have the confidence of, the New Zealand public.

35. The office of the Parliamentary Commissioner on Biotechnology should be established by way of an amendment to HSNO, based on sections 4, 5, 6, 16, 17 and 18 of the Environment Act 1986, which set up the office of the Parliamentary Commissioner for the Environment and its functions and powers.

Recommendation 14.3

that Government establish the office of Parliamentary Commissioner on Biotechnology to undertake futurewatch, audit and educational functions with regard to the development and use of biotechnology in New Zealand.

Biotechnology strategy for New Zealand

36. The Commission's third major proposal is to address an urgent need for the development of a biotechnology strategy for New Zealand. Such a strategy would encompass many of the issues debated by the Commission. It would need to take into account scientific, environmental, economic, cultural, consumer preference and other factors, and the interplay between them. The aim of the strategy would be to ensure that New Zealand kept abreast of developments in biotechnology, and that these were used to national advantage while preserving essential social, cultural and environmental values.

37. We would see the strategy being the responsibility of a government department with policy and advisory skills and functions. MoRST is the obvious and appropriate body to do this. It is responsible for providing direction for science and innovation as a whole, accelerating New Zealand towards becoming a knowledge economy and achieving better outcomes for investment in research, science and technology.[8] Responsibility for a national biotechnology strategy fits well with MoRST's own strategic goals.

38. We envisage that MoRST would consult with bodies such as the Bioethics Council and the Parliamentary Commissioner on Biotechnology and seek

submissions from key stakeholder groups and the public at large in undertaking this responsibility.

Recommendation 14.4

that the Ministry of Research, Science and Technology develop on a consultative basis a medium- and long-term biotechnology strategy for New Zealand.

Independent Biotechnology Advisory Council

39. The Commission notes that the framework of functions proposed for the Bioethics Council, particularly the focus on ethics and cultural issues, encompasses a major portion of the terms of reference for IBAC.

40. IBAC was established to bring about dialogue and increase understanding about biotechnology; to inform Government on biotechnology's environmental, economic, ethical, social, and health aspects; and to focus on the ethical and social issues raised by developments in human biotechnology.

41. The Commission has recommended that the role of fostering general understanding and debate on biotechnology matters should be allocated to the new position of Parliamentary Commissioner on Biotechnology, as described above. The Commission's view is that a Parliamentary Commissioner, along with the Bioethics Council, will provide more adequately for those functions currently undertaken by IBAC.

42. Under its terms of reference, IBAC was given a two-year brief. That period expired in May 2001. The Commission understands that the Minister has extended IBAC's brief until the end of the year. Given the recommendations in this chapter, the Commission would see IBAC's role as being subsumed by the functions allocated to the Bioethics Council and the Parliamentary Commissioner on Biotechnology.