

Ka tangi tonu te ngakau
Ka matautau te hinengaro mo nga wa o mua i noho
tahi ai te tangata me ona rawa.
I te rereketanga o te ao nei i nga mea katoa
ka raruraru nga whakaaro o te tangata
Ka tahuri ki Te Kaihanga, Te Kaiwhakawa, kia homai
te maramatanga, te kaha me te rangimarie
Kia hiwa ra, kia hiwa ra, kia hiwa ra!

*A heart that sees and feels
That stands between past and future
Humanity once in balance with all nature
But as awareness of the world increases
We seek guidance and strength, serenity and peace
Preserving that which is sacred
For all generations to come
Let us always turn to the Great Spirit above
For guidance, wisdom and peace
Be watchful, be alert, be on guard.*

*Patere written for the Commission by
Pihopa Kingi and Haare Williams*

ROYAL COMMISSION on
GENETIC MODIFICATION



27 July 2001

To Her Excellency, The Honourable Dame Silvia Cartwright, PCNZM, DBE,
Governor-General and Commander-in-Chief in and over New Zealand

Your Excellency

Letter of transmittal

Pursuant to the terms of the Order in Council dated 8 May 2000, given under the hand of His Excellency, The Right Honourable Sir Michael Hardie Boys, GNZM, GCMG, the then Governor-General of New Zealand, we now humbly submit our report for Your Excellency's consideration.

We have The Honour to be
Your Excellency's most obedient servants

Thomas Eichelbaum
Chair,
Royal Commission on
Genetic Modification

Jean Fleming
Commissioner

Jacqueline Allan
Commissioner

Richard Randerson
Commissioner

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Executive summary

Executive summary

Genetic modification has been used freely in New Zealand for more than a decade as a research tool, for medical purposes, and in food ingredients. It holds exciting promise, not only for conquering diseases, eliminating pests and contributing to the knowledge economy, but for enhancing the international competitiveness of the primary industries so important to our country's economic well-being.

Our consultations with the people of New Zealand showed that, while most were comfortable with genetic modification for medical purposes, many strongly opposed other uses. Many of the submissions to the Commission focused substantially on food and crops. They stressed that the safety and certainty of the science have yet to be proved, reflecting the fact that, at least for the moment, world consumer preferences are against use of genetic modification in food. First-generation genetically modified crops have shown few obvious benefits for consumers.

Our major conclusion is that New Zealand should keep its options open. It would be unwise to turn our back on the potential advantages on offer, but we should proceed carefully, minimising and managing risks. At the same time, continuation of the development of conventional farming, organics and integrated pest management should be facilitated.

The major theme of the Report is Preserving Opportunities. Our recommendations aim to encourage the coexistence of all forms of agriculture. The different production systems should not be seen as being in opposition to each other, but rather as contributing in their own ways to the overall benefit of New Zealand.

Our inquiry has looked closely into the existing institutional structures dealing with the technological issues that arise. Although some suggestions for enhancement are included among our recommendations, we are satisfied that the basic regulatory framework is appropriate and that the key institutions, the Environmental Risk Management Authority (ERMA) and the Australia New Zealand Food Authority (ANZFA), carry out their functions conscientiously and soundly.

Debate on genetic modification issues in this country is made unique by the partnership between tangata whenua and tangata tiriti created by the Treaty of

Waitangi. The values held by Maori add special emphasis to the ethical and cultural objections many people have to the new technology. In our extensive consultation with Maori, and throughout the Commission's deliberations, we have given much thought to the values New Zealanders hold, to find a sound base for the findings we are now required to make. It became clear that the existing regulatory bodies were not best equipped to address issues of this kind, so one of our recommendations is to set up a separate specialist body, Toi te Taiao : the Bioethics Council, so that these matters can be debated.

We were also convinced that New Zealand needs a strong overall biotechnology strategy, to guide us in the use of all new technologies in this field. As an allied consideration it will be important that a single, independent institution undertakes the general auditing of biotechnological applications, and promotes public education about the new technologies. To this end we have recommended the establishment of a Parliamentary Commissioner on Biotechnology, modelled on the successful precedent of the Parliamentary Commissioner for the Environment.

We envisage that future uses of genetic modification will continue to require rigorous assessment by ERMA before approval. One detail whereby the Commission considers the existing processes could be improved is an addition to the approval types now available. We are recommending a new category, conditional release, where the use of a genetically modified organism can be made subject to terms and reporting back, as a further assurance of safety and to enhance the management of risk.

Technology is integral to the advancement of the world. Fire, the wheel, steam power, electricity, radio transmission, air and space travel, nuclear power, the microchip, DNA: the human race has ever been on the cusp of innovation. Currently, biotechnology is the new frontier. Continuation of research is critical to New Zealand's future. As in the past we should go forward but with care.

Carrying out a full consultation process and preparing a comprehensive report within the space of a year has meant a period of intense effort for the Commissioners and staff. It has also asked much of those who wished to make presentations to us. We gratefully acknowledge all who have contributed.

chapter |

1



Introduction

In simplified language, “genetic modification”, as defined in the Warrant, is:

- the deletion, change or moving of genes within an organism, or
- the transfer of genes from one organism to another, or
- the modification of existing genes or the construction of new genes and their incorporation into any organism.

The Commission considers the term “genetic modification” to be equivalent to and interchangeable with “genetic engineering”.

In terms of the Warrant, the Commission’s inquiry does not extend to the generation of organisms using standard breeding techniques, including cloning, hybridisation or controlled pollination (as these do not involve modification of existing genes). Nor does it cover mutagenesis not involving genetic engineering techniques.

For a fuller discussion of the meaning of genetic modification, see *Genetic Modification: an overview for non-scientists* on pages 362 to 363 of the Reference section of the Report.

1. Introduction

1. The Warrant¹ establishing the Royal Commission on Genetic Modification directed it to receive representations upon, inquire into, investigate and report upon:

- (1) the strategic options available to New Zealand to address, now and in the future, genetic modification, genetically modified organisms and products; and
- (2) any changes considered desirable to the current legislative, regulatory, policy, or institutional arrangements for addressing, in New Zealand, genetic modification, genetically modified organisms, and products.

2. On appointment the Commission instituted a number of processes, on the one hand to inform itself and on the other to consult the general public and obtain views and submissions on the subject matter. Our processes included:

- scoping meetings
- having background papers written by experts in the field
- a public opinion survey
- a total of 15 public meetings, spread throughout New Zealand
- a Maori consultation programme involving 28 workshops and 12 hui
- a Youth Forum
- a public submission process resulting in more than 10,000 written submissions
- formal hearings lasting 13 weeks and involving more than 100 Interested Persons² and nearly 300 witnesses, many from overseas.

3. These activities and their outcomes are described in the appendices. They resulted in a wealth of information being made available to the Commission.

4. People often expressed their views strongly, sometimes passionately, and occasionally angrily, but given the nature of the subject matter, this was to be expected. Although constrained by the need not to pre-judge the outcomes, the Commission experienced many moving moments, especially in the course of the

Maori consultation, as presenters made the forum aware of their deep involvement with matters affecting their whakapapa and culture, and the environment. Likewise, sufferers from rare diseases and their families provided poignant insights.

5. The Commission is grateful to all who contributed to the debate. We cannot possibly mention more than a proportion directly, and indeed there will be a number of significant witnesses to whom the Report will not refer by name. The views of all who have communicated with us through our processes, whether in person or otherwise, have been taken into account in forming our own opinions and in compiling our Report.

6. The Warrant directed the Commission to adopt procedures that would encourage people to express their views on the subject matter, and to consult with the public in a way that allowed people to express their views clearly. The processes outlined above were designed to achieve these ends.

7. At the Commission's public meetings, and in the public written submissions, the great majority of the views expressed opposed any general release of genetically modified organisms, and particularly their introduction to the food chain. People were anxious about the possible consequences of eating genetically modified foods, and also about the risk of damage to the environment.

8. Those members of the public who participated in the public meetings or made written submissions showed a strong sense of conviction that the interests of the country would be best served by maintaining our "clean green" image. People were more open to the use of genetic modification in contained research and for medical purposes. However, the Commission was conscious that participation in these Commission processes was by self-selection. We were uncertain about the extent to which "the average Kiwi" participated. Also, at some meetings those present may have felt the atmosphere was not particularly conducive to the expression of views in favour of genetic modification technology. Largely for these reasons, we commissioned an independent public opinion survey, which was conducted in March and April 2001. This showed a greater balance of viewpoints than the public meetings and submissions suggested. We wish to stress, however, that the terms of reference did not direct us to conduct our inquiry as if it were a referendum. It was made clear that we were to conduct an independent investigation and prepare a report for Government containing the conclusions we had reached.

9. The Commission's programme stimulated interest in the genetic modification debate. Our consultation processes and the coverage they received in the media helped to inform the debate, although, as we shall note later, much

remains to be done in the field of public education. The work of the Commission was well reported by the media, notably *The Dominion* and *Radio New Zealand*. The media treated the inquiry objectively and did not attempt to sensationalise any aspect.

9. We have been extremely well served by the Commission staff, headed by our Chief Executive Officer, Kay Hewitt; Counsel assisting the Commission; the contractors who helped with our programmes, and the team of analysts who have worked painstakingly on the materials received. Details of those involved in the inquiry are set out in appendix 1, and we express our appreciation to them all.

The shape of the Report

The Commission's Warrant directs us, in brief, to explore strategic options for New Zealand in respect of genetic modification. At one extreme New Zealand could become free of all genetically modified material, with no genetically modified products in use or able to be brought into the country, and no research involving genetic modification technology, even in containment. At the other extreme New Zealand could allow full, unrestricted use of genetic modification in all situations. Between these extremes lie any number of intermediate positions, each with its own combination of controls and freedoms, with the degree of control varying with the type of use and situation.

To address this basic strategic question, the Commission has structured its considerations in the following way:

- We start by naming seven core values we believe lie at the heart of this debate (chapter 2).
- These values are then grouped into three spheres or sets of criteria: cultural, ethical and spiritual; environmental and health; and economic and strategic (figure at the end of chapter 2).
- The sets of criteria are outlined (chapters 3, 4, 5).
- The criteria are then used in assessing various potential applications of genetic modification: research, crops, food, medicine (chapters 6, 7, 8, 9).
- There follows a discussion of other key issues: intellectual property, the Treaty of Waitangi, liability (chapters 10, 11, 12).
- We then draw our major conclusion about New Zealand's strategic options in respect of genetic modification (chapter 13).
- Three major recommendations are set out (chapter 14). We then list all our recommendations (chapter 15).
- The addenda to the Report comprise an explanation of genetic modification for non-scientists, the Commission's Warrant, the Treaty of Waitangi, the list of reference notes for each chapter, a glossary of Maori expressions, abbreviations and technical terms, and an index.
- The appendices contain essential supporting material. The first appendix introduces New Zealand and the current status of genetic modification here. It also describes the processes of the Commission, and includes operational detail. The second appendix summarises and analyses submissions from Interested Persons (who took part in the formal hearings), and the final volume covers representations from the public and other activities outside the formal hearings.

chapter |

2.

A shared framework
of values

2. A shared framework of values

1. The choices we make in life, whether as individuals or as a nation, reflect the values we hold. Values give rise to goals, which in turn determine policies and strategies. Values are often hidden or unnamed, and when this happens there is a danger of becoming lost in a debate about strategies and losing sight of what we ultimately want to achieve. In this chapter, therefore, the Commission sets out a framework of values as a reference device to guide the processes of analysis and formulation.
2. But where do those values come from? It would be inappropriate for four people to impose their own values on the life of the nation, and we do not seek to do so. But after weeks of hearings and our many public meetings and hui around New Zealand, it appears to us that it is possible to name a set of values that many New Zealanders would recognise as things we hold in common. The Warrant establishing the Commission also implied certain values by listing various matters we were to take into account in reaching our conclusions.
3. Sharing similar values, however, does not mean that everyone will necessarily reach the same conclusions about strategies to give effect to those values. Those who appeared before the Commission had very different ideas on how to achieve similar goals such as environmental, cultural and economic well-being. But value identification goes some way to ensure congruence between goals and strategies, and to enable different groups to see their own goals more broadly, and in relationship with others.
4. We identify seven values pertinent to this Report:
 - *The uniqueness of Aotearoa/New Zealand* The environment of any country is unique, and New Zealand's is made more so by its geographical isolation, its relatively low population density, and the ecosystem, flora and fauna specific to this nation. Decisions need to be tailor-made to fit those features and circumstances which are uniquely ours.
 - *The uniqueness of our cultural heritage* The Treaty of Waitangi created a special relationship between tangata whenua (people of the land) and tangata tiriti (the settlers who came later). New Zealanders recognise the essential element of Maori heritage in the New Zealand culture of today.

- *Sustainability* The need to sustain our unique but fragile environment for generations yet to come was often and passionately mentioned by many. Tangata whenua use the word kaitiakitanga (stewardship) to describe the same concept. Any estimate of benefits and costs must include sustainability as a central criterion. An environment that is cherished and cared for is not just a survival mechanism; it is for many also a source of spiritual and cultural hope.
 - *Being part of a global family* To be geographically isolated is not to be isolationist. New Zealanders are very much world citizens in terms of travel, trade, and partnerships of knowledge and endeavour. While safeguarding those things that are uniquely ours, we also share in global developments. We live in a creative partnership with other nations, being influenced by them and yet also having the capacity to exercise leadership among them.
 - *The well-being of all* Meeting the needs of all New Zealanders requires a robust economy with equally robust systems to ensure positive educational, health and social outcomes. Economic and social goals are not mutually exclusive. They are, in fact, symbiotic. A strong economy makes possible the provision of effective educational, health and social systems, and a population that has benefited from those systems contributes in turn to a strong economy.
 - *Freedom of choice* As a nation of diverse peoples, cultures and beliefs we need to recognise such plurality by allowing for maximum freedom of choice. Freedom to make my choice, however, also means allowing others the freedom to make theirs. In a democratic nation freedom in diversity requires a flexible and cooperative spirit to ensure that as far as possible everyone's freedoms are maintained.
 - *Participation* A democratic nation requires effective systems of consultation and shared decision-making. The Commission has sought to consult with as many New Zealanders as possible, and to value the viewpoint of "the average Kiwi" as much as the viewpoint of well-resourced organisations. National policies are most likely to succeed when they arise out of processes of participation, and we hope that this Report reflects this fundamental value.
5. We invite readers to compare their own values with those we have set out above and to keep them in mind as a backdrop to this Report.



7 core values

The values in practice

To give effect to the seven core values just named, the Commission established three spheres or sets of criteria to apply when assessing potential applications of genetic modification techniques. The spheres and the relationships between them are illustrated below. While there is some overlap, the cultural, ethical and spiritual sphere broadly reflects the values of the Treaty of Waitangi, freedom of choice, and participation. The values of uniqueness and sustainability, and aspects of the value of well-being, fall within the environment and health sphere. Global family values and other aspects of well-being belong in the economic and strategic sphere.



The 3 sets of criteria

chapter |

3.

Cultural, ethical
and spiritual issues

3.

Cultural, ethical and spiritual issues

Key questions:

- What values do New Zealanders hold in common?
- How do we link values to practical decision-making?

Introduction

1. Chapter 2 described a set of values shared by many New Zealanders and relevant to consideration of genetic modification. These values could be grouped into three spheres: cultural, ethical and spiritual; environmental and health; and economic and strategic. Chapters 4 and 5 consider the latter two spheres. This chapter discusses cultural, ethical and spiritual issues. The issues are difficult.

2. The ethics and cultural categories in the template for submissions from Interested Persons (IPs) were often empty, or filled with a rather general statement such as, “We seek to operate in an ethical manner”. It does not follow that submitters had no views about ethical aspects or regarded them as unimportant. They may have been aware that other groups had a special interest in the subject and been happy to leave ethical aspects to them. Several corporate and professional groups¹ referred to codes of ethics for their organisation.

3. Many of the submissions from Maori groups and individuals referred to spiritual and cultural matters throughout their submissions. We include later in this chapter a focused discussion on Maori culture and spirituality. In addressing the question of ethics generally, the Commission identified three underlying issues.

4. The first concerns the difficulty in resolving some of the complex issues arising in the genetic modification and biotechnology area. Many Interested Persons submitted it was inappropriate for a local ethics committee to debate issues of a national or overarching nature. Local committees often felt a lack of expertise to deal with such issues. In other cases, the local committee came to a

decision after much discussion, only to discover other ethics committees had also spent much time dealing with the same matter. A pragmatic concern was that lengthy debates on complex cultural and ethical matters delayed regulatory processes associated with applications to the Environmental Risk Management Authority (ERMA). The point was not that such matters should not be debated, but that the debate and decision-making should take place at a higher level.

5. A second issue was how to link cultural and spiritual values (such as the sacredness of nature) with specific decisions (such as whether to approve the development of a transgenic cow). Values are important, but without linkages through to the specific decision-making area they can easily be dismissed. Likewise, specific decisions that take no account of a more overarching framework of values lose sight of the deeper values New Zealanders hold.

6. The third issue lies in deciding whether or not there is a common core of values in New Zealand and, if so, what the content of that core might be.

7. In this chapter we set out the various views presented, and structure them under four headings: where our values come from (paragraphs 8–37), identifying a common core of values (paragraphs 38–46), how we link basic values with ethical decision-making (paragraphs 47–108), and institutional frameworks to enable such decision-making to take place (paragraphs 109–118).

Where do values come from?

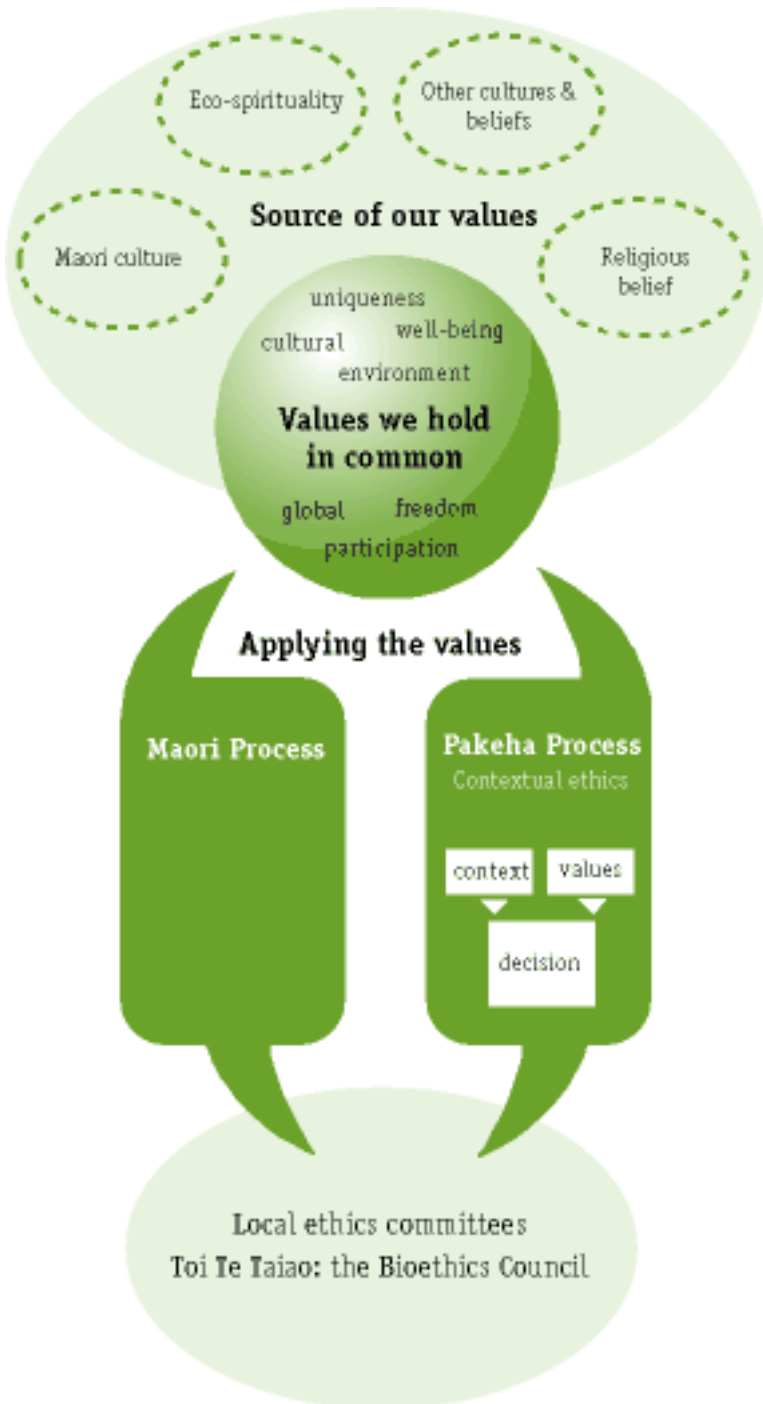
8. Throughout the Commission’s inquiry, we heard that the choices New Zealanders make about the uses of genetic modification are linked to spiritual, ethical and cultural values. These values often arise out of what several submissions referred to as a world view:

[A] world view ... refers to the comprehensive conception or apprehension of the world.²

Matauranga Maori brought (and still brings) with it an intellectual curiosity and willingness to explore all issues; it begins by asking, “Why do we need to know?”³

What people do ... to their world depends on what they think about themselves in relation to the things around them; all of us hold world views that affect our behaviour individually and collectively.⁴

9. A number of these world views, as they related to cultural, ethical and spiritual issues, were made quite specific by the submitters, and these we discuss below. Others did not discuss their world views or cultural assumptions with us explicitly, but the importance to them of particular values and ethical commitments was nevertheless apparent.



10. In non-Maori submissions, we have identified two main strands of “world views”. In addition, Maori submissions often contained an outline of te taiao or referred to key elements underpinning a Maori world view, drawing on traditional concepts.

11. We are conscious in what follows that our descriptions are only brief summaries, that they simplify what are rich and complex ways of looking at the world, and that any individual or community may well draw on more than one of these world views. It is important to make these world views visible in the debate as they have an important place in shaping the choices made about ethical issues raised by genetic modification.

Te ao Maori: the traditional Maori world view

12. Values that are Maori bring a unique dimension to our assessment of the place genetic modification has in Aotearoa/New Zealand. Maori are indigenous only to this country, and their culture is shared with all New Zealanders. Symbols like the koru fly on our national airline and young Kiwis perform haka in London pubs to distinguish themselves from other cultures and ethnicities. This biculturalism is underpinned by the Treaty of Waitangi, signed in 1840 by representatives of the British Crown and representatives of iwi and hapu. “Two people, one nation” means both cultures, tangata whenua and tangata tiriti, need to understand each other’s values, and find commonality so they can effectively communicate. This can be difficult for Maori who feel bound to hold fast to the traditions of their ancestors. A taua (woman elder) at the Christchurch hui, Terehia Kipa (Te Arawa, Tuhoe), said:

Etahi wa, me tahuri ke te waka o tauwi ma, engari ko te kei o te waka o te Maori, me rere tonu kia totika. [Sometimes the canoe of other races makes changes in its direction, but the steering of the Maori canoe should be in accordance with our traditions, it should travel on its set course.]⁵

13. The Treaty partners must share this duty of communication equally. Maori are bicultural as they have to live in two worlds, whereas some Pakeha (non-Maori) choose to live only in a Pakeha world, but are increasingly finding that in Aotearoa/New Zealand they cannot. This can be challenging, especially for immigrants who find that they have not one, but two cultures to learn.

14. Spiritual values of Maori are often inaccessible to Pakeha unless they are intimately involved with Maori families at births, serious illnesses, marriages and deaths, in Maori homes and on marae. Even within Maoridom, this knowledge is not discussed casually or without appropriate reverence. The most sacred concepts are shared in the deep hours of night, on empty stomachs away from food, in

suitable settings, by worthy proponents suitably warded by karakia (prayers). Lack of knowledge of te reo Maori (Maori language) and tikanga (Maori protocol) form additional barriers to understanding concepts difficult to express in English. Some concepts such as tapu, which is particularly relevant to the discussion of genetic modification, are easy to express as they have been adopted into English to fill a void. Others like hara can have a wider pre-missionary meaning still in use, alongside its co-opted use by Christianity to translate “sin”. For Maori, the right to learn this knowledge is both inherited and earned, and knowledge can be conveyed at unexpected times. At our national hui at Ngaruawahia one submitter presenting for some tohunga rongoa (healers using traditional Maori medicines), talked of being told about traditional medicinal plants in the car while taking the Taua to the supermarket to do her weekly shopping.

15. Maori spiritual values we heard about frequently involved the concepts of whakapapa, mauri, tapu and noa (and whakanoa), hara and ke, mana, ihi and wehi, whanau, hapu and iwi. All are relevant not only to understanding the holistic or ecological approach Maori have to the environment, but also to explaining why Maori prioritise a duty of kaitiakitanga or “obligated stewardship”. To Maori this duty is easily explained by tracing whakapapa (genealogy) up through the ancestors, to the Gods, and ultimately to Papatuanuku, the Earth Mother, and Ranginui, the Sky Father. By going sideways in these kinship links, Maori trace descent lines for all living creatures and so have to honour them as kin. Many times being welcomed on to marae, or in the formal speech in Maori introducing Maori submitters, the Commission heard recitations of these whakapapa of indigenous flora and fauna. At Omaha Marae near Hastings, Poho-o-Rawiri Marae at Gisborne and at Turangawaewae Marae in the Waikato, we had sung to us a traditional Maori waiata (song), composed by Enoke Te Pakaru of Aitanga-a-Mahaki in the 17th century, telling of the coming of the kumara to Aotearoa/New Zealand and giving its whakapapa to display the value of kumara to Maori.

16. Maori believe they bear the spiritual costs associated with environmental degradation, irrespective of who initiates the transgression (hara). Sir John Turei (Tuhoē) at the Orakei hui in Auckland put it this way:

In times past this connectedness was an essential part of survival. A breach of tapu (hara), was an offence to the land, to the people (tangata), species of the sky (kirehe o te rangi) and of the land (me te whenua) and this offence led to misfortune (aitua) and sickness or death (mate). [These] were considered to be the consequence of any wrongdoing or hara ...⁶

17. Te Runanga o Ngai Tahu [IP41] spelled it out:

Should they fail to carry out their kaitiaki duties, not only will their mana be removed, but harm will come to members of the whanau or hapu.⁷

18. Fear of harm is a very strong drive to action to prevent further degradation of the environment. Aitua (misfortune and accident) and sickness and death (mate Maori) manifest especially in weaker and dependent family members of those entrusted with the responsibility for the manawhenua.

19. Manawhenua is the primacy over a particular area of land. It lies with a hapu or iwi. Present ownership of the land or even occupation is irrelevant: manawhenua was won by battle, marriage and wits.⁸ It is inherited by whakapapa (genealogy). Manawhenua can be strong or weak, extensive or very limited, or even disputed. But it is always there. There are appropriate protocols for Maori to deal with manawhenua. For instance, Maori outside their own tribal area and within the takiwa (rohe, tribal boundaries) of another iwi have clear roles and mutual obligations as taurerehe (rawaho, visitors and settlers). However, this tikanga framework does not encompass Pakeha, as has been brought into sharp focus by the recent debate over the insertion of a human gene sequence into cattle in the Waikato:

... it's actually up to each individual iwi and hapu to speak about their own mana. I mean I can't go to Tainui for example and say, no you can't agree to put human genes in a cow, that's abhorrent, but at the end of the day that's their business and that's their choice ... and there is no one Maori view; each hapu and iwi have their own view and that's their business.⁹

The ecological world view

No longer can biotechnology rely on a public acceptance of the Enlightenment model of progress driven by a scientific conquering of the power of nature. Increasingly this is replaced by the notion of being part of nature and needing to work in harmony and balance with it.¹⁰

20. Several Interested Persons were explicit in their presentation of the ecological world view, and it could be recognised in others. Friends of the Earth (New Zealand) [IP78], Koanga Gardens Trust [IP72] and the Green Party of Aotearoa/New Zealand [IP83] all provided expositions of this view.

21. An ecological world view is based on an assumption of the interconnectedness of all life, including humans. All of people's lives, economy and mental well-being are ultimately dependent on maintaining the health of the natural world.

22. This position is not a rejection of science, but an approach to science from a different standpoint. As Friends of the Earth believes:

The scientific philosophy of the ecological world view embraces general systems theory which takes the whole as its primary datum. It views the world from an eco-centric standpoint. It does not see humanity as separate from the environment.¹¹

23. An ecological science recognises that introducing a change into the biological system is likely to create effects on the whole system, many of which we will be not be able to predict given the complexity of the system with which we are interacting. This approach highlights that “we do not know what we do not know”, and that “genetic engineering has been easily accomplished but the hazards involved are difficult to predict”.¹² Knowledge is sought to nurture our understanding of ecology and how the whole system works, but to do so in a way that builds respect – “respect for all living things, respect for the boundaries and limits of nature within which we are content to live, and respect for the connections and the processes that allow life to continue”.¹³

24. Friends of the Earth contrasted this approach to science with an approach it sees as more dominant:

Current scientific materialism on the other hand conceives humans as separate from the environment and the world as a collection of objects or categories. Its standpoint is anthropocentric.¹⁴

25. This approach to science is seen as advancing knowledge by breaking systems into smaller and smaller pieces – in biology the smaller part has moved from cell to nucleus, to chromosome, to gene, to the individual base pairs that make up the gene. Such science does reveal important information about the components of systems, but it does not, it is argued, have the capacity to look at the big picture, to factor in the effects of one change upon the system as a whole. And it tends to assume a view of nature as raw material for humans to use to redesign the universe for the benefit of humans. Life can be engineered.

26. This approach to the technology is also being questioned by some scientists who have pointed out that:

The technology is driven by an outmoded, genetic determinism ... The new genetics is compelling us to an ecological, holistic perspective, especially where genes are concerned. The genes are not constant and unchanging, but fluid and dynamic, responding to the physiology of the organism and the external environment, and require a stable, balanced ecology to maintain stability.¹⁵

27. The reductive approach to understanding the world is explicitly connected to a world view that sees humans as in some way outside nature. As Koanga Gardens Trust put it:

... we have developed a belief (cultural myth) that we are independent of, and the master of, nature. That we can “do what we like” and that we can “fix” any negative consequences. This belief is very strong, and it is easy to see how we lend it this support when we contemplate the extraordinary “power” of our technologies.¹⁶

28. The ecological approach is developing alternative ways of thinking about ethics. Ecological thinking seeks ways to extend the moral boundaries to give a new or different moral value to animals and to the environment. In addition, an ecological approach presents ethical issues as being not only about the safety, risks and benefits of genetic technology itself, but also about the wider ramifications of the development of genetic modification technology for the social, political and biological systems of which it is a part.

Religious world views from the Judaeo-Christian tradition

29. A number of Interested Persons presented evidence from an explicitly religious perspective. This included the Jewish community and a number of Christian groups.

30. Each of these, in various ways, drew attention to the relationship between humans and creation, and the implications of living in a world that is fundamentally God’s. “Life is a gift given in trust”;¹⁷ “Coherence of the biosphere is complicated and precious”;¹⁸ “Creation is our being not our enemy”.¹⁹ The orientation of these submissions was towards understanding the place of humans in the biosphere, and the responsibilities that flow from an understanding of that relationship as one of “stewardship”, of responsibility to future generations, of discovery and awe rather than exploitation and ownership.

31. Richard Davis, appearing for the Public Questions Committee (Methodist, Presbyterian, Churches of Christ, Quaker) [IP93], said:

Our religious tradition teaches us that we are much more than mere chemicals. A key message of the Biblical creation story is that without the spirit we are mere dust: “The Lord God formed man from the dust of the ground, and breathed into his nostrils the breath of life; and the man became a living being.” (Genesis 2:7). Humans, cannot then, in the Christian view, be reduced to their genes, in a genetic reductionism. Humans are not merely the interaction of their genes with the material environment. Christians assert that there is a God who is the giver and sustainer of life.²⁰

32. These relationships were described in various terms. The Interchurch Commission on Genetic Engineering [IP49] spoke of a duty to care for the

environment and a call to community with all who share creation. The Quaker Spiritual Ecology Group, Religious Society of Friends [IP50] noted the interdependence and inter-connectedness of all life forms. The New Zealand Jewish Community [IP80] wrote of a “theological or ‘natural law’ objection” to genetic modification implicit in biblical commandments, the purpose of which is to “preserve the essential nature of God’s creation”.²¹

33. In the formal hearings, the Commission discussed with various witnesses the mixed legacy of interpretation of the Genesis creation story. As Stephanie McIntyre, a witness appearing for the Anglican Church in Aotearoa New Zealand and Polynesia [IP42], said at the hearings:

I think it’s important to acknowledge the mixed legacy of the Judaeo-Christian religions with a predominantly human-faced morality. The church has in the past encouraged the tendency to set humanity over against nature in what at times has been a manipulative polluting way of life based on world views that were largely anthropocentric, that gave nature only secondary importance. Unfortunately at times Christian theology has played a key role in ecological and cultural malformation by giving impetus to modern rational scientific conquests of nature.²²

34. Under cross-examination, submitters continued to affirm an interpretation of the Judaeo-Christian tradition as one of care rather than dominion. For instance, witnesses appearing for the New Zealand Catholic Bishops’ Conference [IP38] talked of the world as a place given for human beings for their life and their ends, but this approach still comes back to responsibility to care for or practise stewardship of the environment. As Anne Dickinson, a witness for the Bishops’ Conference, said:

... human beings are the only form of life capable of stewardship and that in itself makes us different, that we are the only life form that can actually act in a stewardship role to the rest of the planet.²³

35. The question of the extent to which humans should manipulate the world was raised in various ways, and tied to a concern or search for wisdom. The Catholic Bishops’ Conference did “not see the technology of genetic modification in itself to be in conflict with ethical values. However ... there may be uses of genetic modification that are unethical or unwise.”²⁴ It argued for an acceptance of ourselves as people with freedom and moral responsibility, but also, in relation to its discussion of germ line gene therapy, that “we as a people do not yet have the wisdom to handle the far-reaching consequences of its use”.²⁵ The Anglican Church spoke of a concern “about the arrogance of people towards the intricate and subtle relationships which sustain life on the planet”.²⁶ It called for a humility before the creator and creation, for learning from the least dominant and the least

powerful, who gained their wisdom from “managing the balance of their lives and their environment”²⁷

36. Many of the religious groups’ submissions were oriented towards responsibility to the vulnerable, a need to care for the disadvantaged, to take them into account, a concern that commercial considerations not outweigh ethical ones. Many submissions affirmed the importance of recognising the values of the Maori world view.

Other cultures and beliefs

37. New Zealand today encompasses an increasingly rich diversity of peoples, cultures and beliefs. Many will see their particular value-set arising from one of the three traditions set out above. Others will draw their values from different sources, some religious, some philosophical. Some may have distilled a set of working values based on their experiences and reflections of life. Some may be guided by universal codes such as the United Nations Declaration of Human Rights. Recognising this diversity of sources, the Commission sought to discern common ground between them.

Is there a common core of values?

38. In a pluralistic society people draw their values from different sources. It is not appropriate for one group to seek to impose their values on others. But in the midst of such diversity, can a common core of values be found as a basis for ethical decision-making? The Commission debated that question and decided that such a common core of values exists.

39. For example, the Warrant establishing this Commission implies certain values to which the nation holds. The Warrant directed us to take into account such matters as the health of ecosystems, human health, consumer choice, cultural and ethical concerns, and economic factors such as research, primary production and exports. We were directed to consider the Crown’s responsibilities under the Treaty of Waitangi, and to consult widely with Maori and the public in a way that allowed them to express their views on such matters.

40. Sections 5, 6 and 8 of the Hazardous Substances and New Organisms Act 1996 (HSNO) also imply certain values when they refer to the economic, social and cultural well-being of both present and future generations, the intrinsic value of ecosystems and the safeguarding thereof, the sustainability of native and valued introduced flora and fauna, the relationship of Maori with taonga, and the Treaty of Waitangi. Later the Act provides for public notification and consultation with regard to some applications.

41. A value-set shared by most New Zealanders was also apparent from the extensive consultations the Commission engaged in. While there were widespread differences of view on how to give effect to shared values, nonetheless there were values we identified as common to submissions.

42. No one doubted, for example, the need to preserve the life-giving capacity of our environment for generations still to come. The Treaty of Waitangi was recognised by many as playing a key role in decision-making, even though there was much discussion about the weight it should be given. The future well-being of all New Zealanders, to be achieved through robust health, educational and economic strategies, was never questioned.

43. Convergences between different value sources were also apparent. Maori, for example, drawing on their spiritual and cultural heritage, have a strong sense of the sacredness and interconnectedness of the earth and all life forms. Judaeo-Christian groups draw on the biblical tradition to reach the same conclusion. Those who come from the ecological world view have a similar holistic understanding of ecosystems based on their perception of the intrinsic value of all life.

44. All of the above considerations led us to the view that, not only was there a common core of values that New Zealanders shared, but also that it was important to name those values as a foundation for ethical decision-making. In chapter 2 we listed those values as:

- the uniqueness of Aotearoa/New Zealand
- the uniqueness of our cultural heritage
- sustainability
- being part of a global family
- the well-being of all
- freedom of choice
- participation.

45. Relating such values to specific decisions, however, requires careful consideration. A recent judgment of the High Court,²⁸ for example, showed just how fine and subtle a process it is to weigh the impact on the spiritual well-being of Maori of the insertion of a human gene into a cow.

46. An effective process needs to be found to ensure that key cultural and ethical considerations are not excluded, or that economic and social consequences do not weigh unduly on those least able to carry them. It is to establish such a framework that we now turn.

Ethical decision-making processes

47. We have seen how people draw their values from different sources, and yet also hold values in common. Identifying such values is only the first step to decision-making as New Zealand deals with the cultural, ethical and spiritual challenges raised by genetic modification. Values need to be set in a framework that allows decisions to be made. Scientific research is conducted subject to ethical considerations. Dr Ingrid Winship (Associate Professor in Clinical Genetics, University of Auckland) told the Commission:

I would say that research and any of what we do in our faculty is not done in a vacuum. We do have strict ethical standards, and there is a process through which all researchers must go in order to adhere to [those] ethical standards.²⁹

Specifically, genetic modification research is already guided at a local level by the decisions of animal and medical ethics committees.

48. In the next two subsections we discuss the process of decision-making, considering both Pakeha and Maori approaches. We use the issue of transgenic animals as a case study to illustrate the process. In the last subsection we discuss institutional structures that we would recommend for making decisions at local and national level.

Pakeha approaches

49. The need for a more focused approach to decision-making was noted by many witnesses, especially with regard to complex cultural and spiritual issues, or ones of overarching significance. For instance, ERMA commented that:

There exists no clear mandate from the New Zealand community concerning the ethics of genetic engineering ... [there is a] lack of any ethical framework which has been developed following wide and informed public debate.³⁰

50. The Catholic Bishops' Conference stated that:

The challenge for all of us lies in developing theological, ethical, social and philosophical perspectives which will enable us to make wise decisions for ourselves, for future generations and for the earth. Our search for wisdom must now be as resolute and innovative as the work of the scientists has been in developing the technology of genetic modification.³¹

We strongly believe that a framework of ethical principles is needed ..., and that regulation should be based on these principles. Cultural concerns may be best dealt with at this principled level rather than being handled on a case-by-case basis.³²

51. But how to develop an ethical framework? Dr Maurice Ormsby, in his witness brief prepared for the New Zealand Wool Board [IP30], said:

... most ethical frameworks can be divided into those that are consequentialist, or those that are deontological. ... Deontological theories hold that actions are right or wrong in themselves ... for example a deontological approach to our reverence for life would argue this is a fundamental value, and one we must not betray regardless of the consequences.³³

52. Consequentialist theories (of which utilitarianism is an example) argue that an action is judged morally right or wrong by virtue of its consequences.

53. Dr Ormsby argued for a utilitarian approach which gives due weight to the interests of all people equally. He argued that this is the appropriate approach to use in public policy, as:

... it does not make any assumptions about what your particular interests or values may be. It merely recommends the policy within which every person's values and interests can be advanced to the maximum.³⁴

54. Utilitarian arguments have been extended to include concern for those organisms capable of experiencing pain and suffering. SAFE (Save Animals from Exploitation) [IP85] told the Commission that most modern ethical theories, including utilitarianism, “refer to a direct or indirect duty of human beings to avoid (unnecessary) harm to animals”.³⁵

55. Some problems with utilitarian approaches were raised with the Commission. For instance, the Green Party questioned whether we can ever have sufficient information to make all the calculations of well-being and utility required by an utilitarian approach. It pointed out the limitations of any utilitarian approach that takes the human individual as the prime measure of value and pays insufficient attention to the natural order of which humans are a part.

56. A utilitarian framework also does not appear to capture a cluster of other issues raised with us. People spoke of the “intrinsic worth” of organisms and of the biosphere. They did not think we should be “playing God”. Gary Comstock, Professor of Philosophy and Religious Studies at Iowa State University, USA, in his witness brief prepared for the New Zealand Life Sciences Network [IP24], discussed the inadequacies of these “intrinsic” concerns when they are applied to objections to genetic modification, and argued that such objections could not be sustained. However, we are aware that they capture something of importance to many people about the extent of human responsibility, and to what extent it is appropriate to use the power that technology gives us.

57. The Catholic Bishops' Conference spoke of human beings as “essentially relational by nature, with our most fundamental relationships being with God, self, others, the earth and all its life forms”.³⁶ It emphasised that decision-making must take into account the needs of the poorest and most vulnerable, an approach that frames the issue as being, at least in part, about social justice and the distribution of benefits.

58. The need to make decisions in a relational or holistic way was also emphasised by some environmental groups. For instance, Friends of the Earth recommended “the institution of sound ecological principles as a basis for resource management and related national and international policy”.³⁷

59. Reflecting on the various contributions presented to us we identified four key elements in the ethical decision-making process:

- a clear statement of the values to be used as criteria (our common core)
- full information on the specific data relating to the case to be decided
- a holistic approach that looks at both the data and the values in a connected manner
- appropriate participation by stakeholders (all with an interest) in the decision-making process.

60. Participants in the process will bring a diversity of views. Different interpretations of the values may be made, and different assessments of the significance of the data as well as of proposed solutions. Some values will be of higher significance than others. For example, the preservation of human life or the ecosystem will take precedence over freedom of choice if a particular decision puts human life and the ecosystem at risk. Weighing the claims of one stakeholder group against those of another also requires fine judgment. Building a consensus that takes account of all the key elements is required in order to avoid flawed decisions.

A Maori approach

61. Maori decision-making is grounded in the different cultural values laid out in the previous discussion of *te ao Maori*. No distinction is made between the process and the outcome. A bad way of going about decision-making cannot lead to a good outcome, one that is acceptable to Maori. In fact, the process shapes the decision.

62. Traditionally Maori decision-making is characterised by the following:

- Consensus is preferred, even if it takes extra time. However, once decisions are made, they are actioned quickly and decisively.
- Emotion is expected, vented and tolerated, especially when *mana* is challenged. Reconciliation then is a part of the way forward to the consensus decision.

- When reconciliation and consensus do not emerge easily, Maori say, “Waiho ma te wa” (give the problem time and space to find the best solution), and will leave the take (subject of discussion) on the floor. This can be strategic withdrawal to better marshal forces for further debate, rather than a withdrawal of the issue. The following meetings indicate whether the take lives or not, not the action at that time.
- Importance accorded by individual speakers to the subject matter is displayed by shortness in speeches, which use formal, allusive, poetic and archaic language. Wit, brevity and passion are appreciated as an honour to Tane, the god of whaikorero (speech-making). The introduction and the waiata at the end can say as much as the body of the speech, and are also used to show the degree of support a speaker has.
- Silence is important. What is not said and who does not speak are equally noted.

63. Whakapapa gives both an order for speakers (and consequent patient acceptance of long silences while speakers prepare to stand), and the means by which listeners weigh contributions. It can also cut out speakers in a way confusing to listeners who do not understand, or adhere to, the intricacies of tikanga. For instance, at Gisborne we heard a prepared submission presented by the brother-in-law (who was within his mother’s rohe) for a kuia. She, as rawaho, was constrained by the presence of the Commission’s own translator. He, as the son of her eldest brother and raised by her father, is the pukenga (repository of knowledge) for the family. That we heard the submission at all was a tribute to her deep knowledge of tikanga and ability to find a way through it. Not all Maori are as skilled. Since breaches of protocol can be hara, whether deliberate or inadvertent, and cause misfortune or death (aitua) or injury or sickness (mate Maori), it can be seen that silence does not necessarily mean assent. It may or may not.

64. This Maori framework does not always fit comfortably when English is used, whether by Maori or Pakeha, as confusion arises over which has “right-of-way”. In a Maori setting, speakers will turn to te reo Maori and tikanga Maori in any conflict. Lack of consensus and argument will always trigger speeches in Maori, which can cut non-Maori speakers out of the discussion. Serious issues, as defined either by outcomes or by association with tapu concepts like the subject of genetic modification, tend to do this too. It is not because Maori are not familiar with Pakeha meeting protocols. For instance, every marae in Aotearoa/New Zealand is run by a committee called the komiti marae. This has a chair, treasurer, secretary and elected or co-opted committee members. Komiti marae meet regularly on set dates, run by agenda, usually take immaculate minutes and are over in the prescribed few hours. They differ from Pakeha counterparts in that non-members

sit in and are involved. Consensus means votes are rarely taken. If important contentious issues are raised, kaumatua will often move into formal tikanga, which is respected and the points made are given added weight.

65. When organising meetings with Maori these things need to be taken into account if a good process and outcome is to be achieved, whether within Maoridom or as a part of the consultation process between tangata whenua and tangata tiriti. Whether the setting is a Maori one such as a marae, or a Pakeha one such as a hired hall, also shapes the outcome. Ahi ka, sometimes expressed as “keeping the home fires”, means that mana is enhanced by residing close to the traditional home marae which may be remote and rural. Hence kaumatua and tohunga (traditional experts) are rarely found far from such settings. Less prestigious representatives are sent to meetings further afield. These Maori are often the ones known in the Pakeha world, but they have less authority and need to check back with their senior advisors frequently to remain authentic. If they do, they remain accountable to their own hapu and iwi. If they do not, they risk being misleading.

66. Thus consultation involves accountability back to the iwi and hapu. In a following chapter concerning the Treaty of Waitangi, there is a model for consultation as developed by a large commercial company with which we were impressed. It is shown in detail to give one successful way of doing it. There are others.

67. The difference in the ways Maori and Pakeha arrive at decisions means that there needs to be careful consultation if common ground is to be found. The values and world views do not need to be shared, but need to be understood and respected if a mutual way forward is to be agreed. Time and time again the Commission heard complaints from Maori that, in the field of genetic modification, Maori were not adequately consulted by scientists and decision-makers. Bevan Tipene Matua (Ngai Tahu, Kahungunu), a lecturer in “Maori and Science” at the University of Canterbury, said at the Christchurch hui:

They [the scientists] are unable and don't want to create or enter into the Maori world or create relationships to ensure that our rights are protected but also the taonga themselves are protected.³⁸

68. Moana Jackson (Kahungunu), presenting for Ngati Kahungunu Iwi Authority at Omaha Marae, Hastings, quoted one of Maoridom's most distinguished kaumatua:

The late Hohua Tutangaeha once said having to be reactive all the time is one of the hardest things for our people. It often limits how well we can address an issue because we are always rushing to meet someone else's time frame or someone else's ideas about what

is important. Every time we are asked to give a perspective we are already responding to something that has been decided or the main ideas are already set in concrete ... as a result our people have often been asked questions impossible to answer in time frames impossible to keep.³⁹

69. Vivienne Taueki in presenting a submission from the Muaupoko Co-Operative Society [IP57] said:

... and you have to go through a public process where you have to bring a lot of very sacred information to an environment that is not correct or appropriate for that information ...⁴⁰

70. The Reverend Edward Ellison (Ngai Tahu) at the hui at Otakou kaik, near Dunedin, told us that:

Even with contained experimentation we believe there are questions and issues to be answered in the way those applications are processed so that we with manawhenua are part of that process, we're not excluded ...⁴¹

A shared way ahead

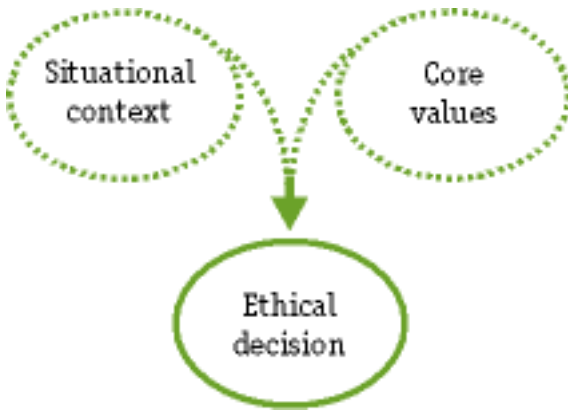
Te taha wairua, kaua tatou hei mahi tatau anake. Engari whakapirihiā tetahi ki tetahi kia pai ai te haere i nga ra e tu mai nei i mua i o tatau aroaro. [The spiritual element is that we should not work for ourselves but instead we should work together so that the future is secure.] Sir John Turei (Tuhoe)⁴²

71. The different responses to the cultural and ethical challenges raised by genetic modification have contributed to our thinking. The challenge remains – how to take the common values that permeate the conversations and translate them into actual decision-making when there still remains a diversity of views about what should be done, or not done.

72. Our view is that ethical decisions arise at the conjunction of values with the specifics of the situation.

73. There is a need for careful analysis of such factors as environmental impact, economic impact and human health. A strong and detailed grasp of the evidence and likely outcomes from the various uses of genetic technology is essential. Alongside that it is also essential to make visible the values that are being used to balance and weigh the significance of those facts.

74. Prioritising values will require careful consideration in the light of particular circumstances. Also, those from different world views may have quite different interpretations of the significance of, for example, the release of genetic modification techniques to control possums, and how to balance different values.



75. There is also a balance to be struck between the rights and aspirations of different groups in the community. Genetic modification will produce situations where some feel their rights restricted by the need to meet standards to protect human health, address cultural and environmental considerations, and allow for diversity in farming. For example, the research and development of new products and processes will need to conform to established regulatory frameworks. Applications of genetic modification for human health that do not meet required standards may not be permitted in New Zealand. Diversity in farming methods necessitates good negotiation skills among neighbours to ensure that one type of crop does not become a threat to another. As with other areas in society, the freedoms of all groups should be protected to the extent that they do not impinge upon the freedoms of others.

76. There is little difficulty in agreeing to the restriction of choice when safety is at significant risk. However, there will be times when we may choose to restrict choice because of a societal decision that there are some uses of a technology that are unacceptable for cultural, spiritual or ethical reasons. For instance, a society may choose to ban the use of cloning for human reproduction, even were it to be “safe” and an individual wished to use the technology.

77. Given the value we place on choice, it is essential that any decisions made to restrict those choices are based on full information carefully considered. The discussion should involve all interested parties, and be made by institutions that have the authority and trust of society.

78. Many factors need to be weighed, but a mutually agreed process will assist. Both framework and implementation become clear in the case study on transgenic animals that follows.

A case study: transgenic animals

79. Transgenics is the movement of genes across species boundaries, for instance the insertion of human genes into a mouse. A range of concerns about transgenics were raised with the Commission. It became clear that there were a number of distinctions that had ethical significance to people. People framed the issues in a number of ways, which attached cultural or moral significance to different groups of organisms.

80. Transgenic organisms are used in various ways; for example, as a tool to understand how genes function, to develop organisms that can produce pharmaceuticals or to develop organisms with advantageous characteristics.

81. Some submitters did not directly identify or discuss any ethical or cultural issues associated with the production of transgenic organisms. Their discussion was confined to the scientific and economic implications of the use of transgenic organisms such as their use in research in containment, the potential for transgenic animals to produce proteins in their milk and the subsequent economic benefits, or the impact of consumer preferences on business opportunities to use transgenic organisms in the food chain.

82. Others named some distinctions, or categories of thought, that they saw as ethically or culturally significant.

83. For instance, SAFE is concerned with animal welfare, and considered the production of transgenic animals raised several issues. Firstly, there is a concern that the potential to produce these animals leads to incentives to increase the number of animals used in research – against recent trends to reduce the numbers used. Secondly, there is a concern for the inherent worth (rooted in the integrity of the genome) and dignity of animals (which equals respect for the entire being) which is violated by genetic modification. Animals, SAFE argues, have a recognised status, based on sentience, that is higher than for non-sentient beings. But that respect for integrity means “even if animals can be treated in a way that does not cause severe pain, and does not damage their health or welfare ... the treatment may still be morally objectionable”.⁴³ The time when an exception may be acceptable would be when “the alteration was beneficial to the animal itself, rather than of benefit to the use, or user, of the animal”. SAFE acknowledged the difficulties raised by the concept of species integrity, but argued the term “integrity” has been introduced to fill a gap between moral theory and moral experience. Technological developments are producing moral dilemmas that are not well dealt with using traditional concepts, and we need to “refine our moral thinking”.

84. The New Zealand Transgenic Animal Users [IP45] approached the issues in quite a different way. It argued:

GM animal research creates additional issues, because of the various perceptions of genetic modification as unnatural, or “playing at being God”. In any consideration of ethics and cultural sensitivities to do with GM animals, we must also weigh up the enormous benefit to medicine and therefore to a large number of individuals that this research brings. It is our view that the benefits of GM animal research offer such promise to so many people by improving knowledge and alleviating human ills, that decisions to not pursue GM animal research must be justified not only in terms of animal welfare, but in terms of the potential human costs that may result through lack of knowledge and inability to develop new therapies.⁴⁴

85. It would seem that for this group any “intrinsic” concerns, such as unnaturalness, were more than outweighed by the potential for considerable benefit to flow from the use of transgenic animals. It focused on the benefits to medicine, but its position could be extended into economic benefits, as has been done by some submitters, such as the New Zealand Dairy Board [IP67], which discussed and encouraged such benefits without explicitly engaging with the ethical issues of transgenics as such.

86. Modifying animals by inserting material from human chromosomes was strongly opposed by both Maori and Pakeha submitters. However, the reasons given are different, and the lines drawn are different. It was Pakeha submitters at public meetings who raised the tapu against bestiality as an argument against transgenics, as did a few anonymous public submissions.

87. Maori and Pakeha both raised the tapu against cannibalism. This was often made explicit. Tuhoe kuia, Mere McGarvey, said:

What happens in terms of crossing a human gene with a tomato? And we as people inadvertently eat the tomato. Is that comparable to cannibalism?⁴⁵

88. As this tapu was substantially modified by the early missionaries, the same submitters often went on to question whether humans had a right to interfere with God’s creation in this way, citing the Maori belief that such arrogance precedes retribution, aitua and mate Maori.

89. Maori in pre-Treaty of Waitangi days did practise cannibalism: it was a way of deliberately diminishing mana and rendering the sacred profane. Not only was the question raised about whose genetic contribution might even be accidentally eaten because of inadequate labelling of the mutton or beef, but there was deep anxiety that genetic material derived from Maori could be used this way in the future. This would then raise individual mana and manawhenua issues as well as

those of hara. These issues caused major battles in the past and no one wished to re-open them in this way.

90. Maori differed from Pakeha submitters in the use of the concept of mauri to explain why transgenics involving living creatures was wrong. Mauri is the life energy or the soul and is shared by all living things. Even inanimate objects like cliffs, stones and especially water have their own mauri. Many submitters took the view that mixing this mauri by creating transgenic animals was wrong. For instance, Angeline Ngahina Greensill (Tainui), a witness for Nga Wahine Tiaki o te Ao [IP64], said:

Everything possesses a mauri or life force and is to be respected. Because everything is inter-related and interconnected, any mutilation, modification or unnatural desecration of any part affects the whole.⁴⁶

91. Atihaunui-a-Paparangi kuia, 90-year-old Te Manawanui Pauro, at the regional hui at Wanganui said:

Ko tenei ahua, e koutou e nga matauranga, kaore e tika ki te hono i toku toto o te tangata ki te kararehe. He kararehe ano te kararehe, he tangata ano te tangata. [It is not right, learned folks, that my blood, the blood of a human, be mixed with the blood of an animal. An animal is an animal, a human is a human.]⁴⁷

92. Tamati Cairns and Paora Ammunsen, when giving evidence for the Life Sciences Network, took the view that this mixing occurs all the time anyway.

The water piped through a family home has a mauri that mixes with the mauri of the drainpipes and eventually the mauri of the water glass.⁴⁸

But added:

However, it is fair to say that the mixing of human genetic material with the living tissue of other creatures or other living humans provides a sharper focus on the mixing of tapu of man with the tapu of other men or species than has customarily been contemplated by Maori tohunga.⁴⁹

93. They explained the role of karakia (prayer, ritual) to enable the mix and avoid hara, and they quoted a Tuhoe tohunga they had consulted:

Kaore he tapu rawa e kore rawa e taea te wananga. Heoi ano he utu to te tapu, ko te mahi o te tohunga, he rapu huarahi e taea te whakamarama ake i te utu mo te iwi. [There is no tapu beyond all tapu that cannot be analysed. However all tapu require some compensation. The role of the tohunga is to minimise the price paid in managing the effects of the tapu on people.]⁵⁰

94. To Maori, the mauri of a species can be damaged if extra or different foreign genetic material is added, or if existing DNA is deleted or “knocked out”.

If it is just mapped or analysed for diagnostic reasons, then there is no problem. George Ria (Rongowhakaata) said at Gisborne:

You referred to the technology identifying species ... no problem about that ... it is not changing the spirit of that particular ika, ngarara [fish, insect] whatever, it is not changing the mauri.⁵¹

95. Two kaumatua at the planning hui at Tunohopu Marae, Ohinemutu, in Rotorua, compared traditional stories about the mixing of species in the formal welcome on to the marae. They noted tribal traditions of demigods who could change at will into birds and monsters or who existed in a chimera form. Both noted that while the notion was not unfamiliar, it belonged in the realm of the gods and smacked of immense arrogance. Haare Williams (Tuhoe, Aitanga-a-Mahaki), Vice President of Unitech, Auckland, at the Rotorua hui at Tamatekapua Marae, told in detail the story of Maui-Tikitiki-nui-a-Taranga challenging Hine-Nui-te-Po, the powerful Goddess of Death seeking immortal life. Maui died.

96. Many times this story was quoted to us. Most saw it as an injunction against tampering with powerful forces involved in life as in the genetic modification of animals. A few took the opposite moral. They noted that prior to this Maui had successfully challenged the God Ra and slowed the sun, fished up the North Island and been rewarded for his audacity. Mr Cairns and Mr Ammunsen suggested that the moral of the story was about better planning!

97. At the beginning of the Commission's work the concept of iratangata was raised by Bevan Tipene Matua and in a paper by Nici Gibbs.⁵² This is a profound concept for Maori, and refers to the essence of humanity. While some Maori have chosen to use the term to refer to DNA, it is far deeper than that and not discussed easily, especially outside marae or by younger people. To the Commission it seemed that there was sometimes confusion of this concept with mauri, and the deeper level of discussion was not evident. Similarly, Mr Tipene Matua, and Mr Ammunsen and Mr Cairns, talked of inadequate debate within Maoridom. The latter noted this reluctance to discuss such issues also applied to other areas of biotechnology such as acceptance of human-to-human organ transplants by Maori, which is currently far lower than Pakeha.

98. It was only Maori who felt that the tapu against incest is transgressed by transgenics. Many referred to old whakapapa showing the interconnectedness of various species in this situation to show transgenics was to them morally wrong. At the national hui at Ngauwawhia, humour was used in a very Maori way to reinforce this point by a spokesperson for Whanganui Iwi Organics group:

Ma nga kaumatua e ako i tou whakapapa. Engari he aha te tika he aha te pono o tenei mea, ka moe a Hohepa i a Merania te kau. Moo! Ka puta ki waho ko doughboy, ko Tote, ko

Lambchop, i a Puha ka puta ki waho ko Boilup. [Your elders should teach you about your genealogy, who your relations are. But listen to this scenario. Hohepa took Merania the cow as a wife. Moo! They begat Doughboy, Salt, and Lambchop. Now. Lambchop married Puha [sow thistle] and they begat Boilup.]⁹³

99. The incest tapu was also raised by those worried Maori genetic material could be used to modify animals or plants in the future. This tapu and the injunction against cannibalism meant Maori made a clear distinction between using human DNA sequences compared with using chemically similar or even identical sequences derived from other mammals.

100. Some creatures are valued by Maori above others. These change from iwi to iwi, hapu to hapu, and sometimes from whanau to whanau. These taonga species may be indigenous to rohe: occasionally they can even be exotic species whose spiritual significance to a whanau relates to an important historical event or tipuna taureherehe (ancestor who came from another tribe or from overseas). Such creatures portend good news (tohu) or bad (aitua) for Maori, and are treated with respect and value in environment management.

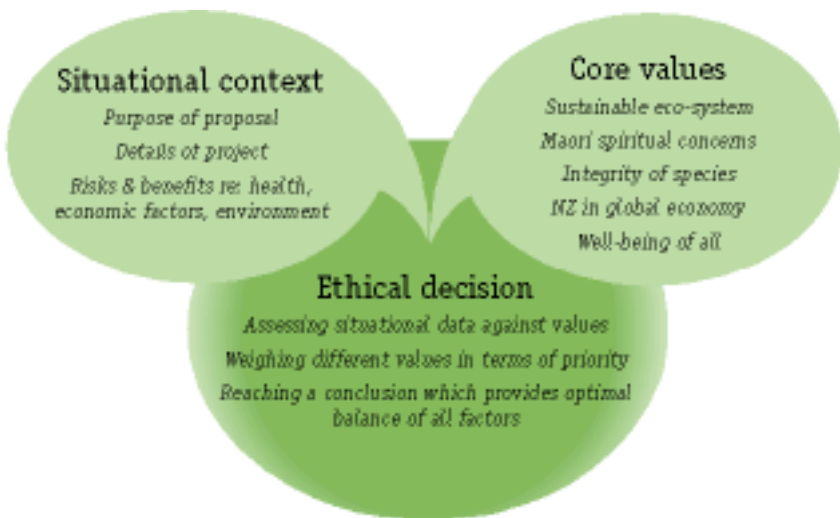
101. At the Napier public meeting which was in a hotel overlooking the Ahuriri marina, the kaumatua who opened the meeting told us of visits to the lagoon of a large dolphin, which sometimes manifested as a whale, which always preceded and sometimes predicted important events for the iwi. During the Commission's hearings a number of references were made to the gene sequencing done on the tuatara, initially without consulting the iwi involved. It was the Commission's kaumatua, Pihopa Kingi (Te Arawa), who observed that while there are eight iwi in the Marlborough Sounds, which is the main habitat of the tuatara, it had been only Ngati Koata who strenuously objected. For this iwi, the tuatara is taonga species and the iwi responsibilities of kaitiakitanga meant consultation in depth was needed prior to any such research being done.

102. The taonga species are not necessarily valued because of their similarity to humans, or their ability to feel or think. While SAFE noted that the Animal Welfare Act 1999 provided extra protection in our law for the great mammals like chimpanzees and gorillas, and marine animals such as whales and dolphins, Maori often value humble species like snails and lizards. Ngati Kuri as WAI 262 claimants, Ngati Wai, Ngati Kuri, Te Rarawa [IP89], are very protective of their puharakeke, a large indigenous snail that is associated with flax and confined to a small range in Northland. At our Dunedin hui at Otakou kaika a lone fantail came into the meeting and sat above the Commission on the rafters and sang very loudly. This was interpreted differently by Maori and Pakeha participants.

103. Thus, the evidence presented to the Commission identified a number of ethical and cultural distinctions and categories that any decision-making body would need to weigh up. We have distinctions between sentient and non-sentient organisms and the importance of that for animal welfare, concerns for the integrity and dignity of species, concepts of benefit (of various kinds). There are distinctions between indigenous and non-indigenous species, and taonga species and those that are not valued in such a way. And there are different concepts and cultural understandings about who or what is responsible for safeguarding or protecting species.

104. Any decision on these issues will require careful articulation of the issues, and a balancing of the various concerns. It will require both consideration of specific decisions (for example, the insertion of human genes into animals) and the development of generic positions that can provide clarity and consistency of guidelines for researchers and institutions.

105. We advanced this case study on transgenic animals to illustrate the ethical decision-making framework outlined earlier. We may draw the different strands from the discussion and frame them under the headings in this manner:



106. We noted previously from the High Court judgment in the *Bleakley* case that at one level a process of this kind is already followed by ERMA in implementing HSNO. The principles and matters laid down in sections 5, 6 and 8 of HSNO approximate to the core values named in this Report. In terms of situational context, both HSNO and its methodology specify the types of factors ERMA is required to take into account in giving effect to the principles and purpose of the Act.

107. The Commission is not, therefore, proposing a novel procedure. We see value, however, in making clear the basic elements in reaching ethical decisions. We emphasise that when key elements are excluded from the process flawed decision-making ensues, with consequential damage to people and the environment.

108. While ERMA is following the procedure at one level, it is also asking for a body operating at a higher level to address some of the more complex and overarching issues that now come before it. Other Interested Persons echoed this concern, and we address that matter in the concluding part of this chapter.

Institutional responses to cultural, ethical and spiritual issues

109. In addition to the call for decisions made within a framework of values, a number of submitters proposed that ethically based policy decisions should be made at a higher level than the level addressed by ERMA or current ethics committees.

110. Existing ethics committees cover research both with human subjects and with animals. They deal with many issues on a case-by-case basis. Their roles are clear, and we heard nothing that suggested fundamental changes are needed.

111. The need for an additional, higher-level body was frequently noted. For instance, ERMA pointed out its difficulties in responding to a range of concerns:

... The balancing up of spiritual beliefs and scientific endeavour has been problematic as this is not a matter solely for judicial weighing up. A broader approach is required to provide a context in which HSN0 can operate in dealing with these kinds of issues.⁵⁴

... no institution is entrusted with the big picture ethical issues.⁵⁵

112. The Parliamentary Commissioner for the Environment [IP70], answering a question put by Chris Webster for the Maori Congress [IP103], told us:

What seems to be very difficult here in New Zealand now is to create those arm's-length institutions which inevitably have to be funded with public funds, and do it in a way that instils total public confidence and enables them to be sufficiently funded.⁵⁶

113. We see a compelling need for a body to address the big picture issues where new forms of technology pose societal questions that go beyond individual choice. We therefore recommend in chapter 14 the establishment of Toi te Taiao : the Bioethics Council, whose task will be to consult with the community on significant ethical issues and develop guidelines to assist existing ethics committees.

114. We see the question regarding transgenic animals, for example, as one where the Bioethics Council would develop guidelines at a policy level. Case-by-case assessment by ERMA would still be required in order to consider the details specific to each application.

115. Other issues the Council might consider are when and under what conditions would germ line gene therapy be acceptable, or what uses of genetic testing should be available in New Zealand?

116. In establishing guidelines the Council would need to be familiar with the facts of specific situations, but in addition would consider the issues raised in a much broader framework. It would, for example, consult with Maori nationwide, while leaving ERMA to take into account the views of local Maori on a specific application. The Council would seek expert advice on environmental implications at a national level, or the strategic significance of such a development to the nation's economy. If the application were a medical one, it would consult on health implications for the population at large, and possible social consequences. The Council would regularly consult with ethicists, and at times with religious leaders on spiritual issues.

117. It is important that the Bioethics Council contributes through its decision-making processes to the building of trust between the biotechnology community and the wider society, and also to the development of a more coordinated approach to policy development and consultation.

118. In the absence of an effective framework for ethical decision-making, decisions about the use of biotechnology will be made by default. It is vital that the Bioethics Council promote continuing consultation and active choice, allowing developments in biotechnology to be based on the values we hold in common. Membership will need to include people with appropriate expertise, and represent the range of world views and cultural values. We discuss this further in chapter 14.

chapter |

4



Environmental
and health issues

4. Environmental and health issues

1. This chapter discusses some of the issues of environmental and health safety that were raised in the evidence before us. The Commission responds to these issues in more detail in subsequent chapters of the Report.
2. Those who thought the ongoing development of genetic modification was of benefit to New Zealand largely based their arguments on the economic benefits or disadvantages inherent in a decision either to permit or limit the use of the technology. Issues of the safety of the technology could not be ignored, however, and many of the proponents of genetic modification sought to provide information that would allay public concerns about the risk of releasing genetic modification, genetically modified organisms and products from laboratory confinement.

Key questions:

- What are the scientific hazards of gene technology?
- What are the possible impacts on the environment and human health of uses outside laboratory containment?
- Can gene technology be managed safely?

Concern about the risks

3. During the course of our consultation, many concerns were expressed about the risks of gene technology. Some people were so opposed to the technology for cultural, ethical and spiritual reasons they did not wish it to be used in any circumstances. The main issue discussed, however, was whether genetic modification could be used safely in the wider environment or whether such use should be confined to the laboratory, either for research or for some

health purposes. Many people said the risks of genetic modification could be contained within the laboratory where, within reason, its safe use could be assured. But they submitted the technology was inherently unsafe outside the laboratory and there was an unacceptably high level of risk associated with its use, even under field trial conditions.

4. The belief that risks were unacceptably high reflected submitters' underlying concerns that negative impacts of uncontained genetic modification

L-Tryptophan¹

L-Tryptophan is an amino acid, one of the building blocks of proteins. Tryptophan is important for brain function and is normally obtained from dietary protein. In the 1980s tryptophan became popular as a dietary supplement for such conditions as insomnia and depression. Tryptophan can be purified from plant and animal proteins, but is obtained more economically by vat fermentation. In this process, tryptophan-producing bacteria are fermented in tanks with sugars and a nitrogen source. When the tryptophan levels in the vat are high enough, the solution is purified by filtration. The bacteria used may be genetically modified. At the time, several companies, including Showa Denko KK, used vat fermenters and genetically modified bacteria to produce tryptophan.

Late in 1989, people consuming high doses of L-tryptophan began showing up with eosinophilia-myalgia syndrome (EMS), a new illness characterised by painful and swollen muscles, rashes, gastro-intestinal problems and large numbers of white blood cells in the body. In the United States 37 people died, 1500 were disabled and around 5000 were affected. These patients were all taking tryptophan from a single Showa Denko KK batch that used not only a new genetically modified organism producing a more concentrated product but also a different filtration system using less charcoal, which bypassed a membrane filtering step to purify the product.

The batch was found to contain 60 contaminants of which six were responsible for causing EMS. Three toxins (a dimer of tryptophan, along with two others) were identified by 1993, but it was not until 1999 that the remaining three toxins were identified accurately.

The United States courts decided that the manufacturing process rather than genetic modification was at fault. It is unclear whether the high concentration of tryptophan made by the genetically modified bacteria or the changes in the filtering system were responsible for the build up of contaminants. Attempts were made without success to reproduce possible faults in the filtration system. At the time, other tryptophan products made using genetically modified organisms were available on the market, but no problems were reported with them, suggesting that the use of genetically modified organisms alone was not to blame.

Although the first cases of EMS were not notified until late 1989, by early 1990 the Food and Drug Administration had recalled all dietary supplements containing manufactured L-tryptophan.

may be irreversible and rapidly get beyond control. These concerns are addressed throughout this Report: for example, discussion on the invasiveness of genetically modified organisms (paragraphs 51–57 of this chapter), xenotransplantation (paragraphs 61–72, chapter 9: Medicine), possum control (paragraphs 104–114, chapter 7: Crops and other field uses) and genetically modified forests (paragraphs 70–77, chapter 7).

5. For many who opposed the use of genetic modification outside the laboratory, especially in relation to food and food supplements, the events surrounding L-tryptophan (see page 43) illustrated the dangers of the technology.

6. The L-tryptophan disaster was used frequently by submitters to illustrate many of the aspects of genetic modification that caused public concern: the inherent unpredictability of gene technology; the potential for widespread and significant harm; the difficulty of implementing regulatory controls and standards; the lack of integrity by the companies that use gene technology; the need for dietary supplements to undergo the same vigorous testing as medicines; and problems associated with establishing liability for harm. Mere McGarvey (Tuhoe), speaking at the hui at Poho-o-Rawiri, Gisborne, said:

We want to say that we do not oppose genetic modification in general, but wish to remind everyone here and the Royal Commission that technology out of control is potentially intolerable and dangerous and could lead to calamitous consequences.²

7. Since no direct link was established between using genetic modification in the production of the dietary supplement and eosinophilia-myalgia syndrome (EMS), the incident cannot be taken as clear evidence of the inherent risks of genetic modification or the need to prohibit the use of genetic modification outside laboratory containment. There are, however, some useful lessons. For example, the short time it took the United States authorities to withdraw the product in question illustrates the need for such authorities to maintain the ability to respond rapidly to indications of harmful effects. The length of time it took to identify accurately all the toxins responsible for the harm, however, highlights the need for ongoing research into the hazards of the technology.

Scientific risks

8. Many submitters spoke at length about their concerns regarding the risks of genetically modified organisms escaping into the environment. They were concerned that such escapes could lead to the production of new pests and pathogens, to “super weeds” or to disturbance of the natural ecology. The risk of escape, however, depends on factors such as the nature of the organism and its use.

For example, there are different risks associated with a weakened bacterial strain used within a containment laboratory, a caged transgenic mouse, a transgenic sheep or cow in a secure enclosure and a genetically modified crop capable of producing fertile genetically modified pollen and seeds.

9. Humans have traditionally developed crops and animals with improved or desired characteristics by methods of systematic selection and breeding which ensure that strains displaying the desired characteristics are retained. Those that do not are discarded. This deliberate engineering of crops and animals has been seen as benefiting human society and has therefore been accepted. Occasionally natural mutations of genes or chromosomes have occurred that have been deemed desirable and these too have been retained.

10. More recently, radiation mutagenesis has been used to create new plant varieties. Radiation mutagenesis causes chromosome breaks and rearrangements, or deletions. We were told by Dr Johannes Wirz, a senior scientist at the research institute at the Goetheanum in Dornach, Switzerland, and a witness for Bio Dynamic Farming and Gardening Association in New Zealand [IP61], that the dose of radiation given is usually enough to cause between one to three breaks per chromosome. Other evidence, however, suggested that the genome could be completely rearranged as a result of gamma irradiation.³ Extensive outcrossing of variants created by this technology has occurred, but there was no evidence that concerns about radiation mutagenesis were equal to the level of concern over the use of genetic modification. The development of desired characteristics through the application of genetic technology was not, we were told, so readily acceptable because of the nature and extent of the risks associated with the technology.

11. If manipulation of genetic characteristics by traditional means has never been perceived by the public as having the same level of risk as genetic modification, and if there is not the same concern about radiation technology, the public perception of risk from transgenic crops and animals must arise from the nature of the artificial genetic changes.

Risks associated with the gene construct

12. Each genetically modified organism contains a “gene construct”, which confers the required characteristic. A construct consists of some or all of the following DNA sequences, each of which may carry different risks:

- vector sequences (from viruses, bacteria or plasmids), to aid incorporation of the new genes into the organism’s genome
- promoter sequences (such as the 35S promoter from cauliflower mosaic virus), to switch on the transgene in the genetically modified organism

- selection marker genes (such as antibiotic resistance genes), to enable the transgenic organisms to be identified
- the new gene that confers the desired characteristic to the genetically modified organism.

Vector sequences

13. The major perceived risk arising from the use of DNA from viruses or other microorganisms as transgenic vectors is the possibility of the generation of new diseases through recombination of the vector sequences with DNA from known pathogens. Dr Robert Anderson, a retired scientist with the Physicians and Scientists for Responsible Genetics New Zealand [IP107], wrote:

Genes, like viruses, can infect the body, which should warn of the potential risks of transgenic organisms serving as a reservoir for new diseases and as a medium for the evolution of new pathogens because of their altered physiology and biochemistry.⁴

14. Dr Mae-wan Ho, Visiting Reader at the Open University in the United Kingdom, speaking by video link as a witness for GE Free New Zealand (RAGE) in Food and Environment [IP63], described the creation of a new mouse pox virus by Australian researchers who were trying to make a vaccine for fertility control. The issue was raised by other submitters as an example of the lack of safety of genetic modification.

What they did was supply a gene from the protein interleukin 4 into the vaccine, and this succeeded. It was made from the relatively harmless mouse pox virus, which was used just as a vehicle to carry egg proteins into the mice. The hope was that the interleukin 4 would induce the immune system to make more antibodies against the mouse egg, thereby killing it. When the researchers injected the vaccine into the mice, however, all the mice died. In fact, this synthetic virus was so lethal that it also killed half of all the mice that had been vaccinated against mouse pox.⁵

15. It is clear that such experimental work requires rigorous containment and careful controls, but the Commission received no evidence suggesting that the new virus had escaped from containment or had infected any mice not involved in the experiment. Unexpected results such as these are a part of and, to some extent, the purpose of research.

Promoter sequences

16. Another perceived risk was the activation or suppression of other genes by strong promoters in the modified gene construct, especially when the construct was inserted randomly into the genome.

17. Some submitters had particular concerns about the use of the cauliflower mosaic virus promoter (CaMV 35S) to drive the expression of new genes in plants and animals because of the risk of activation of previously dormant genes. They

suggested that new diseases might arise, through gene activation or from the new transgenes with strong promoters jumping within the genome. Dr Mae-wan Ho said:

CaMV is closely related to human hepatitis B virus, and less closely, to retroviruses such as the AIDS virus. Although the intact CaMV specifically infects plants of the cabbage family, its isolated 35S promoter is promiscuous across domains and kingdoms, and is active in all plants, algae, yeast, bacteria as well as animal and human systems. It can substitute in part or in whole for promoters of other viruses to give infectious viruses. It is known to have a 'recombination hotspot' where it is prone to break and join up with other genetic material, hence increasing the likelihood for horizontal gene transfer and recombination. It has the potential to reactivate dormant viruses, which have now been found in all genomes, plants and animals included, and to recombine with other viruses, dormant or otherwise, to create new viruses.

In addition, the fact that it is active in animal and human cells means that, if transferred into their genomes, it may result in over-expression of certain genes that are associated with cancer.⁶

18. Dr E. Ann Clark, Associate Professor of Plant Agriculture at the University of Guelph in Canada, speaking as a witness for the Green Party of Aotearoa/New Zealand [IP83], said:

In GM crops, genes coding for chitinase activity [are] stimulated to overproduce at very high levels (hyperexpress), typically using the CaMV S35 promoter. The result is the presence of [a] very high level of chitinase not normally seen in nature. What will happen to non-target fungi, including mycorrhizae, when residues of a GM crop designed to hyperexpress chitinase activity is soil-incorporated?⁷

19. Dr Robin Ord, genetics consultant and law student appearing for Pesticide Action Network New Zealand [IP87], saw a political aspect to the debate:

As regards the much discussed cauliflower mosaic virus 35S (CaMV) promoter patented by Monsanto – I believe that the patent for the worldwide use of the enhancer gene that goes with it is or was owned (at least in part) by Lord Sainsbury, who also happens to be or have been the UK Minister of Science, and has sat on committees promoting GM foods ... Lord Sainsbury has decided me against GM for the immediate future.⁸

20. Dr Daniel Cohen, a plant scientist in the Plant Health and Development group of HortResearch [IP5], also discussed the concerns about the CaMV 35S promoter in his witness brief:

Most of the experimental data cited by Ho et al ... is not disputed. It is well known that viral sequences recombine and on very rare occasions new strains of virus evolve. ... Horizontal transfer is common among bacteria and transfer of viral and prokaryotic sequences has occurred during the evolution of plants and animals. What is disputed is

the extrapolation of data from laboratory experiments under controlled, highly selective conditions to making claims that under field conditions major environmental and public health problems will occur.⁹

21. Dr Cohen told the Commission that CaMV was present in New Zealand brassicas and infection rates of up to 50% had been reported. He argued that the virus had clearly been part of the human diet in Europe, Asia and Australasia for a considerable period of time and that:

... if ... this virus has a tremendous power to recombine with other viruses and cause disease in other plants and animals, we might expect some evidence of remnants of the virus in other organisms. Extremely sensitive PCR tests have been developed to detect traces of the 35S in foods as evidence of GE ingredients. Such tests would be impossible if horizontal transfer had taken place.¹⁰

22. In this last sentence, we understand Dr Cohen to be saying that if the 35S promoter had jumped to other plants and organisms, the test for genetically modified ingredients would lack reliability. In a letter to the Commission, the Ministry of Health confirmed that, until recently, New Zealand relied on such tests for the 35S promoter and the nos terminator sequence to indicate the presence of genetically modified ingredients from 17 of the currently permitted genetically modified foods.

Selection marker sequences

23. We noted the concern from some submitters about the use of antibiotic resistance genes as markers for selection of transgenic organisms. It was suggested that the use of these markers might increase the spread of antibiotic and drug resistance genes, leading to new diseases. This fear was summarised on a workshop summary card from the Whangarei Public Meeting:

The use of antibiotic marker genes (tool of GE) may prove to be dangerous – creating super bugs. GE food plants containing antibiotic resistant marker genes can transfer to bacteria in the gut making these resistant to that antibiotic.¹¹

24. Te Runanga o Ngai Tahu [IP41] was also concerned about the use of these genes:

Can antibiotic resistant genes integrate with the beneficial bacteria in the human digestive system and develop virile [strains] of harmful bacteria that are resistant to antibiotics? Who is liable if this happens and we are faced with serious infections that cannot be treated with traditional antibiotics? The relative speed with which genetically modified organisms are rushed into the environment without knowing possible future affects appears to be more “suck it and see” than scientific.¹²

25. The Environmental Risk Management Authority (ERMA) published a discussion paper in December 2000 entitled “The Use of Antibiotic Resistance

Marker Genes in Genetically Modified Organisms”. The summary of this report suggests that the use of these marker genes has had little or no effect on the incidence of antibiotic resistance:

The major source of the development and spread of antibiotic resistant microorganisms in humans is the human use (and often overuse) of antibiotics in both the community and hospitals. Within hospitals person-to-person transmission is aided if infection control practices are less than ideal.

Some antibiotic resistant bacteria occur naturally in the environment but many are a result of contamination with human and animal excreta in sewage, slurry and manure. Antibiotic resistance is therefore also acquired through ingestion of resistant microorganisms from animals or soil contaminating food or water.¹³

26. Alternatives to antibiotic resistance genes are currently available and more are under development. The Advisory Committee on Releases to the Environment (ACRE) Best Practice Subgroup of the Department of Environment, Transport and the Regions in the United Kingdom said:

Many selectable markers in common use encode resistance to antibiotics, although a number of alternative selection systems are available. Possible alternatives include reporter genes; genes that confer resistance to cytotoxic agents and genes that confer an ability to utilise compounds that are normally inaccessible.¹⁴

27. Furthermore, post-selection methods for excising the marker genes using site-specific recombination are being developed.¹⁵

Risks associated with the inserted gene

28. Genetic modification confers a desired trait on a plant or animal. Submitters who commented on risks associated with the inserted gene sequence were concerned with the eventual expression of that trait and the risks of the expressed gene on human health and the environment. Further discussion on this issue can be found in chapter 7 (Crops and other field uses) and chapter 9 (Medicine).

Horizontal gene transfer

29. Horizontal gene transfer is the transfer of genetic material from species to species, through the uptake of DNA and its incorporation into a new genome. Horizontal gene transfer appears to be common between microorganisms, such as bacteria and fungi. Professor Brian Goodwin, Professor of Biology at Schumacher College, Dartington, in the United Kingdom, and a witness for Sustainable Futures Trust [IP51], described the phenomenon in his witness statement:

There is clear evidence that genes transferred to plants can transfer to soil bacteria and thence to other plants. This requires that there be DNA sequences in the construct that are

homologous to those of bacteria. All constructs used in genetic engineering have such homologies ... Therefore horizontal gene transfer can be expected to occur ... It has been shown that such transfers occurred from transgenic sugar beet to soil bacteria, as monitored by the movement of an antibiotic marker gene from transgenic plant material to a strain of *Acinetobacter*.¹⁶

30. Professor Goodwin supplied the Commission with scientific references to show that there are many routes available for such transfer to occur:

Plant material that remains in the field after harvesting can decompose and release DNA into the soil, where it can be stabilised by adsorption to polymers such as humic acid or soil particles and then be taken up by soil bacteria by transformation, or directly by the plants. Bacteria are capable of transferring genes to either closely or distantly related species, and transfers are known to occur from bacteria to yeast cells to plant cells and to mammalian cells. All species are therefore genetically linked via horizontal gene transfer.¹⁷

31. A number of submitters said, however, little is known about how common the movement of genetic material is between transgenic animals and other species or of the effects of horizontal gene transfer on soil ecology. Dr A. Neil Macgregor, a soil scientist from the Institute of Natural Resources, Massey University, a witness for Physicians and Scientists for Responsible Genetics, described this as an area of intense current research effort:

Below ground, information about the effects of GE-plants and animals is growing but still rare and extremely fragmented. There is sufficient evidence to suggest that even in fragmentary form, that biological mechanisms in soil will likely play a crucial role in the overview [of] how GE and other production technologies should be developed, if at all. A living genetically modified plant exists in a tight ecological relationship with the soil microflora. Although the product of the modified gene (eg Bt) may be exuded from the live plant, little is known about actual DNA transfer from live plants.¹⁸

What happens to the DNA we eat?

32. The Commission heard many concerns that, through horizontal gene transfer, genes from ingested genetically modified organisms would be taken up by the body.¹⁹ Nearly everything we eat contains DNA,²⁰ in fact, humans consume between 0.1 and 1.0 g of DNA per day.²¹

33. Most of the DNA we eat is broken down into fragments too small to be functional.²² This occurs first by food preparation and cooking, and then by digestion through enzyme and microorganism action, which begins in the mouth, and continues through the gut.²³ A recent study using sensitive DNA detection techniques on farm animals fed Bt corn found no trace of Bt-corn genes, though fragments of natural chloroplast DNA were found in the blood

lymphocytes of cows and the muscle, liver, spleen and kidney of chickens.²⁴ Other similar studies have been unable to detect either transgenic or natural plant DNA in cow's milk.²⁵ Investigations into the effects of feeding high concentrations of DNA²⁶ to mice have, however, shown that some of this DNA survives digestion.²⁷ Though most was excreted,²⁸ some was transported into the white blood cells and into organs like the spleen, liver and kidney. When pregnant mice were fed DNA, fragments were found to transfer to foetuses through the placenta.²⁹

34. These data do not, however, demonstrate that plant DNA can be transferred to, and stably maintained in, mammalian cells,³⁰ as there is no evidence to suggest that these fragments do anything except function as nutrients.³¹

35. Experiments have shown that injection of naked DNA into rabbits causes an immune system response or an allergic reaction.³² This process is the body's natural defence against larger DNA fragments passing through the gut barrier, and is now being used to create vaccines.³³

36. Because DNA is part of all plants and animals, it has always been a part of the human diet. The body, therefore, is designed to deal with it. Furthermore, many gut microorganisms are known to carry antibiotic resistance genes and no problem with transfer to gut epithelial cells has ever been reported.³⁴ Indeed, experiments in gene therapy have shown it to be very difficult to introduce genes into human cells.³⁵ Nevertheless, more investigation into the effects of substances entering the body is required, especially with respect to those people with known gut diseases.

Cross-pollination and outcrossing

37. The transfer of genetic material through cross-pollination or sexual reproduction within one species was sometimes referred to as vertical gene transfer. Professor Klaus Ammann, Director of the Botanical Garden, University of Bern, Switzerland, appearing for the New Zealand Life Sciences Network [IP24], told the Commission:

The environmental risks of genetically engineered crops have been categorised as follows (Journal of Molecular Ecology, vol 3, 1994):

1. Invasiveness of the transgenic crop (in the agricultural system as a weed or in natural habitats)
2. Invasiveness of transgene itself (vertical gene flow through hybridisation with wild relatives)
3. Side effects of the transgenic products (for instance effects on non-target organisms).³⁶

38. The risk of the escape of a transgene through vertical gene flow is different for plants and animals. Plants distribute their pollen and seeds using wind, insects

Kaatz's bees³⁷

Various submitters described a case of apparent horizontal gene transfer of a herbicide resistance gene into the intestinal microflora of honeybees. The Pacific Institute of Resource Management [IP84] said:

The German Television station ZDF reported on Sunday May 21, 2000 that a German researcher found a gene transfer from genetically engineered rapeseed to bacteria and fungi in the gut of honeybees. Professor Hans-Hinrich Kaatz from the Institut für Bienenkunde (Institute for Bee Research) at the University of Jena experimented during the last three years with honeybees on an experimental field with transgenic rapeseed in Saxony, Germany.

The rapeseed was engineered to resist the herbicide glufosinate. Professor Kaatz built nets in the field with the transgenic rapeseed and let the bees fly freely within the net. At the beehives, he installed pollen traps in order to sample the pollen loads from the bees' hind legs as they entered the hive. This pollen was fed to young honeybees in the laboratory. Professor Kaatz then took the intestine out of the young bees and spread the contents on growth medium to grow the microorganisms. He probed the microorganisms for the *pat*-gene, the gene that confers resistance to glufosinate. In some bacteria and also in a yeast he found the *pat*-gene. This indicates that the gene from the genetically engineered rapeseed was transferred in the bee's gut to the microbes.³⁸

Dr Beatrix Tappeser described this result as a "clear indication of horizontal transfer which has been, and is still, characterised as highly improbable". This case became a rallying point

and animals (birds eat the fruit, or seeds are picked up on wool or fur). Animals mate and therefore "contain" their eggs and sperm to a greater extent. Fish reproduction falls somewhere between these two examples. It would seem to be easier to contain the outcrossing of transgenic animals than transgenic fish or plants.

39. The Green Party was concerned about the escape of transgenic fish from commercial hatcheries. Their submission stated:

One NZ example which has caused concern is the development in containment (until discontinued in February 2000) of transgenic salmon modified to express extra growth hormone and thus to grow much faster than natural salmon.

The salmon were being raised in outdoor tanks, with water from a spring circulated through the tanks and then into the river. Until public concern led to a review of conditions by ERMA the screens designed to prevent the escape of eggs were not required to be regularly checked for holes and the mesh size was close to the lower range of egg size. There is still no way of knowing for sure whether any eggs escaped into the river and grew into adults.⁴⁰

around which the discussions of horizontal gene transfer flowed. However Professor Klaus Ammann suggested that the results described were far from conclusive. Professor Ammann stated that he knew Professor Kaatz's work well and was "one of the committee members to revise his projects". He told the Commission that the research was a long way from being completed and had never been published in a scientific peer-reviewed journal, although Dr Tappeser stated, "Professor Kaatz had submitted his research to the science journal, *Nature*, but they had refused to accept it". Professor Ammann also considered that there was "no proof that this ... gene is not coming from normal sources". Under cross-examination from Greenpeace [IP82], Professor Ammann denied that horizontal gene transfer had ever been shown to be a significant risk:

There have been at least 100 experiments conducted to prove that there is horizontal gene transfer from a higher organism like [a] flowering plant to bacteria, and it has not been proven. And, I must say I am appalled by Greenpeace Europe who, on the basis of two lines in an announcement of the German TV channel, just made a big story out of it. I think that's not the way we should proceed ... I can understand concerns, but I cannot understand blowing up a case which has not been scientifically proven. ... I think everybody in this room should be concerned about horizontal gene transfer, but it just simply doesn't occur, you know. And, in many cases, where it would be really interesting to know it occurs, there have been done lots of experiments and nothing has been proven, nothing.³⁹

The scientific world awaits the publication of the final results of Professor Kaatz's research with interest. Until then, this remains an unproven case of horizontal gene transfer between a plant and intestinal microorganisms.

40. The Green Party submission pointed to research using Japanese medaka carried out at Purdue University, Illinois. Computer modelling suggested modified fish might displace wild fish by out-competing them for food and by interbreeding with them. The Green Party said:

Purdue University researchers found last year that a 0.1 percent intrusion of transgenic fish into a wild stock could bring that population to extinction within 40 generations where the gene reduces the offspring's ability to survive. They dubbed this theory the 'Trojan gene hypothesis' on the grounds that the gene gets into the population looking like something good but ends up destroying the population.⁴¹

41. However the public submission from New Zealand King Salmon said it was hard to predict the impact transgenic fish would make on ecological systems because testing the transgenics in the wild would require release. New Zealand King Salmon considered the impact of transgenic fish on the wild population would depend on the number of escaped salmon, their potential to reproduce and the potential of the transgene to confer advantage in the wild.

Randomness of gene placement and lack of gene stability

42. A further risk arises from the method of transgenesis used to create the genetically modified organism. Genetically modified organisms can be created by the random insertion of one or more copies of the gene construct into the DNA of the organism. Then some of the resulting genetically modified organisms may not be viable, if transgene insertion has disrupted essential genes. Even when the resulting genetically modified organisms are viable and stable over several life cycles, the transgene may later move within the genome, with unpredictable consequences. In her witness statement, Dr Mae-wan Ho said:

GM constructs are also structurally unstable, and are frequently rearranged, deleted or repeated in part or in whole. The resultant GMOs, likewise are unstable and do not breed true, so significant genetic and epigenetic changes may occur in subsequent generations, multiplying the unpredictable risks to health and biodiversity. Current regulatory systems do not take this into account.⁴²

43. We heard evidence from research scientists that new techniques are being developed to overcome risks associated with the gene construct and the method of transgenesis. Dr Phillip L'Huillier, a molecular biologist presenting for AgResearch [IP13], gave evidence that AgResearch's transgenic sheep and cows were created using a method called homologous recombination, which gives rise to a more specific gene insertion. This technique is similar to the methods used in animal cloning and results in the new gene being placed accurately within the genome, at a site normally occupied by a known, normal gene.

44. Similar techniques that can be used to integrate transgenes specifically into chloroplast DNA in plants are under development. The ACRE report stated:

Transgenes can be integrated into chloroplast DNA by homologous recombination. In this way the precise location of the gene can be controlled. Because of the specificity of the integration event, fewer duplications or illegitimate insertions occur.⁴³

45. This report also recommended that transgenic plants should be as similar as possible to their unmodified equivalents:

There are a number of reasons to aim to produce transgenic plants with as little extraneous DNA as possible:

- it facilitates analysis (characterisation, including sequencing) of the insertion site
- it aids the monitoring of stability and inheritance of the transgene
- it reduces the chances of pleiotropic effects
- it simplifies the environmental risk assessment

- it removes one of the main criticisms of the technology regarding the propagation of plants containing antibiotic resistance genes and other marker traits, eg herbicide tolerance.⁴⁴

46. The Commission is aware that the rapid pace of development of this technology will lead to improved techniques for the transgenesis of plants and animals over the next decade.

Environmental impacts

47. There were two main focuses for the anxiety about the use of genetic modification: the potential impact on human health, and the potential environmental impact. The level of concern about the latter was particularly high. The view expressed by one of the public submitters appeared to be shared by many:

... humans are messing with something very unique and ... doing so may cause irreversible harm to the ecosystem.⁴⁵

48. Several of the organisations and individuals we heard were concerned that, if genetically modified organisms and products were released for use outside laboratory containment, the inherent instability of the technology and the high risk of human error meant it was likely modified organisms would escape from genetically modified crops and animals and contaminate unmodified plants, insects and animals in both the natural and the agricultural environments. Underlying the concerns about these adverse impacts was a widely held belief that the effects would be irreversible. Dr David Suzuki, a Canadian ecologist, wrote in his witness brief for the Sustainable Futures Trust:

The difference with this technology is that once the genie is out of the bottle, it will be very difficult or impossible to stuff it back. If we stop using DDT and CFCs, nature may be able to undo most of the damage – even nuclear waste decays over time. But GM plants are living organisms. Once these new life forms have become established in our surroundings, they can replicate, change and spread, so there may be no turning back.⁴⁶

49. The damage done by modified organisms, some submitters suggested, could be cumulative rather than acute. Dr Macgregor, for example, suggested that environmental harm could result from an accumulation of ecologically insignificant instances of horizontal gene transfers in the soil biosphere. He suggested there were largely unexplored areas of soil ecology for which testing procedures were not being developed.

50. The issue concerning submitters was not the speed with which such damage would be caused, but that it would be irreversible. The submission

received from the Green Party emphasised that harm caused to the ecology of the soil or through the food chain if New Zealand released genetically modified organisms into the environment would not be remediable. Some submitters, therefore, suggested no genetically modified organisms should be released from laboratory use until further research into potential risk pathways had been carried out. Other submitters clearly believed there should be a total ban or long-term moratorium on all uses of genetic modification in New Zealand.

Invasiveness of genetically modified organisms

Ecological impacts

51. Many submitters raised the possibility of invasive genes altering natural ecosystems as a result of the release of genetically modified organisms. A number of witnesses suggested that, because research sought to identify the linear effects of genetically modified organisms, insufficient attention was paid to the wider, ecological impacts of the hazards. Dr Peter Wills, a theoretical biologist and Associate Professor in Physics at the University of Auckland, who appeared for a number of New Zealand organisations,⁴⁷ referred to the need to look at and understand the “strange interconnectedness” of ecosystems. Dr Doreen Stabinsky, Science Adviser on the Genetic Engineering Campaign to Greenpeace US and Greenpeace International, told the Commission that studies done in the United States reviewing the results of field tests showed that ecological data had not been systematically collected. She suggested that, even if ecological data had been collected, there was a very limited base of knowledge about ecosystems and the interrelationships between organisms, and between organisms and their environment.

Weediness

52. Weediness is a characteristic of plants that allows them to be aggressively invasive, thereby upsetting natural ecological balances. Many submitters expressed concern that genetic modification of plants, particularly agricultural crops, would result in an increase in weediness.

53. Dr Stabinsky contended that the use of genetic modification to confer desirable traits on agricultural crops, such as insect or drought tolerance, could also confer characteristics on the recipient plant that made survival easier. A plant developing these characteristics had the potential to persist in the environment by withstanding either natural selection or conventional agricultural weed control methods, and thus increase in number. The development of weediness in plants, therefore, had implications for natural and agricultural ecosystems. It was suggested there was also potential for cross-pollination of future crops by the

genetically modified crops. However, recent data from a 10-year survey of genetically modified crops in the United Kingdom showed modified plants had no more tendency to weediness than their unmodified equivalents. These crops had all been modified for resistance to herbicides or insects. The study showed that all the genetically modified crops had a poor survival record in the field and were eventually replaced by wild counterparts.⁴⁸

Outcrossing

54. The transfer of unexpected traits to living organisms could result from either sexual or non-sexual genetic transfers. The particular examples of outcrossing brought to the Commission's attention were from the accidental release of genetically modified salmon into the wild, and cross-pollination from genetically modified plants. Cross-fertilisation by genetically modified animals was not addressed, probably because the containment of such animals is easier and because, at present, modification of animals is not carried out extensively. Apart from welfare concerns, the issues relating to animals focused on the consumption by humans of products from genetically modified animals and the potential for horizontal gene transfer to organisms in the soil through animal excreta.

55. The hybridisation of unmodified plants by pollen from modified plants was of concern for a number of reasons. There was the potential for unmodified plants to develop unintended characteristics, such as weediness, that would have environmental effects. A number of submitters were concerned that foods manufactured from crops unintentionally cross-pollinated by modified crops would not be subject to the usual safety assessment processes. Accidental contamination by StarLink™ corn was cited as an example of this happening. Without assessment, it was feared, allergens and toxins resulting from genetic modification would not be detected.

56. Environmentalists and Maori expressed concern at the potential for indigenous plants to be cross-pollinated by exotic, genetically modified plants of the same genus. Maori were particularly concerned that plants that had traditionally provided food resources would be altered by cross-pollination, affecting their value as a resource and causing spiritual pollution.

57. Control of pollen flow was the focus of a number of submissions. Many submitters emphasised the difficulty of establishing satisfactory separation distances between modified crops and unmodified plants. Beekeepers highlighted the role that bees played in pollen transfer. The focus of their concern was primarily the commercial threat posed by the presence of genetically modified material in honey and other bee products.

Targeting the wrong species

58. A perception of modified genes and the modification process as inherently unstable and unpredictable caused many submitters to suggest that genetic modification would result in alteration to non-target species. Plants, animals and insects introduced into New Zealand in the past were used as illustrations of the devastation that unintended effects cause to non-target organisms. The Green Party, for example, said:

... New Zealand's ecosystems have evolved in isolation from the rest of the world since the time when the Gondwanaland continent drifted apart. Our indigenous species tend to be very different from species in other countries. While New Zealand's ecosystems have been modified by introduced pests such as possums, deer, goats, gorse and others the lesson from these is that they have behaved differently from in their country of origin and their ecological impacts have been different.⁴⁹

59. Many submitters isolated aspects of the research carried out on the effect of Bt-resistant corn on Monarch butterflies and cited these as examples of the potential for genetic modification to impact adversely on other species in the environment (see box opposite).

60. The Commission noted that a number of research projects being carried out in Crown Research Institutes included research into non-target effects. AgResearch advised research was currently being undertaken on the environmental impacts of new technologies, including the impacts of transgenic plants expressing insecticidal toxins. This involved quantification of the effects on the soil ecosystem, including soil foodweb composition, biomass and nutrient status. Research into pest control, especially the control of major environmental pests such as possums and stoats, we were told, included evaluating the effect of any proposed controls on non-target species. This work was being carried out by Landcare Research [IP12], which was involved in a range of projects aimed at the control and eradication of many introduced animal and plant species.

Reduction in biodiversity

61. People were particularly concerned that genetic modification would lead to a reduction of New Zealand's biodiversity. Submissions from environmental organisations, such as Greenpeace and the Royal Forest and Bird Protection Society of New Zealand [IP79], emphasised the depletion already caused by the introduction of exotic species and by cultivation, and the importance of protecting

Non-target species: Monarch butterflies and Bt corn⁵⁰

Bacillus thuringiensis (Bt) is a soil bacterium that produces a protein with insecticidal qualities. Traditionally, a fermentation process has been used to produce an insecticide spray from these bacteria. In this form, the Bt toxin occurs as an inactive protoxin, which requires digestion by an insect to be effective.

Crop plants have now been engineered to contain and express the genes for Bt toxin, which they produce in its active form. Bt corn is used primarily to control corn borer (a lepidopteran insect), which is difficult to control by spraying. Bt-corn strains are therefore toxic to lepidoptera (moths and butterflies).

Monarch butterfly larvae feed exclusively on the leaves of milkweed plants, which are commonly found in and around cornfields in the United States. Pollen from nearby corn can become distributed on the leaves of these plants, and therefore be eaten by these larvae.

In 1999, two studies showed that Monarch butterfly larvae, and larvae from related species, had lower survival rates eating leaves dusted with Bt-corn pollen than after eating leaves dusted with non-Bt corn pollen. People used these studies to suggest that Bt corn was responsible for the recently observed decline in the Monarch butterfly population. However, the Environmental Protection Agency (EPA) noted that these preliminary controlled study data were not useful for risk assessment of widespread or recurring Bt-corn pollen effects on Monarch butterflies without additional field study information.

As a result the EPA issued a call-in of data on this topic. Shortly thereafter the data was presented to a scientific advisory panel for their recommendations. This resulted in a report evaluating many studies on the effects of Bt-corn pollen on Monarch larvae mortality.

Investigations have revealed that while a large percentage of Monarch butterfly larvae may feed on milkweed found in the corn belt region of the US, there is no overlap between breeding time and time of pollen shed through most of this region. Other studies have shown that corn pollen does not move far from the field, and that the quantity of pollen settling on an area decreases rapidly with distance. Together with toxicity studies showing low toxicity of many major Bt-corn strains, this implies that pollen densities that could represent significant exposure to feeding larvae are found only within five metres of cornfields, and then rarely. Even within corn fields pollen densities were usually found to be too low to cause mortality in Monarch larvae. Some preliminary investigations have suggested that Monarchs may avoid laying eggs on milkweeds surrounded by corn plants.

These findings indicate that, outside corn fields, Monarch larvae exposure to Bt-corn pollen is minimal, and that, within fields, Monarchs will have a low probability of encountering a toxic level of pollen.

The report also suggests that the elimination of pesticides through the use of Bt corn may be beneficial to Monarch butterfly populations, and concludes that there is not sufficient evidence to support the belief that there is significant risk to Monarch butterflies from Bt-corn use. The EPA is however continuing to monitor this situation.

New Zealand's unique flora and fauna from further threats. A member of the Royal Forest and Bird Protection Society, Nelson/Tasman Branch [IP43], Jocelyn Bieleski, said:

Our natural ecosystems in New Zealand are unique, and their isolation, until recently, has made them vulnerable and valuable beyond measure. Indigenous forest – indigenous flora and fauna and fish belong here in their own right. ... The forest is one of our living ecosystems which has successfully adapted and developed to a complex self-maintained diverse community, which has sustained its integrity over eons. Yes, there has been genetic change as adaption applies, but this has not been engineered by humans in haste. ... Genetically modified organisms will threaten the indigenous biodiversity. With their release will also come changed soil composition, pollen production and insect mutation. Through mutations new bacteria and viruses are likely.⁵¹

62. The Commission, however, heard evidence of the potential for genetic modification to protect and preserve biodiversity. The Sustainable Futures Trust, for example, gave cautious recognition of the value of genetic modification for conservation purposes, but only where there can be an assurance of no adverse effects. Landcare Research described research currently under way into a possible genetically modified control for possums and for wasps, and the public submission from the Department of Conservation referred to its involvement in research involving conservation genetics where species are accurately mapped. It was clear from the Landcare Research submission that, while it sees genetically modified controls as being possibly the only method of dealing with this major environmental threat, it is adopting a cautious approach to the use of the technology. Other Crown Research Institutes indicated that genetic modification, rather than posing a threat to biodiversity, might provide the solutions to some of the hitherto more difficult problems associated with the management of natural resources and the environment.

Human health impacts

63. The Commission heard almost an equal amount of worry expressed about the dangers of genetic modification to human health as to the environment.

64. Some concerns were expressed about the use of the technology for medicines and therapeutics. Medicines, however, are subject to rigorous testing which minimises the potential for harm. In addition, submitters believed any adverse effects from using genetically modified pharmaceuticals and therapies would be limited to the individual. The use of the technology for personal health was, therefore, an issue of individual choice. As long as there was careful research into and limitations on any unethical uses of the technology, and as long as

pharmaceuticals and therapies were rigorously tested and clearly labelled, and patients advised of the genetic origin of any of the treatments they received, there appeared to be a greater acceptance of the use of genetic modification in these areas. However, because dietary supplements tend to fall between pharmaceuticals and food and may have less regulatory oversight than food, they were one use of genetic modification regarded as posing a special risk. Issues relating to the use of genetic modification for personal health are discussed in greater detail in chapter 9 (Medicine).

65. Submitters suggested that the development of characteristics such as herbicide resistance in genetically modified crops would lead to an increase in the use of more toxic herbicides. Particular mention was made of the link between glyphosate herbicides and non-Hodgkin’s lymphoma in humans. The Commission’s own research uncovered a considerable number of papers (one of which was presented by the Life Sciences Network during cross-examination of the Pacific Institute of Resource Management [IP84]) showing there was no significant risk of non-Hodgkin’s lymphoma with glyphosate exposure and that Roundup was one of the least toxic herbicides currently available.

66. Submitters suggested the consumption of food either containing genetically modified ingredients or manufactured by a process using genetic modification would create serious risks of damage to human health. While there was some reference to possible carcinogenic effects of genetic modification⁵² and to alterations to the nutritional value of modified foods,⁵³ the main worry was the creation of new allergens in foods that have not hitherto been considered allergenic, and new toxins in foods previously considered safe. Safe Food Campaign [IP86], for example, said:

Part of our concerns centre around the “scientific risk-based approach” that ANZFA takes when testing GM foods. We do not believe that the allergenicity, toxicity and substantial equivalence tests are adequate to approve GM foods for consumption. Tests for allergenicity, like those for toxicity, are only for known allergens and toxins. As some GM foods include genes from organisms outside our diets, we believe that some GM foods may contain allergens and or toxins previously unknown to us and therefore outside those tested for.⁵⁴

67. We noted, in particular, the expressions of anger that genetically modified food had entered the New Zealand market without any regulatory requirements other than those for conventional food. Permitting unassessed food to remain on the shelves, submitters suggested, exposed consumers to unacceptable risk.

68. Issues relating to genetically modified food are dealt with in greater detail in chapter 8 (Food).

Questioning the need

69. A number of submitters questioned whether there was a need for genetically modified products and technologies, particularly in agriculture. Submitters such as the Green Party suggested that genetic modification was seen as a “magic silver bullet” to solve problems without addressing the causes. Dr John Clearwater, an entomology consultant, in particular to the organic apple industry, and a witness called by Physicians and Scientists for Responsible Genetics, said:

Many genetically engineered species are the product of the “magic bullet” concept that seeks a single, dramatically effective solution to a problem.⁵⁵

70. The use of genetic modification, submitters suggested, was a “reductionist” approach to often complex problems that required a more holistic solution. In particular, there appeared to be little demand for a technology with so many risks. In its written submission, the Canterbury Commercial Organics Group [IP65] asked:

Lack of clear need, adverse impacts on the organism “benefited” by the technology, lingering public health concerns, scientific uncertainty, and the need for clear labelling all lead to the questions: Why do we need these products? What consumers are clamouring for them?⁵⁶

71. A number of submitters also considered that genetic modification tended to deflect attention from alternative solutions and technology, and to divert funding from the research and development of alternative health treatments and food sources which did not create the same degree of risk as genetic modification. The organics industry particularly felt it had not benefited from government research funding, and the Commission was pleased to note that additional funding was made available to this production sector during the period of our inquiry.

72. The Commission heard evidence that there might not always be a choice between genetically modified and unmodified solutions. For example, Dr Kenneth McNatty, a scientist with AgResearch, told us that, because animals are becoming increasingly resistant to conventional parasite control methods, research is under way into the development of genetically modified alternatives. Although some have suggested that treatments based on organic principles would provide more effective and safer control of animal and plant pests, there might be situations in which genetic modification would provide the best and possibly the only effective alternative to conventional methods. Landcare Research, for example, emphasised that using genetic modification in response to major environmental threats, such as from possums, that caused significant damage and did not respond to other

control methods, might be the only possible alternative:

At present, pest problems in New Zealand, like possums and stoats, are being addressed by the best management strategies we have. The current way New Zealand is managing pests has substantial risks, particularly those from the use of poisons. GM offers more precise and better targeted ways of addressing these intractable pest problems, which could reduce or avoid the risks of current control methods, and reduce New Zealand's reliance on large scale use of broad-spectrum poisons.⁵⁷

73. We also heard evidence from representatives of sufferers of rare diseases that genetic modification would provide the only viable option for treatment.

74. The Commission considers there may often be a need to find the most appropriate solution, in all the circumstances, regardless of whether it involves genetic modification or not. Short-term gains will always need to be balanced against long-term solutions in the decision-making process.

The corporate context

75. There was a significant level of doubt as to whether genetically modified products were anything more than a cynical manipulation of the consumer for corporate profit. Allan Fricker, speaking for the Sustainable Futures Trust, said:

In the case of genetic modification in agriculture, and to a lesser extent in health, it is the commercial sector that is involved that carries those costs of development and production. And commerce cannot afford not to develop its products, not to apply and to sell its products. And so, in a sense, the commercial imperative gets in the way of the decisions that need to be made.⁵⁸

76. Concerns about corporate involvement in the development of genetically modified products were raised particularly in relation to issues of liability for any harm caused by the technology and the creation of intellectual property. These are dealt with in later chapters. The Commission considers, however, that concern about corporate involvement in the development and promotion of genetic modification has had important implications for public perception of the safety of genetic modification. First, the relationship between commercial interests and science in the development of gene technology caused doubts about the integrity of science, of scientists and of the scientific process. Second, it was suggested that the commercial impetus behind genetically modified products, particularly food products, might influence and undermine the effectiveness of the regulatory agencies responsible for ensuring the safety of those products. In particular, we heard considerable criticism of the Australia New Zealand Food Authority (ANZFA) leading us to invite ANZFA to attend a special hearing to

respond. Issues relating to ANZFA and food safety are discussed in more detail in chapter 8 (Food).

Concern about scientists

77. A number of submitters raised the issue of public confidence in science and scientists. Some of the concern rested on doubts about whether scientific knowledge was sufficient to assess the risks of using genetic modification. Sometimes, however, the lack of trust of scientists in particular was explicitly linked to the relationship between commercial interests and the funding of science. For instance, Dr Morgan Williams, Parliamentary Commissioner for the Environment [IP70], while discussing the work commissioned on the control of possums and the possible use of genetic modification technology, told us:

... what we've found, and it came out through this possum GE study, was that [the] New Zealand community's asking, how independent is our science voice today? Who actually owns that voice? ... and there's a widespread perception that the soul of science is, or has been, bought, and ... the objectivity, rightly or wrongly that was bestowed upon science in previous decades, is not seeking to be as strong as it was.⁵⁹

78. Dr Roger Wilkinson, who appeared as a witness for Landcare Research, was responsible for the research into possum control carried out on behalf of the Parliamentary Commissioner. He said:

People don't trust genetic engineering. ... They also don't trust genetic engineers. Some groups described how scientists have let us down too many times ... The Industry group observed the lack of trust in proponents. ... Scientists were described in the Opponents group as arrogant. ... Biotechnology companies were described as being interested only in profits: ... Someone in the Provincial group even suspected a conspiracy. ... Motives of scientists were regarded as important, along with the source of their research funds and who their employers were.⁶⁰

79. Some submitters suggested that, because of commercial pressures, scientists and the corporate developers of genetically modified products might not carry out proper assessments of the risks of releasing genetically modified organisms. We heard this suggestion particularly in relation to the production of genetically modified food where the integrity of companies in providing research results was questioned. In New Zealand, scientists are guided by the code of ethics promulgated by the Royal Society of New Zealand. We were told by Emeritus Professor George Petersen, the immediate Past President of the Academy Council of the Royal Society of New Zealand [IP77], that:

We have already collaborated with ERMA New Zealand in drawing up guidelines specifically for researchers in the field of genetic modification, as defined under the

HSNO legislation, and this has been published which ERMA and distributed widely. ... I expect that we will incorporate these recommendations, and probably others, in our own general code of ethics that is due to be reviewed over the next few months.⁶¹

80. In response to questioning by the Commission about the integrity of scientists being compromised by the source of funding for their research, Dr Audrey Jarvis, appearing for the Interchurch Commission on Genetic Engineering [IP49], agreed that as long as scientists retained their integrity and independence, the source of funding was not an issue. She said:

... the integrity is terribly important. This has always been important for scientists. There will often be the odd scientist who does not have integrity. ... I guess any person [may] not have integrity. ... we're not saying that scientists don't have integrity. ... I've been to talks, been involved with scientists involved with ERMA, ... and they have concerns about the ethical issues ...⁶²

Precautionary principle

81. Arguments for prohibiting the release of genetically modified organisms into the environment or for preventing the importation of genetically modified food often invoked the precautionary principle as the basis for this approach.

82. Since its introduction into environmental law in the 1970s the precautionary principle has been widely incorporated into a range of international laws, treaties, protocols and other instruments. Although it has become a principal tenet of international environmental law, it remains the focus of much debate, particularly in relation to biosafety and biotechnology. In addition, many differing definitions of the principle are found in different contexts.

83. Two formulations of the principle were held up by submitters as being applicable to the release of genetically modified organisms in New Zealand. In relation to possible environmental damage, Principle 15 of the 1992 United Nations Conference on Environment and Development (the Rio Declaration) was cited. This states:

Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

84. Article 11.8 of the United Nations Cartagena Protocol on Biosafety (the Biosafety Protocol), agreed in Montreal in January 2000, is relevant to the release of genetically modified organisms for food or animal feed. It states:

Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified

organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimise such potential adverse effects.

85. Greenpeace New Zealand [IP82] called for the precautionary principle to be implemented in the Hazardous Substances and New Organisms Act 1996 (HSNO). The principle, Greenpeace suggested:

... mandates action to prevent harm to the environment, without requiring full scientific certainty that the threat of serious or irreversible harm will be realised. Invoking the precautionary principle, Aotearoa/New Zealand will ban:

- The deliberate release into the environment of genetically modified organisms in Aotearoa/New Zealand for the purposes of both field trials and commercial release.
- The importation for food processing, human or animal consumption of living entities such as maize kernels, tomatoes or cereal grain that if released by accident or negligence could germinate and replicate in the environment. In the cases of seeded fruits and vegetables, these foods should be banned for import on the basis of the ability for the seed to retain their viability after passing through the human digestive system.⁶³

86. The Green Party also invoked the Biosafety Protocol which, it said:

... gives countries the power to protect their environment under international law. The agreement covers trade of genetically engineered organisms, including bulk commodities, seeds, animals and microorganisms. It is intended to protect countries from potential environmental impacts of importing genetically engineered organisms.⁶⁴

87. In its submission, the Green Party made reference to the precautionary approach set out in section 7 of HSNO.

All persons exercising functions, powers, and duties under this Act, ... shall take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects.

88. A number of the submitters suggested that a delay or ban on the release of genetic modification would accord with this approach.

89. Other submitters, while not specifically invoking any of the formal definitions of the principle, sought other ways of explaining their view of the approach that should be taken. Safe Food Campaign, for example, suggested:

... [a] 'no regrets' approach would prove beneficial no matter what outcomes eventuate from genetic modification. If the best case scenario develops, with very few problems of minor consequence eventuating from genetically engineered foods, and only minor

problems being experienced from the release of genetically modified organisms, New Zealand would still have benefited from the enhanced economic returns from the premiums gained from organic markets.⁶⁵

90. Friends of the Earth (New Zealand) [IP78] considered the theme of its Interested Person submission was best summed up:

... in the precautionary principle. It is our position that knowledge of the risks of genetic modification (GM) is at present extremely limited, uncertain and often based on assumptions that do not reflect the public interest.⁶⁶

91. Submissions and witnesses on behalf of a number of the Crown Research Institutes pointed out that precaution is an element of scientific methodology, particularly of risk assessment. Dr Max Kennedy, from Industrial Research Limited, was a witness on behalf of the New Zealand Biotechnology Association (NZBA) [IP47]. To questions from Luke Anderson for GE Free New Zealand on the application of Cartagena Biosafety Protocol, he said:

I think the concept which the Biosafety Protocol is putting forward, which is risk assessment and a detailed consideration of that on a logical basis, is something that the NZBA supports wholeheartedly. I think that the concept of doing anything without that risk assessment is really not something that is sustainable or supportable.⁶⁷

92. Dr Kennedy went on to say that concern for protecting biodiversity or human health from risks posed by genetically engineered organisms was part of normal risk assessment methodology. The whole purpose of such methodology, he suggested:

... is to consider the unknowns and to try to quantify those unknowns. So the fact that there is debate over it shouldn't be a surprise and it is not really something that risk assessment is unfamiliar with.⁶⁸

93. The role of the precautionary principle in New Zealand law was considered at some length in the closing legal submission presented by the Life Sciences Network which pointed out that, although none of the international formulations of the principle were incorporated into New Zealand domestic law:

... the concept of caution is incorporated into domestic legislation and policy by the promulgation of the Hazardous Substances and New Organisms Act 1996 ("HSNO" or "HSNO Act") itself. More particularly, that approach is overtly to be found in section 7 of HSNO requiring the adoption of a cautious or precautionary approach.⁶⁹

94. Although we heard much discussion of the precautionary principle and the precautionary approach from those who opposed the release of genetically modified organisms into the environment, there was no consensus on the meaning of either term. The meaning of precaution often rests in the values held by the speaker.

95. The Commission considers there is more merit in hearing and responding to the message contained in the words than in seeking to define the meaning or determine how the principle should be applied. In any event, we were not convinced that a single principle could be applied across the board to the use of genetic modification in New Zealand. Decisions on the use of the technology must rest on a range of factors, including the risks and acceptability to the public of the proposed use. They are factors that should inform the process of managing genetic modification.

Risk analysis

96. It was clear to the Commission that a number of the people who spoke before us doubted genetic modification could be subjected to the usual methods of scientific risk analysis. In their view this was both because of the inherent instability of the process of genetic modification, and because there was, as yet, an inadequate body of knowledge on which to either base an assessment of the risks or establish risk management mechanisms.

97. Dr Mark Lonsdale, an ecologist with CSIRO in Australia, who appeared as a witness for the Parliamentary Commissioner for the Environment, spoke of the four pillars of risk analysis. He named these as being:

- Comparative risk analysis, which is how you compare one risk with another
- Risk assessment, which is how to decide what the risks are of a particular technology
- Risk management, which is how, having made a decision to proceed, you then manage the risks
- And then risk communication, which is how you talk to people about those risks and get people on side and keep them on side.⁷⁰

98. Dr Lonsdale added monitoring as a fifth pillar:

... to detect the impact of hazards at an early stage ... or to provide data to refine future risk assessments.⁷¹

Risk assessment

99. Submissions from organisations involved in the research and development of genetically modified organisms emphasised the importance of research and the application of gene technologies being based on high-quality science and scientific knowledge. In its submission, the New Zealand Association of Scientists [IP92] said:

Wherever possible, factual information and data should be used to address the risks and benefits of research, field trials and the release of GMOs and products. With research that

involves risk, with field trials and with release, each situation should be considered on an individual, case-by-case basis.⁷²

100. Dr Wills raised doubts whether it was possible to assess the risks of genetic modification accurately. He suggested that accepted methods of assessing risk were inappropriate for genetic modification because the risk factors associated with the technology could not be known or quantified in advance.

101. Other witnesses also suggested there was insufficient scientific knowledge of the behaviour of genetically modified organisms to allow for proper assessment of the risks. Professor Terje Traavik, a virologist from the Department of Medicine at the University of Tromsø, Norway, and a witness for Greenpeace, speaking in the context of horizontal gene transfer, said:

There is already sufficient evidence on the unpredictability of genetic engineering techniques and the interaction of genetically engineered organisms with the environment to indicate that we do not understand enough about the short, medium or long-term consequences of their release. Horizontal gene transfer from GMOs is a real option. Such events may result in extensive and unpredictable health, environmental and socio-economic problems. Under some circumstances the consequences may be catastrophic. Our present level of knowledge about horizontal gene transfer is inadequate for reliable risk assessments. This applies to GMOs in general as well as to any particular GMO.⁷³

102. However, Dr Cohen, a scientist in the HortResearch Plant Health and Development Group, said that scientific methods had been developed to evaluate and quantify the two components of risk assessment: assessment of the probability that something might occur and assessment of the consequences that might follow in the event of an occurrence.

103. In addition, the Association of Crown Research Institutes (ACRI) [IP22] and other organisations involved in researching genetic modification did not accept that gene technology was inherently unpredictable or that there was insufficient scientific knowledge to assess the risks adequately. In its submission, ACRI said:

... that sufficient reliable research information exists, or is being rapidly developed, to allow society's decision-makers to have a workable understanding of the risks of the technology.⁷⁴

104. The Commission also heard evidence that some of the anticipated risks of genetic modification were unlikely to arise, or would arise only in specific circumstances and were, therefore, capable of being managed.

Risk assessment models

105. Dr Lonsdale pointed out that risk assessment is “a very involved process”. He suggested:

We are early in the development of this science as it applies to GMOs. Even for small-scale releases, there is a feeling amongst proponents that they are being asked to address endless questions to no purpose, and a counter-view amongst regulators that they may be missing something. This is in part because of the newness of the technology, but there is also a need for systems thinking that will identify the range of risks that are pertinent to a particular GMO.⁷⁵

106. The ACRE report explains the basic principles of best practice in the design of genetically modified plants and sets these within the context of risk assessment. Other agencies in New Zealand and elsewhere are revising existing assessment models to ensure that, based on current scientific knowledge, risk assessment methods identify the hazards and risks of the technology.

107. Public interest in risk assessment models is also high. The Commission had the benefit of a number of submissions from the public that addressed this issue. Wendy McGuinness provided a substantial public submission in which she addressed issues of decision-making in relation to the use of genetic modification. She said:

My personal view is that the only way through this debate is the adoption and implementation of a rigorous decision-making methodology as to whether genetic modification should be adopted in terms of the scale, form and timing.⁷⁶

108. The question of whether decisions on the use of genetic modification should rest on scientific principles of risk assessment, or should include wider issues was mentioned in some of the submissions we received. In its written submission, the New Zealand Arable-Food Industry Council [IP56] expressed its opinion that:

... regulatory authorities give primary consideration to scientific assessment of risk in making GM decisions; the Council strongly opposes the possibility that political considerations become involved in GM risk assessment.⁷⁷

109. Many of the groups asking for prohibition of the release of genetically modified organisms, however, were concerned that too much reliance was being placed on scientific risk analysis methods. Those people who opposed genetic modification on cultural and ethical grounds were particularly concerned that there appeared to be no mechanism for taking such considerations into account when making decisions on genetic modification.

110. Proponents of genetic modification, we noted, did not necessarily disagree with the view that factors other than scientific factors should influence decisions on genetic modification. The Life Sciences Network, while supporting the

effectiveness of scientific risk assessment, also suggested:

At its most scientific, risk assessment and management is the process by which people, communities, organisations, countries make informed judgements about proposed activities and actions weighing relative risks and benefits. Having made the assessment it is then possible to ensure a positive balance of benefits over risks is maintained.

However, the assessment of risk is only partially scientific and factual. Many risks are unable to be characterised in an objective sense and must be determined and weighed using subjective criteria.⁷⁸

111. The New Zealand Dairy Board [IP67] also acknowledged the cultural, social, political and economic aspects of the risk management process. The Board, however, said this type of factor should not:

... be allowed to impinge upon or distort the science. That should be as objective as it is possible to achieve. Other concerns should not be ignored, but they should be recognised and assessed for what they are, and not used as a basis for exaggerating, or minimising, the extent of the risk as assessed scientifically.⁷⁹

Risk communication

112. As noted earlier, Dr Lonsdale discussed risk communication as one of the pillars of risk analysis. He pointed out that the costs of bad risk communication were high and that risk communication itself should be an area for research. He suggested that a model of communication “involving dialogue with regulators, stakeholders, and the public is likely to be more fruitful”.⁸⁰

113. A number of other submissions mentioned the need for more information about genetic modification to be made available. The Federation of Maori Authorities [IP69], for example, suggested:

Transparency and easy flow of information will contribute significantly to educating the public in the issues we potentially face in having biotechnological research, development and practice undertaken in New Zealand.⁸¹

114. The New Zealand Association of Scientists supported the need for communication, saying:

We think that communication is paramount. We believe that there has been too little communication. Science has worked in a world of its own and failed to recognise its wider social responsibilities and communication. We believe that this forum is part of the process of disseminating information, and we believe that the more widely these issues are discussed, at least the more knowledgeable and the more rational decisions will be made.⁸²

115. The Royal Society of New Zealand [IP77b] in its submission discussed the public perceptions of genetic modification and pointed out that feelings of lack of

control contributed to a sense of the lack of safety of the technology. Rosemary Du Plessis, the Society's social science representative, said:

There is public concern about GM research, and the effects of field trials, and the commercial release of GMOs. Improving mechanisms for public participation and decision-making about the use of GM technologies is one, not the only way, of improving people's sense of control over the risks that are involved in this field.⁸³

116. Dr Lynn Frewer, a psychologist at the Institute of Food Research in Norwich, England, appeared as a witness for Crop and Food Research [IP4]. Dr Frewer's witness brief discussed public attitudes towards genetically modified food:

Research has demonstrated that risk perception is "socially constructed" – that is, the way that people represent risks psychologically is a more important predictor of the way in which people will react to risks than probabilistic risk assessments used by technical risk experts to assess different hazards.⁸⁴

117. Dr Frewer went on to say that risk perception research had demonstrated that risks that were perceived as involuntary and unnatural were viewed as more threatening than those over which people perceived they had a choice, even if the probability of occurrence of the involuntary risk was very low.

118. Some submissions suggested some of the concern about the safety of genetic modification might be dissipated if the public were more informed about genetic modification and its risks. In a background paper prepared for the Commission, Dr Michael Berridge wrote:

Public perceptions about the risks and benefits of GM technologies are not always based on facts and are frequently dictated by uncertainty about the nature of gene manipulation, lack of knowledge about genes and natural genetic variation, and a lack of public trust in scientists and the scientific process ... The main issue here is one of communication – the need to raise the level of public dialogue and to provide factual information and realistic evaluation of benefit and risk.⁸⁵

119. The Commission agrees that the issue of communication is central to the future management of genetic modification in New Zealand. The level of concern about the potential risks to the environment and to human health is significant. While measures such as those discussed in later chapters of this report can and should be taken to manage the scientific and environmental risks of the technology, we consider careful thought should be given to the nature of the communication between scientists and others that should be an integral part of all management strategies. In his witness brief, Dr Cohen pointed out:

There are two major components of in the analysis of risk. Firstly the probability that something might occur and secondly the consequences that might follow in the event of

an occurrence. Scientific methods have been developed to evaluate and quantify both of these risk components. However, public perceptions of risk can arrive at completely different conclusions about both of these components.⁸⁶

120. Dr Cohen made reference to the perception of risk sometimes being modified by an “outrage reaction” if a strongly held opinion is challenged. The Commission had the opportunity of viewing a video on general principles of risk communication by Dr Peter Sandman, a social scientist from the United States of America.⁸⁷ Dr Sandman also referred to the concept of “outrage”. He suggested that the public viewed risk as being a combination of “hazard” and “outrage”, where “hazard” was the actual risk and “outrage” the public’s perception. Outrage, Dr Sandman suggested in his video, was as real, and therefore as measurable and manageable, as hazard. Since facts do not quench outrage, Dr Sandman’s basic message was to emphasise the need for communication, transparency, consultation and acknowledgement of the areas of scientific doubt and public concern.

121 There is clearly a high level of concern about the environmental impacts of genetic modification, not just among the public but also among some members of the scientific community. Much of the evidence we heard about the risks of genetic modification, although properly drawing attention to possible hazards and risk pathways of genetic modification, is however the subject of ongoing debate, and we heard evidence from other witnesses, particularly scientific witnesses, that the risks of adverse impact could be assessed and managed. Some of the claims of possible environmental and health damage were exaggerated or based on inconclusive research data or on unproven hypotheses.

122. The Commission found it regrettable, for example, that the research into the health hazards of genetically modified potatoes carried out in the United Kingdom by Dr Pusztai had not been completed and therefore was not subjected to the normal scientific process of review. It must, therefore, be considered inconclusive. Dr Elaine Ingham, a witness for the Green Party, suggested research she had conducted showed that a bacterium designed to digest crop remnants to produce alcohol, *Klebsiella planticola*, could have had catastrophic consequences had it escaped into the ecosystem, but this evidence was discredited.

123. The Commission acknowledges that many of the scientists who appeared before us are committed to ensuring a cautious approach to the development of genetic modification because of concern about its potentially negative impacts. We are concerned that a significant degree of polarisation appears to have developed within the science community between those who promote the benefits and therefore the use of genetic modification and those who stress the

risks of this technology. The public would be better served by balanced, informed public debate about the issues raised by research and their implications for the use of the technology.

124. Most of the Interested Persons who appeared before the Commission urging caution suggested that the risks of gene technology were such that further research must be carried out and more scientific knowledge developed before the hazards and risks of genetic modification could be properly assessed. Some clearly thought that, because of the inherent uncertainties of the technology, it was unlikely there would ever be sufficient knowledge to provide an adequate assurance of safety. The point of tension between those who saw genetic modification as having the potential to provide benefits to the environment and those who saw it as having potentially catastrophic impacts lay, therefore, in the belief or otherwise that the risks of the technology could be subject to current scientific risk assessment processes and risk management techniques.

125. Issues relating to genetic modification do not give rise to easy debate. Nevertheless, we consider all the stakeholders in biotechnology should be prepared to continue the exchange of views and information that has been an important part of the Commission's process.

chapter |

5.

Economic and
strategic issues

5. Economic and strategic issues

Key question:

Will genetic modification technology enhance or damage New Zealand's economic and strategic prospects in terms of:

- international competitiveness
- the knowledge economy
- trade?

Purpose of this chapter

1. The Warrant states that the Commission may investigate and receive representations about (among other things):

... economic matters (including research and innovation, business development, primary production, and exports).

2. The broad macroeconomic issues and the future strategic direction of New Zealand have pervaded the discussions of the impact of genetic modification. In chapter 2 (A shared framework of values) we looked at the values we consider relevant in the debate about genetic modification. Of those values, those most relevant to this chapter are “being part of a global family”, “the well-being of all” and “freedom of choice”. In this chapter we discuss and attempt to balance the many perspectives we heard on economic and strategic issues.

3. This chapter contains points made by submitters that we consider important and on which we will draw in making our major conclusions in chapter 13.

4. Some submitters contended that to have no genetic modification technology in New Zealand would have negative net effects on the New Zealand economy. Others stressed that New Zealand's organic economy should be allowed to fulfill its potential, and that New Zealand's “clean green” image should be enhanced rather than undermined. We are aware that all systems of agriculture are currently evolving and interacting positively with each other. The question of international consumer preferences in our export markets is important to New Zealand's future. We consider that they cannot be accurately predicted at this time and we want all

sectors of the economy to be able to grow to meet export demand, whatever it may turn out to be.

5. The table below shows New Zealand's commodity exports as a percentage of total exports, and the percentage growth in each export sector from the year ended February 2000 to the year ended February 2001. Major commodity exports dominate, with "milk and milk products" the largest of these.

New Zealand: Exports of Main Commodities

Commodities fob, including re-exports, data for 12 months ended February*		
Commodity	% of total, year to Feb 2001	% increase, year ended Feb 2000 to year ended Feb 2001
Milk and milk products	20.1	33.7
Meat and meat products	12.7	22.7
Wood and wood products	9.5	27.2
Mechanical & electrical machinery and equipment	7.7	26.7
Wool, leather and textiles	7.0	19.0
Fish and seafood	4.4	9.4
Aluminium and aluminium articles	4.2	26.3
Fruit and nuts	3.7	0.6
Petroleum and petroleum products	2.0	61.6
Iron and steel and articles	1.7	8.1
Other commodities	26.8	3.8
Total merchandise exports	100.0	
Average % increase, 2000 to 2001		24.0

*Data for December 2000, January 2001 and February 2001 are provisional.
Source: Statistics New Zealand. fob = free on board.

Will genetic modification technology enhance or damage New Zealand's economic and strategic prospects?

International competitiveness

Likelihood of enhancement

6. Some submitters, particularly producer boards and some private companies, believed that genetic modification technology would be important for New Zealand in maintaining its international competitiveness. The Association of Crown Research Institutes [IP22] considered in its written submission that:

New Zealand's future can only be assured if it can develop new competitive products and services able to capture premium prices because of the nation's capacity to innovate. ... genetic modification technologies provide a rare opportunity for New Zealand to position itself in the global competitive economy. The key to a bright future is for New Zealand to capture the benefits of research, science and technological innovation.¹

7. Many submitters said New Zealand's international competitiveness would be enhanced by use of genetic modification technology. The New Zealand Forest Industries Council [IP9] and Carter Holt Harvey/Fletcher Challenge Forests [IP17] both said in their submissions that biotechnology can make an already sustainable industry even more sustainable by improving profitability and environmental performance and enhancing international competitiveness.

8. New Zealand Biotechnology Association [IP47] considered in its submission that genetic modification had the potential to "lift New Zealand's economic performance and quality of life",² while New Zealand Vegetable and Potato Growers' Federation/New Zealand Fruitgrowers' Federation/New Zealand Berryfruit Growers' Federation (Vegfed, Fruitgrowers, Berryfed) [IP75] told us that genetic modification offers the potential to reduce production costs through a reduction in inputs. These lower production costs are likely to improve New Zealand's international competitiveness and result in a higher level of investment, giving higher production, employment and export opportunities.

9. In its written submission, Genesis Research and Development Corporation [IP11] explored the matter of international competitiveness in some depth in examining the possible benefits of genetic modification technology to New Zealand. Genesis Research and Development considered these to be:

- Immediate job creation as part of the knowledge economy. Almost all these positions were new jobs to the economy, and most staff were well qualified

and well paid. There would also be downstream employment effects from these new jobs.

- Expansion of the highly skilled workforce. The average age of the workforce in a start-up biotechnology company was typically young, and many new or recent graduates were employed. According to the 1999 World Competitiveness Report, well-qualified New Zealanders were twice as likely to emigrate as those in the United States. Technology companies such as those in the biotechnology sector would help limit this brain drain of science graduates.
- Attraction of foreign investment and shareholder wealth. New biotechnology companies often traded at a loss in their early years until they could make income from royalties or sales. During this time they might be financed by investment from overseas partners. Successful products would create wealth for New Zealand shareholders and also contribute directly to the New Zealand economy through the payment of tax and other effects.
- Maintenance of a competitive economy. Genetic modification technology was research and development intensive. Investment of this type was being made in various parts of the world. The prerequisite to enter this growing economic sector was venture capital, an innovative research idea and a skilled workforce. All of these elements, not least the skilled workforce, were very mobile between developed nations.

10. New Zealand Biotechnology Association considered in its written submission that genetic modification technology would benefit all New Zealanders because of its positive impact on the national economy, and the resultant increase in our standard of living. Conversely, if we turned away from genetic modification our country would lose ground to the developed nations of the world, and we would all be subjected to a decline in our quality of life.

11. At hui, public meetings and in the formal process, some Maori groups expressed a willingness to consider the use of genetic modification technology on their land. The Federation of Maori Authorities (FoMA) [IP69] said in its written submission that, while there was much that was not yet understood about biotechnology, theoretically at least, it could be of great use to Maori. It was potentially a means of managing the commercial operations of Maori authorities in a sustainable and ecologically sound way; reducing production costs and improving product quality, thereby increasing earnings.

12. FoMA made other points about the potential economic benefits of genetic modification to Maori, saying that those Maori landowners who were in a position to do so could invest in and undertake joint ventures with biotechnological

research and development companies. It also considered biotechnology should be recognised as a potential catalyst for further productivity throughout the primary production industries and for greater economic growth in the domestic New Zealand economy.

13. In its public submission, Te Puni Kokiri noted possible economic benefits for Maori from genetic modification:

Maori could possibly gain some economic benefits from the genetic modification of plant and animal stocks. For example, some Maori corporates and landowners could benefit from genetic modification, research and development, and as users of resulting genetically modified organisms.³

Chances of damage to New Zealand’s economic prospects

14. A range of submitters, in particular those from the organics sector, expressed deep concerns to the Commission about the possible negative economic impacts of genetic modification in primary production on the future of New Zealand’s export industries. The Organic Product Exporters Group (OPEG) [IP53] represents nearly all companies currently exporting organic products from New Zealand and includes all organic certifiers.

15. OPEG, in its written submission, said consideration should be given to the negative implications for organic producers of the commercial use of genetic modification technologies in primary production. OPEG foresaw potential damage from genetically modified organisms being released into the environment: contamination of organic products, the reputation of New Zealand’s organics industry and the erosion of the “clean green” image of New Zealand, so important for marketing New Zealand’s products and services. OPEG stated that, if organic products were contaminated by genetically modified elements, organic certification for the product would be lost as no current organic production standards in New Zealand allow for such contamination. It also believed that companies’ reputations, brand values, and the market reputation of the whole organics sector, would suffer if contamination were to occur. OPEG considered the negative effects would extend to other sectors similar to organics. These included Integrated Pest Management (IPM) systems, conventional producers not using genetic modification and the tourism sector.

16. Dr Caroline Saunders, Associate Professor of Commerce at Lincoln University, and a witness called by OPEG, told us that an economic analysis of the performance of genetic modification in primary production in New Zealand could not be carried out as genetically modified organisms had not been commercially released here.

17. Looking at overseas evidence, Dr Saunders noted: “Despite current commercial release of genetic modification benefiting producers in reducing costs and/or increasing yield, how far this has translated into actual increased producer returns is questionable”.⁴ She also noted the definite shift in consumer preference away from genetically modified food and the increased demand for genetic modification-free food, particularly in the Japanese markets and the key retail outlets in Europe. Dr Saunders said economic impacts of genetic modification included some benefits, such as the patents developers of technology might be able to obtain. However, she commented that these benefits might be less certain for New Zealand as most of the marketing and developers of technology were overseas.

18. The written submission from ZESPRI International [IP46], the marketing organisation for New Zealand kiwifruit, expressed concern about the potentially negative impact that commercial genetic modification production might have on New Zealand’s kiwifruit industry, particularly on exports to Europe, Japan and Southern Asia.

19. The written submission from the New Zealand Council of Trade Unions [IP95] stated “New Zealand should not allow the release and commercial application of genetically modified organisms as the damage to our trade could be of great significance”.⁵ The Council of Trade Unions noted that 70% of New Zealand exports were currently based on primary production and were principally exported to developed country markets. The Council was concerned that continued access to these markets might be compromised by a genetic modification-based exporting strategy “unless there is a startling turnaround in consumer perceptions of the acceptability of genetic modification foods at the niche end of the market”.⁶

20. Similarly, the Royal Society of New Zealand [IP77b] stated in its written submission that current economic analysis of the use of genetically modified organisms in commercial land-based production of food, fibre and nutraceuticals suggested “there may be benefits if New Zealand delays a decision on commercial release”.⁷ The Royal Society noted that the first wave of genetically modified food products had performed poorly in global markets and that this situation was unlikely to improve in the medium term.

21. Dr Hugh Campbell, a social geographer called as a witness by OPEG, introduced to the Commission the term “the greening trajectory” which encompasses organic production and IPM. Dr Campbell told the Commission that the comparative advantages for New Zealand from the use of these techniques were “moderately good” because of the high natural endowment of its growing

environment, its established international linkages and its early market position, but that for genetic modification techniques there were few comparative advantages for New Zealand.

22. Dr Campbell said that the introduction of genetic modification organisms into the environment would have several impacts at the level of the individual grower:

Organic producers already face costs resulting from a variety of testing procedures to prove the purity of their product. However, the extent and cost of testing for possible genetic modification contamination is not known. Some current testing regimes cost organic growers up to \$1000 per annum, but it is speculative as to whether genetic modification tests would cost a similar amount.

It is important to note that a limited genetic modification industry operating as a minority aspect of some sectors would not destroy organic production through physical contamination by genetic modification crops and no members of the organic industry make such a claim. There are clearly extra costs that would be imposed but these would not be overwhelming to the majority of organic growers. The threats posed to organics only escalate dramatically if genetic modification production becomes widespread.⁸

... the emergence of pest resistance cannot at this stage be calculated without knowing the extent and nature of potential genetic modification horticultural crops. Any impacts that might eventuate, however, would have considerably larger economic implications for IPM crops than for organic due to the mere scope of these developments.⁹

Being technologically ready

23. Many producers significant to the New Zealand economy told us they wanted to keep their options open by being ready for changing international market demand and not lose ground in comparison with their international competitors. For example, New Zealand's producer boards would like to be able to carry out research that would enable them to have the technology ready to apply, if in the future the international market demand shifted in favour of tolerance of genetic modification. Vegefed, Fruitgrowers, Berryfed told us that:

The organisations we represent have in the past two or three years been through ... a detailed foresighting process ... and, probably one of the overall issues that's come out of that whole process is this concept of being technology ready. The Industry needs the people, it needs the science, and it needs the capability to maintain those so they are there to use when we're ready ... the industries haven't specifically referred to genetic modification and gene technology in that area, but it is one of a number of areas where we believe we need to be technology ready.

So, able to service the market at short notice, rather than having to build capability to be able to service the market. By the time we build the capability to get there, someone is likely to have beaten us to the market. So, we need to be technology ready, we need to be able to deliver these products very quickly into international markets.¹⁰

24. Warren Larsen, Chief Executive Officer and a witness for the New Zealand Dairy Board [IP67], told us under cross-examination that the Board would like to be able to use the technology:

... tomorrow, or today, because the opposition are clearly moving fast down this path. And what's happening is that unlike in the past few years where a big multinational corporation would try to spread its efforts over all of the categories, we observe now where they are specialising in particular areas. One in processed cheese, another in ice cream, another in fats and oils, another in liquid milk and another one in chilled dairy desserts and yoghurt. Now, we are trying to carve out a niche for ourselves globally as well, and these players are getting bigger, they are occupying these segments in depth, their knowledge capability unashamedly is their key objective, and we cannot afford to not be in that race. So, all of this knowledge and capability, we really need now. And I... think we ... have been slow to really grasp the nettle in a biotechnology area.¹¹

25. Dr Kevin Marshall, Group Director for Global Research and Development, added that:

Our competitors are moving very rapidly. We have been told that Nestle, one of our big competitors, has something like 100 people working in this area of gene technology. We will rapidly get behind if we don't move quickly.¹²

26. John Yeabsley, a Senior Fellow of the Institute of Economic Research and a witness for the Dairy Board, expanded on this issue in his witness brief:

Competitors are continually looking for new ways to replicate success so as to transfer the value in existing NZDB business to themselves.

So looking closely at all the future options for development is an important part of ensuring that the New Zealand dairy industry fully capitalises on the present advantageous position it has reached. Biotechnology, poised as it is on the verge of changing the workings of many markets, is an obvious avenue to pursue; and one in which it would be expected that the NZDB would have a relative advantage.

... there seem to be degrees of concern among potential consumers as to where the products fit into their preferences. A reasonable presumption might be that there would be fluidity in people's views for some time. In the meantime, there will also be additions to knowledge about the potential and actual modes of employment, as well as the risks of, biotechnology. So the businesses with prospects in this field have to remain in a position to react to rapidly evolving science, which may offer bright prospects, and equally to shifts in consumer sentiment, which could also be radical.¹³

27. The New Zealand Wool Board [IP30] said in its submission that New Zealand should have a strategy that:

... allows farmers and companies to pursue GM opportunities where they offer advantages, ... the successful producers will be those that are responsive to the trends in world markets – which will all be moving, but in unpredictable directions and at unpredictable speeds.¹⁴

28. The Commission fully endorses these views and agrees that New Zealand should be in a position to take advantage of emerging international trends and have every opportunity to maintain and enhance its competitiveness.

Commodity or niche products?

29. Some submitters suggested that as a country New Zealand should move the focus of its exports away from commodity products, which tend to be produced in large quantities and are sold in a relatively undeveloped state. They favoured the production of a wider range of value-added products targeted towards niche markets, where higher prices could be obtained because of the specialised nature of the products.

30. We note from the written submission of AgResearch [IP13] that returns from many of New Zealand's commodity exports have dropped because of a steady decline in commodity prices for the last several decades. This has forced New Zealand to look for new opportunities from which to gain leverage from its primary production base, to develop new niche products with high added-value returns, many of which could be based on genetic modification and other biotechnologies. Veterinary and human medicines are included among new high added-value niche products generated by genetically modified animals or crops. In the opinion of AgResearch, opportunities like these are vital to a competitive agricultural sector, besides allowing a reduction in chemical inputs to high-volume food and commodity crops. HortResearch [IP5] made similar points in its submission, saying that New Zealand could not base its future on commodity production.

31. The perception of commodities and niche products as mutually exclusive alternatives was seen as a “red herring” in Dr Janice Wright's background paper on the economics of genetic modification.¹⁵ Dr Wright said that New Zealand already had a mixed economy in which both commodity and niche products are important. The Green Party of Aotearoa/New Zealand [IP83] took this view in its submission also, saying that the choice was not a black and white one.

32. Similarly, Dr Wright said that to see the adoption of genetic modification technology and a national commitment to organic agriculture and horticulture as alternatives was another “red herring” choice. In reality a decision to refrain from

genetic modification was very different from a decision to “go organic”. Currently we had a mixed economy that included non-genetically modified, land-based conventional production, IPM production and an organics sector.

33. However, Dr Alex Sundakov, a witness called by the Wool Board, commented that:

Over time all niche businesses become commodities. For example, one of the cheapest commodities in the world today is the personal computer. Moreover, as particular product features become widespread, they tend to turn from an advantage to a liability. For example, being able to trace product origin back to the farm initially offered some producers a competitive advantage, and attracted a price premium. However, since traceability has become a general requirement, it no longer confers any premium, but continues to impose costs ...

In competitive agricultural markets, commodity prices generally tend to reflect production costs. For example, as production costs of “organic” foods decline, so do their prices. The increased availability of such foods also reduces their profitability. To the extent that world markets do not require their products to be genetic modification free, reduced costs arising from genetic modification will lead to lower prices.¹⁶

34. Dr Sundakov suggested that, from an economic point of view, the best strategy would be to allow producers to make their own assessments of market trends and opportunities, thereby “taking a large number of bets” and enabling New Zealand to adapt to changing market situations:

In the face of uncertainty over demand patterns, supply patterns and prices in world markets, economic analysis suggests that it would be a high cost strategy to ban the release of genetic modifications. New Zealand needs to be able to pursue all opportunities for selling products at the best prices whether genetic modification or not; so long as producers using genetic modifications do not contaminate the production of genetic modification free producers. New Zealand will make the greatest gains from investing in lots of innovations aimed at all the world markets as they evolve, rather than by restricting itself from the new techniques when possible harmful effects on other parties and the environment can be contained or managed in other ways.¹⁷

Costs of avoiding genetic modification technology

35. We heard evidence that New Zealand faces significant economic risk from complete avoidance of genetic modification technology. Avoidance would impact particularly heavily on industries focused on research, on research institutes and on universities.

36. The Dairy Board expressed concern in its submission, echoed by others, that: The major social and economic risk to New Zealand (and to the New Zealand dairy industry in particular) is that the New Zealand dairy industry will be prevented from developing

and using genetic modification, while its competitors are not. The New Zealand dairy industry is uniquely placed to benefit from research and development into, and possible commercial use of, genetic modification technologies. These are essential tools to the New Zealand dairy industry in maintaining its competitive position. If the New Zealand dairy industry is prevented from using these tools, they will be locked up by the very type of multinational corporation seen as posing a threat. The threat to New Zealand from such corporations will be increased, not decreased, by a ban on genetic modification use.¹⁸

37. The Association of Crown Research Institutes said in its submission that “the economic risks in avoiding genetic modification were significant as the technology offered significant strategic opportunities for New Zealand. The benefits from niche genetic modification products flowed on to all New Zealanders.”¹⁹ HortResearch said in its submission that it believed it had a responsibility to maintain its research in this area to keep strategic options open for New Zealand horticultural industries in the future.

38. New Zealand Forest Research Institute [IP2] told us that “if New Zealand wishes to play a role in international forestry science, it needs to be researching at the forefront of technology. Similarly, New Zealand’s forest industry will suffer a loss to its competitive advantage if it is prevented from applying state of the art technology.”²⁰

39. Lincoln University [IP8] considered in its written submission that denying access to genetic modification techniques would deny researchers access to valuable research information and reduce significantly the ability of individuals to develop their research to a high intellectual standard, and of industries to develop their products and markets.

40. Some submitters such as Biotenz [IP25] expressed concern that, if there were increased levels of regulation of research involving genetic modification, this would ultimately be paid for by the taxpayer through higher research costs, and by the consumer through higher prices. These increases in cost had to be balanced by a comparable increase in the level of safety provided by the increased degree of regulation. A comparable point was made by Matthew Kent, a PhD student and witness appearing for Lincoln University, who claimed that additional regulation would manifest as reduced scientific productivity, the suppression of scientific inquiry, the migration of professional scientists overseas and a reduction in student quality and performance within New Zealand. Mr Kent considered that both in the long and short term any additional restrictive changes in legislation would adversely affect the image and quality of science, and would result in a significant economic and social loss to New Zealand.

“GE-Free” and exclusively organic farming options

41. Many submitters suggested the best strategic direction for New Zealand was to be free of genetic modification. For example, Commonsense Organics [IP66] considered that “New Zealand has the opportunity to ‘brand’ itself as genetic modification-free with particular benefits to the expanding organic industry”.²¹ The Royal Forest and Bird Protection Society, Marlborough Branch [IP40] agreed that “New Zealand could obtain a global economic advantage from maintaining GE free agricultural and horticultural crops”.²²

42. The Bio Dynamic Farming and Gardening Association in New Zealand [IP61] considered in its written submission that strategic outcomes and opportunities would arise from New Zealand being an organic nation. It believed New Zealand should be exploiting its natural resources in a sustainable manner and that, although not in a position to be able to feed the world, New Zealand was in a perfect position to be able to offer to the world the world’s “best holistic food quality”.

43. In her public submission, Ute Bassermann said the demand for organically grown, genetic modification-free products in Europe was big: “Here I see a good chance for New Zealand to better its negative trade balance. Organic food production offers great opportunities for many healthy, worthwhile workspaces. New Zealand can finally live up to its clean green image by becoming an organic nation by 2020,” she said.

44. The Pesticide Action Network New Zealand [IP87] believes that New Zealand should become genetic modification-free, not allowing any outdoor genetic modification technology or commercial developments, and that instead we should channel our energies towards becoming an organic nation.

45. The Green Party said: “Given the trend in the demand for organic products, the Green Party believes that releasing genetic modifications into our environment would squander a great opportunity to develop a perfect niche for New Zealand.”²³

46. Dr Saunders considered that New Zealand had a unique position. As an island nation without the threat of cross-pollination from genetically modified crops it could maintain a genetic modification-free status, unlike many continental countries. Even countries like the United Kingdom had problems with the cross-pollination of canola and other crops. New Zealand was thus uniquely placed to take advantage of any shift in consumer preferences towards genetic modification-free food. In accepting genetic modification there was a risk of losing this genetic modification-free status.

47. In his public submission, Andrew Hubbard stated that because of its geographic isolation and consequent ease in applying strict biosecurity, New Zealand was one of few countries that would be able to guarantee genetic modification-free food.

48. Some Maori expressed a preference for organic methods. Toko Te Kani (Ngai Tamanuhiri), Chair of the Turanganui-a-Kiwa Kaumatua Council, speaking at the Gisborne regional hui, told us:

If I had my way, I'd totally ban all herbicides and the use of sprays in that form and encourage everyone to go into organic farming. Since the advent of organic farming through the likes of Watties and those sorts of firms ... with sweet corn locally, the returns have been much higher than ordinary sweet corn. Same with tomatoes.²⁴

49. At the Ngaruawahia national hui, Teremoana Jones (Nga Puhī) represented Te Tai Tokerau Organic Producers Incorporated Society (TOPIS). She told us that:

TOPIS opposes absolutely any activities that modify or assist in modifying in any way the gene compositions of flora and fauna either native or introduced ... TOPIS was formed over several years ago by a group of concerned citizens, both Maori and Pakeha in the Tai Tokerau who are concerned enough to want to grow a clean uncontaminated food.

The members of TOPIS represent a diverse range of interests, namely fruit growers, livestock farmers, honey producers, forest growers, agriculture, both salt and fresh water [fisheries], aroma therapy, essential oils, poultry farmers, earth worm farmers, flower growers, compost processors, organic producers, dairy producers and animal breeders. TOPIS policy: we oppose the field testing or production of any genetically modified food, food produce or food product.²⁵

50. At the Rotorua regional hui, Poihaere Morris (Ngati Awa) said:

That is where the Maori can lead the way because we have a lot of whenua that is just sitting there. Part of my project is gathering all the resources, the networks out there that can teach us how to turn our whenua to BIO-GRO certification. There's an opportunity there for anyone who wants to look at organics for the export market.²⁶

51. Te Runanga o Ngai Tahu [IP41] expressed its abhorrence of genetic modification and said it believed the benefits and control of this technology would accrue to "national and multinational companies, universities and researchers".²⁷ It stated that this loss of control would mitigate against its ability and desire "to act as kaitiaki for Te Runanga's taonga".²⁸

52. The Commission heard considerable emphatic evidence in favour of organic agriculture. Zelka Grammer, a tamarillo orchardist and nursery owner called by the Bio Dynamic Farming and Gardening Association, told us about her target market: "We seek the high end of the market for our exports, the

wealthy people with the means to buy the best food. Are they going to pay a premium for GE tamarillos?”²⁹

International obligations

53. Some submitters advised the Commission that a ban on genetic modification foods, crops, seeds, or imports of these or other genetically modified goods may put New Zealand in breach of its commitments under the World Trade Organization (WTO) and invite retaliatory actions by our trading partners.

54. Dr Campbell summarised the measures other countries had taken to protect their domestic agricultural industries and to allay the fears of consumer groups in their countries:

The WTO in recent years has attempted to move towards tariff reduction, and avoid the development of technical barriers to trade (TBTs). However, since 1995 there has been a tendency for European Union and Japanese mechanisms of trade protection to move away from TBTs in the form of tariff and price support, towards what is termed “green protectionism”. Green protectionism involves the indirect support of domestic agricultural producers, and the political appeasement of urban consumer group fears, by slowly increasing “environmental” and “food safety” criteria used to penalise food imports ...³⁰

55. Submitters told us they feared that if New Zealand banned genetic modification technology in its imports from other countries, those countries would use measures such as “green protectionism” against New Zealand’s exports. Horticultural exporters from New Zealand had begun to identify green protectionist barriers as early as 1992, and the emergence of these barriers had intensified since then. The WTO had attempted to control these measures stringently by identifying them as TBTs. A significant current trend in market access was the emergence of green protectionist barriers against products such as genetically modified imports.

56. In its written submission the Meat Industry Association of New Zealand [IP32] said that although retaliatory barriers could be imposed against New Zealand’s exports, it would not be easy to do so. Any retaliatory steps by other countries to limit food imports from New Zealand must be justified by sound science and could not be of indefinite duration. The Meat Industry Association also said that New Zealand would imperil its trading future by reneging on its international trading commitments unless there was persuasive evidence that genetically modified organisms were injurious to animal, human or plant health. Similar points were made by the New Zealand Dairy Board in its closing submission, by Federated Farmers of New Zealand [IP34] and others.

57. ZESPRI made a different point related to New Zealand’s international obligations, saying in its submission that if New Zealand were to allow

commercial genetically modified food production, “adverse consumer opinion and retail trade action [in our export markets] could lead to non-tariff barriers to market access” which “would jeopardise over NZ\$700 million pa in kiwifruit export turnover, and \$400 million of export earnings”.³¹

58. In her background paper,³² Dr Wright made a third point about New Zealand’s international obligations. She explained that the Environmental Risk Management Authority (ERMA) was required to perform an economic analysis to take account of the economic and related benefits to be derived from the use of a hazardous substance or new organism. In addition it was also required to take New Zealand’s international obligations into account in assessing an application for the release of a genetically modified organism. If the economic analysis showed that the release of the genetically modified organism would not provide a net benefit to the New Zealand economy (a plausible scenario if the applicant was based overseas) and the application were rejected, there would possibly be grounds for a complaint to the WTO. Dr Wright submitted that the requirements for ERMA to consider economic benefit to New Zealand and to take international obligations into account might be in conflict.

59. A number of submitters drew attention to the point that, besides obligations under the WTO, New Zealand had commitments under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). Article 27 of the TRIPS Agreement required members to recognise both product and patent processes without any discrimination as to the type of technology, including biotechnology. In biotechnology, product patents had been granted on, among other things, DNA sequences, genes (including human genes), microorganisms, transgenic animals and plants. Processes involving fundamental techniques in recombinant DNA technology had also been patented.

60. The Ministry of Foreign Affairs and Trade pointed out that Article 27.3 (b) [of TRIPS] stipulates that members may allow their national patenting system to exclude plants, animals and essentially biological processes from being patented. They must, however, provide patent protection for microorganisms and microbiological and non-biological (inventive) processes. The Pacific Institute of Resource Management [IP84] suggested that Article 27.3 (b) should be amended to prevent such exclusion. The Safe Food Campaign [IP86], on the other hand, said that the global flow of resource possible under TRIPS had the potential for the exploitation of New Zealand’s “biological, intellectual and cultural heritage”.

61. The Ministry of Foreign Affairs and Trade noted that the debate surrounding the patenting of life forms was contentious, and was continuing in the context of a current mandated review of Article 27.3 (b). Another issue arising from this

Article was “farmers’ rights”, or the ability of farmers to save seed where that seed was the subject of intellectual property rights. These themes had arisen in other international forums and discussions were continuing.

Consumer preferences

62. Perceptions and preferences among consumers in our major export markets will largely determine the degree to which New Zealand’s exports will be in demand on the international market. ZESPRI quoted in its written submission consumer research studies around the world that had shown a significant level of concern about genetically modified foods. Concern was greatest in Europe but existed in Japan and to a lesser degree in other Asian countries and the United States. ZESPRI’s marketing staff in Europe had confirmed the adverse reaction of consumers to genetically modified food.

63. OPEG made a similar point in its written submission, saying that currently there is a high level of consumer resistance to the consumption of genetically modified food in many of our significant agricultural export markets. Research in 2000 by Dr Campbell suggests that this consumer resistance is increasing and has developed even to the level of a food scare that may take a considerable period of time, if ever, to change.

Economic modelling

64. We received a small number of submissions that included econometric models that attempted to show the perceived future effect of degrees of genetic modification entering the New Zealand economy. Dr Saunders used a partial equilibrium model to explore three different scenarios. These involved varying levels of consumer preferences in our international markets for genetically modified food, a drop in production costs for producers of genetically modified food, and farmers in New Zealand and certain other countries either converting to genetic modification to some extent or remaining genetic modification free. The results obtained by Dr Saunders from modelling these scenarios suggested that if international consumer preferences moved away from genetically modified food, producer returns would increase, and that New Zealand would not have a competitive advantage in genetic modification food production.

65. Dr Adolf Stroombergen, a witness called by the New Zealand Life Sciences Network [IP24], also presented results from an econometric model. Dr Stroombergen used a general equilibrium model to explore six alternative scenarios involving:

- increased productivity and lower production costs because of varying degrees of use of genetic modification techniques (two scenarios)

- sales from the genetic modification research industry stimulating the New Zealand economy
- agricultural benefits from genetically modified possum immuno-contraception
- the rejection of genetic modification in New Zealand to varying degrees concurrent with the rest of the world embracing it
- a complete genetic modification moratorium.

66. Dr Stroombergen's results suggested that if New Zealand embraced genetic modification there would be a positive effect on GDP, exports and employment, while the avoidance of genetic modification would lead to decreases in these variables.

67. Dr Stroombergen also pointed out that while organic products might always be more expensive because of higher production costs, economic principles suggested that any excessive profits associated with organic production would be short-lived:

Very high premiums of 50% or more for organic products only occur in very small markets. As soon as the market expands, the price premium declines. This is nothing more than standard supply economics. There may always be a price premium for organic products simply because they tend to be more expensive to produce, but any super-normal profits will eventually be eroded as new organic farmers enter the industry. It is not credible to believe that New Zealand can secure high net returns through supplying organic products to world markets whilst competing countries (such as Denmark and the Netherlands which have significant organic sectors) do nothing. An entirely organic farming sector in New Zealand is thus not a plausible scenario, even if there were no conversion delays and even if biotechnology delivers no benefits other than lower production costs – both extremely unlikely.³³

68. Similar points were made by Dr Sundakov, who gave evidence for the Wool Board and for the Meat Industry Association. He said that the New Zealand meat industry could maintain its “natural image” despite any presence of genetic modification research in the country and that, based on economic principles, a complete ban on genetic modification in New Zealand would enhance meat export markets to a very limited degree, mainly because competing markets would be able to offer the same guarantee. He also pointed out that there were historical instances in the United States where consumer resistance to a technologically enhanced food had decreased, such as to meat from animals that had been injected with bST growth hormones to enhance milk production.

69. The Commission notes that whether or not genetic modification may be of economic benefit to New Zealand will be largely determined by the degree to

which consumers in our export markets prefer, tolerate or reject genetic modification, and that witnesses who presented economic models made assumptions about this degree of acceptance, tolerance or rejection. We consider that it is too early to predict consumer reaction with any certainty.

70. We note, however, that economic reasoning suggests that it is not a realistic option for New Zealand to develop its organic sector at the expense of conventional farming and/or the use of genetic modification techniques, as in the long run it is unlikely that abnormal levels of profit would be made. We also note that while organic products may always sell at a price premium, one of the reasons for this is likely to be their higher production costs.

The knowledge economy

Intellectual capital issues

71. The effect of an avoidance of genetic modification technology on the skill levels of the New Zealand workforce was important to research institutes and universities. In considering New Zealand's strategic options, AgResearch said its experience indicated it was crucial to consider New Zealand's ability to recruit and retain the type of high-calibre scientists needed for leading edge research. It also believed that if New Zealand followed an option of excessive caution or restriction, its best and brightest young scientists seeking careers in the biological sciences would emigrate.

72. Landcare Research [IP12] told us it had about 10 staff directly using genetic modification and more than this again working on genetic modification-related research. If because of decisions on the use of genetic modification technology employment opportunities were foreclosed, these staff would leave New Zealand to further their careers overseas. This loss of talent would mean Landcare Research's ability to achieve its strategic intent, as agreed with the shareholders in its statement of corporate intent, would be markedly reduced. The Institute of Molecular BioSciences at Massey University [IP15] made the point that an avoidance of genetic manipulation technologies in New Zealand would make it more difficult to recruit well-qualified staff because support for research requiring genetic modification technologies could be limited.

73. Besides staff retention, Professor Marston Conder, Deputy Vice-Chancellor (Research) and witness for the University of Auckland [IP16], mentioned that skill and knowledge retention would be important issues. Under cross-examination, Professor Conder emphasised "the importance of genetic modification technology to higher education and research, and in particular to the training of the students".

74. Several universities, such as the University of Auckland and the University of Otago [IP19], commented that genetic modification technologies were now crucial for the successful conduct of research and teaching to international standards in various fields including biochemistry, clinical biochemistry, molecular biology, medicine and some areas of engineering.

75. Lincoln University and the University of Auckland made the further point that with the globalisation of universities there was an increasing expectation from international students that universities would undertake research from a global perspective. Technologies such as genetic modification were accepted in all modern, technologically-orientated countries.

76. Dr Martin Kennedy of the Christchurch School of Medicine, a witness appearing for the Human Genetics Society of Australasia [IP59] and New Zealand Transgenic Animal Users [IP45], said that even now, under regulations associated with implementation of the Hazardous Substances and New Organisms Act 1996 (HSNO), researchers were having difficulty developing the transgenic mice required for their research and for this among other reasons had gone to Australia where the approval process was easier.

Intellectual property

77. The economic aspects of intellectual property in the context of genetic modification are centred around the tension between the cost of access to patented knowledge in the form of licence fees and the desire of propagators of knowledge to recover their costs, and to protect their investment and put it to profitable use. The possible concentration of knowledge in a few hands is an extension of this argument. These issues are explored more fully in chapter 10 (Intellectual property).

78. The ability to patent is relevant to a knowledge economy in that it provides skilled employment and enhances the national infrastructure. On behalf of the A2 Corporation [IP26], David Parker said that:

If New Zealand can create ideas which have intellectual property protection, in the form of patent protection, then the potential revenues to New Zealand of commercialising those ideas internationally are often significant.³⁴

New Zealand's "clean green" image

79. BIO-GRO New Zealand [IP58] said that New Zealand would gain a very strong advantage from being able to brand all its food products as genetic modification free.

80. Many submitters told us that the introduction or release of genetic modification into New Zealand would have a negative effect on our “clean green” image which was used formally as a branding tool for international marketing, and which also contributed to New Zealand’s international reputation as a tourist destination.

81. For example, OPEG said the introduction of genetic modification technologies posed indirect risks by devaluing the market’s perception of New Zealand’s “clean green” image, an image of significant value in the positioning of New Zealand organic product exports. The Royal Forest and Bird Protection Society of New Zealand [IP79] considered that:

... in addition to our productive systems being underpinned by healthy ecosystems, our “clean and green” environment is a major selling point in itself and will reap increasing rewards in the 21st century. New Zealand primary producers target customers who enjoy high-quality products that come from a healthy and unpolluted environment. This is also the foundation of our tourism industry. However, our increasingly demanding international clients expect the green image to be backed up by reality.³⁵

82. The Nelson GE Free Awareness Group [IP100] said “many tourists are looking for the clean green image”.³⁶

83. There was concern that a change from New Zealand’s current position of no genetically modified organisms in open release would mean New Zealand’s export markets would suffer significantly. ZESPRI told us that its marketing research suggests that a perception of genetic modification status for New Zealand food production will influence the buying behaviour of consumers for all New Zealand products. Russell Simmons, an organic dairy farmer and a witness for Bio Dynamic Farming and Gardening Association, maintained that the customer perception of a “clean green” New Zealand will be dealt a devastating blow with any release of genetically modified organisms into our environment.

84. Te Runanga o Ngai Tahu said in its submission:

The world looks to New Zealand to be clean and green, its future must be based on that, niche marketing, adding value and providing to the world those things the rest of the world has lost.³⁷

Branding

85. We heard from several submitters that New Zealand’s “clean green” image is used internationally for branding and that it has considerable commercial value. Dr Sundakov told us that the New Zealand meat industry had invested heavily over the years to build a valuable international brand image, which included the perception by consumers that New Zealand meat is produced in

a natural environment, and that this branding generates premiums for New Zealand producers over similar products from other countries.

86. We also heard that if genetic modification were introduced into New Zealand this might have a negative effect on this image and branding. Vegefed, Fruitgrowers, Berryfed asked us to be conscious of the potential economic impact that the first commercialised genetically modified crops might have on New Zealand’s “clean green” image. While not meaning to imply that genetic modification was necessarily “un-clean and non-green”, it considered that “clean and green” was a real marketing tool which might be affected by association with genetically modified crops in New Zealand.

87. Dr Saunders said that New Zealand’s “clean green” image had enabled it to: ... target, maintain, and grow market share. The production of genetic modification food, given current attitudes, may well not be compatible with these markets and this image. This broader branding of New Zealand as clean and green provides benefits to a range of industries, not least of which is the growing organic food industry. While it is certainly possible that individual food production sectors could position themselves as genetic modification or genetic modification-free (with appropriate regulatory protocols to separate the two), this “mixed marketing” strategy may not work.³⁸

88. We also heard that New Zealand’s “clean green” image has a variety of meanings, and that its value in branding is as a perception, rather than a defined reality. For example, Colin Harvey of New Zealand Agritech [IP73] stated that:

There is much debate ... as to whether we are clean green organic or clean green free roaming animals, pasture green. ... I personally see ourselves as being clean green free ranging animals grown on pasture ... animal welfare is an important aspect of clean green, and so is the pasture base of that, but I don’t necessarily see it’s saying they are chemically free, because we have significant problems, for example, with internal parasites in New Zealand. We can’t as yet rear animals ... on an economic basis that are truly chemical free.³⁹

89. John Guthrie, a Demeter-certified Bio Dynamic® grower and witness for the Canterbury Commercial Organics Group [IP65], said he considered New Zealand already lacked credibility as a “clean green” country, and that this had been highlighted in a recent tourism report.

90. In the opinion of Dr Morgan Williams, the Parliamentary Commissioner for the Environment [IP70], all forms of agriculture in New Zealand are undergoing a process of evolution that is taking all agricultural systems towards a more “ecological” approach. Dr Williams also observed that all are important to New Zealand’s future, that the boundaries between them are not necessarily fixed, and that advances in one form of agriculture have positive influences on other forms.

Organic economy in New Zealand and overseas

91. Dr Campbell provided some background information about the current and possible future values of the organic economy. His research results suggest that:

... the value of the New Zealand organic export industry will reach NZ\$60 million at the end of 2000. This combines with a domestic market estimated at NZ\$32 million in 1999 to represent a total market of NZ\$92 million (up from NZ\$3 million in 1994). One non-organic industry manager predicted that organics may “peak” at 20% of national production.⁴⁰

92. Dr Campbell went on to say that such predictions could not be confirmed as they depended on how New Zealand agriculture and horticulture developed. As an example, two potential scenarios might be considered:

- If organics remained a predominantly horticultural phenomenon, the industry could reach between 10% and 20% of horticultural production. These levels had been reached in several mature organic production sectors in Europe. For New Zealand, this would indicate a maximum value of NZ\$170–340 million in exports.
- If organics became established in pastoral industries, the potential mature value of organic exports would be vastly larger if even 10% of production was converted.

93. In general, organic market reports showed that the land dedicated to organic production, and the demand for and profits from organic products, increased significantly worldwide in the latter half of the 1990s. The organic market was expected to continue to grow throughout the world at an estimated average annual rate of between 20% and 25%, although some predicted that market growth would reach 40%.

94. Dr Campbell’s overall conclusion about the use of genetic modification technology in New Zealand was that it seemed unlikely a pluralist strategy could work if New Zealand intended to utilise genetic modification technologies as a widespread component of horticultural production.

95. James Kebbell of Commonsense Organics, a large organics retail outlet, provided further detail about aspects of the organic economy in New Zealand, saying that organic production and sales were growing at a very fast rate, globally and in New Zealand. Globally the growth was in excess of 30%. The average annual growth of Commonsense Organics over the nine years since it was established was 43%. The number of producers had also grown at significant rates. In 1991 there were less than 200 certified organic producers in

New Zealand and there are now more than 800. Mr Kebbell also mentioned that in New Zealand the consumer demand for organics did not appear to be a passing fad.

96. The Royal Society of New Zealand also commented that organic agriculture in New Zealand had expanded rapidly, earning NZ\$60 million from exports in the year 1999–2000. We noted in the Ministry of Economic Development’s public submission that in the year 2000 organic exports represented 0.1% of total New Zealand exports. When all forms of “environmentally enhanced” agriculture were combined, the Royal Society of New Zealand estimated they would comprise just under NZ\$1 billion in exports for the year 2000. John Manhire of OPEG said his organisation estimated that organic exports alone from New Zealand would reach \$500 million by 2006.

97. Dr Campbell told us that the United States Department of Agriculture had analysed the global organic market and suggested that the organic market was the fastest-growing food sector in the United States. Constraints on growth in this sector were related to supply development, not consumer demand. Dr Campbell considered that the United States agricultural sector could not convert to organics quickly enough to fill the demand, and that New Zealand had some natural comparative advantages both in its environment and style of farming that could enable it to move into organic production ahead of competitor nations.

98. In a paper presented with OPEG’s submission, Dr Campbell explored the organic economies in other countries. Denmark had one of the fastest growing organic economies in Europe, due largely to government subsidies for conversion to organics and other measures supporting the development of the organic economy. In 1999, 20% of Denmark’s dairy production was organic, and 3.6% of farm land was dedicated to organic production. Average premiums for organic food in Denmark were in the region of 30–50%. The Netherlands also had a fast growing organics sector, largely due to organic dairy farming. We also heard from the Canterbury Commercial Organics Group that Denmark was considering a complete conversion to organic agriculture.

99. We heard, however, from Dr Marshall, a witness for the Dairy Board, that the Danish dairy industry now had a surplus of organic milk, and that about half the total organic milk was currently being mixed into traditional dairy products. He told us also that in the Netherlands a significant number of dairy farms had converted to organics, but that this had been stopped as of November 2000.

100. Dr Campell's paper included the following table summarising the value, growth rates and premiums in 21 organic markets around the world for the 1998–99 year. The table suggested that many economies had organic sectors that were comparable with or larger in size than New Zealand's, and that were growing at rates comparable with New Zealand's organic sector.

	Value of organic market (US\$ million)	Annual growth in organic market	Average premiums
Brazil	\$150	20%	25–35%
Canada	\$571	25%	10–50%
USA	\$4,000	20%	10–20%
Argentina	\$3	25%	N/A
Mexico	\$15	N/A	30–40%
Taiwan	\$9.5	30%	up to 400%
Japan	\$3,000	N/A	10–30%
Hong Kong	N/A	15%	15%
Korea	\$61	N/A	50%
Germany	\$1,500–1,800	10%	30%
Denmark	N/A	N/A	30–50%
UK	\$836	100%	25–100%
France	\$610	25%	25–50%
Slovakia	N/A	N/A	15%
Poland	N/A	N/A	10–30%
Austria	\$152	N/A	10–50%
Italy	\$900	20%	20–200%
Spain	N/A	N/A	20–50%
Australia	\$132	60%	35%
New Zealand	\$16	70%	10–100%
TOTAL	\$12,255		

Social equity

101. The Maori Congress [IP103] considered that the genetic modification technologies now being developed would tend to reinforce the existing patterns of capital ownership. The Congress felt an ever-tightening loop or a relationship was established through these patterns, so that not only Maori but also the poorest people and the most endangered landscapes and ecosystems were then considered commodities instead of being part of an integrated environment.⁴¹ It also called for a move away from the conventional chemical agri-technology industry towards fully adopting organic production by 2005.

102. Friends of the Earth (New Zealand) [IP78] explored equity issues associated with genetic modification in its written submission, emphasising that the risks associated with genetically modified food and medicines could outweigh the benefits, and in particular:

... GM food may appear to advantage poorer families by being cheaper and more affordable than more expensive, organic non-GM alternatives, but the resulting widespread intake of GM food would have the especially large potential to adversely affect human and other species. Children of poorer families would have no choice but to eat GM foods and could therefore be disadvantaged in terms of health, immunity, food diversity and other potential harms unknown to us at this point in time. In effect, any advantages of GM products in the short term are insignificant compared with the potential disadvantages to humans and other species in the longer term; these disadvantages would affect all of us including the very groups of persons who may have benefited and/or profited from GM.⁴²

103. The New Zealand Grocery Marketers Association [IP54] called as a witness Michael Rosser, a former Director-General of Health in New South Wales, who explained that:

Should there be price rises in the range of 0–6% for different types of food – depending on its likely genetic modification status – the rises will impact on people in the lowest income decile more than other deciles below the sixth decile (the “average wage” decile) due to the poorest people purchasing more of the (processed) food groups where there is likely to be a greater impact from the introduction of the proposed Standard A18 [which requires all ingredients to be labelled if of genetically modified origin].⁴³

104. At the Ngaruawahia national hui we heard from Angeline Ngahina Greensill (Tainui) that “people who can’t afford to buy will buy the cheapest product, which is going to be GMO stuff; yes, they’re going to get the sickest; its going to be our people”.⁴⁴

105. A speaker at the Whangarei public meeting told us that:

With problems worsening in South Auckland and other low income areas around the country, I find it an utter disgrace that GE food sits on our supermarket shelves waiting for these unsuspecting buyers. For the kiddies in these areas brought up on soft drink, highly refined foods and takeaways, all of which now contain GE ingredients, the future currently looks extremely bleak.⁶

chapter |

6.

Research

6. Research

Key issues:

- The essential role of research in New Zealand's future
- Regulation of genetic modification research to ensure safety without stifling innovation
- Ethical and cultural issues in research
- Creating the right balance when allocating funding.

Introduction

1. Many submitters stressed the importance of research to New Zealand's future. Researchers and businesses were enthusiastic about the potential of future genetic research to bring benefits to health and the environment. Others, including many environmental groups, took a more cautious approach to the possibilities of the science. Submitters often distinguished between research in containment, and uncontained research and its impacts on the environment.
2. In this chapter we discuss the contribution of research to New Zealand's future, the current social and regulatory environment for research involving genetic modification, and changes that have been proposed to the current regulations. We also discuss the issue of research funding.

Asilomar to the present; the New Zealand context

3. The molecular structure of DNA was identified in 1953. In subsequent years understanding of the processes of DNA replication increased and by the early 1970s researchers had begun to understand how DNA could be cut and spliced between species. The consequent spliced DNA became known as recombinant DNA.
4. Some scientists raised concerns about the safety of these early experiments. In July 1974 the USA National Academy of Sciences called for a moratorium on

certain types of DNA experiments until the hazards had been evaluated. In 1975 scientists involved in gene research and experts in bacteria and viruses gathered at a conference at Asilomar in the United States. They evaluated the safety issues and established which strains of bacteria scientists should work with, recommending those that could not survive or reproduce outside the laboratory. They developed a set of guidelines for working with such bacteria. Thus the scientists took the physical risks seriously and voluntarily regulated their own activity.

5. The Environmental Risk Management Authority (ERMA) [IP76] described in its evidence the origin and development of controls on genetically modified organisms in New Zealand. In 1975 the Medical Research Council (MRC) requested the drafting of recommendations for recombinant DNA research, and directed that these be followed by all MRC-funded research. In 1977 there were requests for expanded guidelines. The then Department of Scientific Research (DSIR) laboratories, research associations, universities and the Ministries of Health, Forestry, and Agriculture and Fisheries were directed or requested to follow these. There was no private genetic research at that time.

6. The guidelines assessed experiments on a case-by-case basis. Research was to be done in specific containment facilities, and institutions appointed biological safety officers who ensured those containment requirements were fulfilled.

7. In July 1977 the Minister of Science and Technology set up a working party on novel genetic techniques to advise whether such work should be carried out in New Zealand, whether the interim guidelines were adequate, appropriate and effective, whether legislation was required and whether such legislation should cover the wider question of microbiological hazards in research. Their report was presented in April 1978.¹

8. In July 1978 Cabinet appointed an Advisory Committee on Novel Genetic Techniques (ACNGT) to “adjudicate on all proposed experiments with respect to the capabilities and training of the scientists involved, the suitability of the laboratories in which the experiments would be carried out and the possible risks inherent in each experiment”.² Enforcement of the recommendations of ACNGT rested with the controlling authority of the institution where the research took place. These research organisations also were required to appoint a biological safety officer (to provide supervision and advice on appropriate containment measures) and additionally an Institutional Biological Safety Committee (IBSC) (to approve research). Experiments were categorised on the basis of risk into four, later five, categories. From 1982 the IBSCs were delegated to approve lower risk experiments and were required to notify ACNGT. Other experiments were referred to ACNGT for approval.

9. Developments led to establishment of the Field Release Working Party, which recommended in 1987 that the Ministry for the Environment establish a committee to assess all proposals to field test or release genetically modified organisms. In 1988 the Minister for the Environment established the Interim Assessment Group (IAG). From this time all proposals for government-funded research outside contained laboratories, and the fermentation of genetically modified organisms in volumes greater than 10 litres, had to be submitted to the IAG. ACGNT continued to be responsible for contained experiments in glasshouses and laboratories. The private sector was also invited to apply for assessment by IAG³ and did so voluntarily. The moratorium on field release, in place since 1978, was lifted at this point. Neither ACGNT nor the IAG had any legislative authority, and from 1988 the government began moving towards what was to become the Hazardous Substances and New Organisms Act 1996 (HSNO).

Technologies in use in New Zealand

10. We heard evidence of the wide range of genetic modification methods in use in research in New Zealand. Many submitters distinguished between the use of genetic technology to study the structure and function of genes in containment laboratories, and the development of a genetically modified organism for use, in or out of laboratory containment, as a crop or a product.

11. Much genetic research in New Zealand involves the use of genetic modification technology to isolate, identify and characterise genes from a wide range of species, including humans. Most of this research is carried out in containment and is low risk, because any modified organisms produced are of low virulence and are not able to reproduce outside the laboratory. New Zealand research using gene technology spans land-based production, human health applications, animal welfare and feed, environmental protection, and industrial applications. Some of the uses are described below.

12. The production of DNA libraries involves the isolation of DNA from a species. This DNA is cut into even-sized, smaller pieces and the pieces spliced into plasmids, viruses or artificial chromosomes from bacteria or yeast. These are then grown in bacteria or yeast to amplify the number of copies of each DNA fragment.⁴ This form of cloning (the reproduction of organisms with the same genetic material) involves the creation of novel organisms containing DNA from at least two sources, and is therefore covered by the Commission's Warrant. The organisms used to amplify the number of plasmids or viruses are unable to survive outside the laboratory. They are weakened so that they can grow only in a special

medium containing the right nutrients, and therefore pose little or no risk outside the containment laboratory.

13. The use of cloning to identify and isolate genes, for example for sequencing or structural studies, is widespread in all university, medical and Crown Research Institute (CRI) laboratories studying gene structure and function in New Zealand. AgResearch [IP13] uses this technique to study the genes of cattle, sheep, plants, microorganisms, humans and mice. Dr Richard Newcombe, a plant molecular biologist with the HortResearch [IP5], stated:

... HortResearch has created a variety of genetically modified organisms in containment including 1) bacteria that store our genes from plants in gene libraries, 2) bacteria and yeasts that express the protein products of genes to determine the protein's activity and 3) transgenic plants that disrupt or over-express genes to test their function in the plant.⁵

14. Dr Phil Cowan, leader of the research programme on possum control for Landcare Research [IP12], described the range of techniques used in this work:

The current research programme uses genetic technologies for the cloning and sequencing of possum genes; the production of recombinant proteins for vaccination trials; the production of genetically modified bacteria expressing possum proteins ("bacterial ghosts"); and the production of transgenic plants expressing possum proteins. Most of the genetic modification is carried out by collaborators outside of New Zealand. The GM products from overseas are tested on possums in our contained facilities in New Zealand to evaluate their effect on possum infertility.⁶

15. Dr Dianne Gleeson, a population geneticist, also with Landcare Research, told us cloning techniques have helped to identify species of native fish to aid in conservation management. Dr Kenneth McNatty, a reproductive biologist with AgResearch, said that these techniques are used in research on the biology of fertility, whereas Dr Parry Guilford, a research scientist in the Cancer Genetics Laboratory at University of Otago [IP19], used similar methods to identify the gene causing familial stomach cancer in a New Zealand family. Further examples are given in Appendix 1 to this report.⁷

16. Other New Zealand research aims to understand how genes function in the whole animal. The importance of the use of transgenic mice was discussed by the New Zealand Transgenic Animal Users [IP45], which described how it can provide animal models for inherited or non-infectious disease, allowing the development of new treatments or cures. Dr Ingrid Winship, Associate Professor of Clinical Genetics at the University of Auckland, giving evidence for the Human Genetics Society of Australasia [IP59], said that:

There are also many animals that have the same disorders as humans. So, hip dysplasia in certain dogs is analogous to hip dysplasia in humans. So, when we talk about animal

models, they're not all artificially created. There are animal equivalents which manifest in the same way on the basis it is the same genetic disorder in animals.⁸

Professor Garth Cooper, Professor of Biochemistry and Clinical Biochemistry at the University of Auckland [IP16], explained the importance of animal models in the testing of genetically modified medicines:

There is a system of clinical trials that has been developed over probably a couple of decades or more, I think in part in response to the thalidomide disaster that happened in the United States ... [which] involves preclinical and then clinical trials. Preclinical trials are undertaken in animal models, and under normal circumstances there will be a requirement for trials of two species, of which one must be non-rodent.⁹

17. The development of the polymerase chain reaction (PCR) in the early 1990s made many of the cloning techniques used to amplify DNA concentrations obsolete. PCR has the advantage of avoiding the creation of new genetically modified organisms. Dr Graham Wallis, Senior Lecturer in genetics, University of Otago, described the use of PCR in ecological and conservation genetics research and said “We do not create any animal, plant or fungal genetically modified organisms.”¹⁰

18. It was clear from the submissions received from Interested Persons that this technology is developing rapidly, and many new applications will emerge in the next few years. Associate Professor Michael Eccles, also a research scientist from the Cancer Genetics Laboratory at the University of Otago, appearing for the Transgenic Animal Users, discussed developments in the treatment of genetic diseases and of some forms of cancer using gene therapy. Professor Christine Morris, a researcher in cancer genetics at the Christchurch School of Medicine, speaking for Human Genetics Society, talked of the potential use of molecular diagnosis and treatment response monitoring for some types of cancer, enabling more targeted treatment. Crop and Food Research [IP4] described proposals for the modification of the biochemical pathways for carotenoids and flavonoids to improve nutritional quality and colour and to develop new colour combinations of ornamental flowers. The technology was also being used to develop potential pharmaceuticals and to introduce new pest and disease resistance characteristics in plants.

19. The Commission's survey of public opinion indicates that many New Zealanders know that genetic modification technology is used in research here. They are aware of its use in research using plants (79% of those surveyed), research using animals (67%) and medical research (72%). The numbers who approved of such research were greatest for medical research (65%) and research using plants (52%), with genetic modification research using animals approved by only 29%.¹¹

20. It was difficult to assess to what extent public submitters were aware of the extent or use of genetic modification in research. In responding to the Warrant item on current uses and purposes of genetic modification in New Zealand, most limited their comments to genetically modified food. It is not clear if that was because they were primarily concerned with food, or because they chose not to comment on other areas despite being aware of them. Given the figures from the public survey, the first of these options seems more likely.

The contribution of research to New Zealand's future

21. Much evidence stressed the contribution of research to the future of New Zealand in terms of economic development, the education and knowledge sectors (also discussed in chapter 5: Economic and strategic issues), and the environment and health.

Economic benefits

22. A large number of Interested Persons argued that considerable benefits are expected to flow to New Zealand from genetic research. Many of these would be economic, building on and developing current primary industries. For instance, the New Zealand Dairy Board [IP67] argued that biotechnology will enable increased on-farm productivity benefits, for example through improved forage plants, and will enable diversification through production of new products, particularly those with functional foods, nutraceutical and pharmaceutical applications. Genesis Research and Development Corporation [IP11] stated that genetic research would also have important flow-on effects to other parts of the economy by employing a highly skilled workforce, attracting foreign investment and generating valuable intellectual property. Genesis Research and Development considered also that “success in health technology can be extended into New Zealand primary industries to add value to commodity industries and to benefit the environment”.¹²

23. Woven through many submissions was an affirmation of New Zealand's international research competitiveness. First, New Zealand is at the forefront of genetic research with animals. For instance, Mark O'Grady, chief executive officer presenting evidence on behalf of the New Zealand Wool Board [IP30], told us that:

New Zealand has a head start in the area of the ovine or sheep genome, and currently has many of the world's preeminent scientists in this field. However, other countries and other

research institutes overseas are beginning to realise the opportunities that lie dormant in this area. And, if we're slow to respond we'll rapidly lose the competitive advantage and head start that New Zealand currently has in this area.¹³

24. In addition to expertise in sheep and cattle genomics, New Zealand has a healthy animal population, free of many of the diseases found elsewhere. This makes it an attractive venue for animal industries, such as those that produce pharmaceuticals in milk.

25. Secondly, New Zealand has a skilled workforce that is also competitive in terms of the costs of research. As Dr Arie Guersen of Genesis Research and Development said under cross-examination:

We can do research ... cheaper here in New Zealand than ... in the US or in Europe, and that makes it attractive for [our overseas partners] to invest in a company [in] New Zealand.¹⁴

Salaries for scientists are lower than overseas, and there are savings from such costs as healthcare that would be required in the United States.

26. Thus, a strong case was made about New Zealand's comparative advantages in science and the value of research to the New Zealand economy.

Educational benefits

27. Genetic research generates direct benefits in the education and "knowledge" sectors. The Universities of Auckland, Otago and Canterbury [IP7] pointed out the importance of staff having access to new technologies for the creation of new knowledge from research into biological systems, the development of experimental therapies for human disease and the development of new biotechnologies. Such access is part of attracting and retaining high quality staff in an international market, and ensuring high quality scientific education for students. They argued that it is important to educate students in genetic technology not only to develop the research capacity of New Zealand, but also to ensure that we have the expertise to manage genetic technology in such areas as medicine and border control.

Environmental benefits

28. Dr Gleeson discussed the contribution of genetic research to understanding the diversity of indigenous populations and to consequent decisions about protection of habitats and biodiversity. Landcare Research also pointed out the contribution of genetic modification research to other aspects of conservation biology, to pest control and to bioremediation.

29. Dr Andrew Pearce, Chief Executive for Landcare Research, considered that research leading to a genetically modified possum control agent “offered opportunities to avoid or mitigate environmental, health and trade risks arising from New Zealand’s use of more than 90% of the world’s consumption of 1080 to kill environmental pests”.¹⁵

30. Dr Stephen Goldson, AgResearch’s Science Leader of the Biocontrol and Biosecurity Group, stated:

The use of genetically modified organisms for studies in taxonomy, ecology and insect pathology is essential for advancement of fundamental knowledge in ecology and biology. Genetically marked microbes allow studies to be carried out to a level of detail that was not previously possible, with a consequent increase in knowledge of ecosystem function. There is little uncertainty about such an outcome and it is likely that appropriate use of molecular biology and marked organisms will become an increasingly common part of laboratory practice. Such work provides a pathway to understanding that would be impossible without using genomic techniques.¹⁶

31. Dr Goldson said that his research was also aimed at improving the understanding of potential environmental risks associated with genetically modified organisms, such as horizontal gene transfer. This work also served to develop new general insights into ecological systems and new pest management systems.

Health benefits

32. Virtually all current medical uses of genetic modification can be classified as research. In medicine, research is an on-going process that involves the monitoring of product safety. Commercialisation of products and processes occurs at the point of moving to wider community-based research, such as that involved in epidemiology, rather than at the end of laboratory-based research. Among other things, epidemiologists study the statistical relationships between any new treatment and the development of unwanted or unexpected effects. This enables targeted research to verify whether an association of factors has a causal relationship. However the ultimate standard in medical research is a “double-blind, prospective, crossover trial” and until enough such trials are completed, medical researchers and the medical profession take a conservative approach to new developments.¹⁷

33. Various patient groups argued for the importance of gene technology in understanding medical conditions, and improving both diagnosis and treatment options. We heard from Genesis Research and Development and Malaghan Institute of Medical Research [IP10] about their work to create vaccines for asthma, psoriasis, tuberculosis and some solid cancers. These issues are explored further in chapter 9 (Medicine).

Concerns about research

34. Some submitters were not supportive of research involving genetic modification. In many cases their arguments were to do with aspects other than immediate physical safety. For example, Nga Wahine Tiaki o te Ao [IP64] argued:

It is within the main principles of mauri, mana and w'akapapa that Maori raise their absolute disagreement regarding genetic engineering and modification. If these principles are damaged or tampered with in any way, thus upsetting the holistic world balance, so too will be the mauri, mana and w'akapapa of Maori and following generations.¹⁸

35. Koanga Gardens Trust [IP72] questioned the paradigm or the assumptions behind the use of science and in particular of genetic modification, and is:

opposed to any continuation of any "Genetic Engineering" until such time as we see in place a real desire by all parties involved to honestly address the "paradigm" within which it will operate.¹⁹

36. For some the risks of such research are such that it should never be done, or at least not at this stage. For instance, Nelson GE Free Awareness Group [IP100] called for "a complete ban on Genetic Engineering trials and crop releases and a fully legislated moratorium".²⁰ Physicians and Scientists for Responsible Genetics New Zealand [IP107] called for a moratorium on the release of any genetically modified organisms into the environment and the incorporation of genetically modified organisms, their parts, processes and products into the food chain.²¹

37. Others were prepared for research to continue in containment, but were more concerned about field tests (trials) or release into the environment. Their main concern was the safety of the environment. For instance, the Golden Bay Organic Employment and Education Trust [IP104] considered there is an unacceptable risk once research moves outside a strictly defined, monitored and enforced laboratory environment. The Northland Conservation Board [IP68] specified a ban on all field trials or releases of crops, and Friends of the Earth (New Zealand) [IP78] called for:

an immediate halt to the further development of GM medicines without proper research and controls; and the strict legislative containment of any research involving genetic modification to the laboratory.²²

38. Physicians and Scientists for Responsible Genetics raised concerns about the safety of research in containment in connection with the disposal of genetic material. It argued that we still have significant gaps in our knowledge of the genome, and do not know which recombination activities could take place in the environment, saying that "Effects on the microbial flora of the environment are not adequately minimised under current procedures".²³

39. Dr Robin Ord, a genetics consultant and law student, appearing for the Pesticide Action Network New Zealand [IP87], raised concern about the lack of monitoring for the escape of genetic material from containment, in his cross-examination of the New Zealand Plant Protection Society [IP36]. The society responded, to its knowledge, no work was being done in this area and it would support such work being undertaken. In his witness brief, Dr Ord mentioned that “New Zealand does not have regulatory structures in place or testing facilities to monitor or manufacture in containment”.²⁴ In particular he was concerned with the issue of “scaling up” in commercial situations, “where a mutation may be amplified through PCR” to a far greater proportion of the end product than would occur in nature.

40. Research that moves beyond strict laboratory containment raised concerns about the environmental impacts of research involving genetically modified organisms. As discussed in chapter 4 (Environmental and health issues), under horizontal gene transfer and other topics, we agreed that more research is needed into the environmental risks that genetically modified crops and non-food uses might pose for the ecosystems into which they could be released.

41. We note the concern of some submitters about the use of antibiotic resistance genes as markers for selection of transgenic organisms.²⁵ This is discussed in chapter 4, paragraphs 23–28.

The regulation of research in New Zealand

The current regulatory environment

42. Two key pieces of legislation control genetic modification, genetically modified organisms, and associated environmental protection risks: the Hazardous Substances and New Organisms Act 1996 (HSNO) and the Biosecurity Act 1993. The purpose of HSNO is to protect the environment and the health and safety of people and communities by preventing or managing the adverse effects of hazardous substances and new organisms. HSNO does not regulate or provide controls for genetically modified organisms once they have been approved for release into the environment.

43. Under HSNO (Low-Risk Genetic Modification) Regulations 1998, low-risk genetic modification work is carried out under PC1 or PC2 conditions as defined by the Australia/New Zealand Standard 2243.3, “Safety in Laboratories, Part 3: Microbiology”. PC1 conditions deal with situations where there is low individual and community risk, and where the microorganism is unlikely to cause human, plant or animal disease (Category A). PC2 deals with situations where there is a

moderate individual risk and a limited community risk, and the microorganism may cause human, animal or plant disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment (Category B).

44. Higher levels of containment are also specified in this standard, and would be considered as part of any approval of research on higher risk organisms. In New Zealand there are few laboratories offering higher levels of containment (PC3 and PC4); these are designed to deal with organisms, genetically modified or otherwise, that are of known risk to health or the environment.

45. While some research involving whole organisms is able to proceed in strict containment, this is more difficult for other work. For instance, large transgenic animals such as sheep or cows can be genetically modified to produce a specific protein in their milk. The size and nature of such ruminants means that it is better for their welfare to be grazed in secure paddocks. As the following HSNO definition shows, such an experiment is a field test:

“Field test” means, in relation to an organism, the carrying on of trials on the effects of the organism under conditions similar to those of the environment into which the organism is likely to be released, but from which the organism, or any heritable material arising from it, could be retrieved or destroyed at the end of the trials; and includes large-scale fermentation of microorganisms.

46. Field testing, as well as laboratory research, are both classified by HSNO as contained research:

“Containment” means restricting an organism or substance to a secure location or facility to prevent escape; and includes, in respect of genetically modified organisms, field testing and large scale fermentation.

47. It is important to note that when an organism is defined as contained ERMA can impose controls in the form of obligations or restrictions controlling adverse effects on people or the environment.

48. To develop a genetically modified crop, it may be necessary to extend the research beyond laboratory containment to understand the effects of the new organism on the environment. Field tests enable research on the effect of the transgenic organisms on soil ecology in a semi-contained situation. Some aspects of effects on insects, including bees, can also be investigated. However the effects of a new genetically modified crop on the wider ecosystem may have to be studied in a wider controlled release situation. New genetically modified medicines or vaccines developed in the laboratory, such as the asthma vaccine described by the Malaghan Institute, will require controlled release when they move into clinical trials.

49. The Biosecurity Act 1993 provides mechanisms for the exclusion, eradication and management of pests and other unwanted organisms in New Zealand. New organisms, including genetically modified organisms, are considered as risk goods under the Act. New organisms that have containment approval from ERMA are “restricted organisms” and must be held in an approved containment facility. Laboratories registered for research requiring high levels of containment are audited by the Ministry of Agriculture and Forestry (MAF) for compliance with the Act.

50. Dr Iain Lamont, a Senior Lecturer in Biochemistry at the University of Otago, stated each registered research facility is audited six-monthly both internally by the institution and externally by MAF to ensure it complies with the Standard relevant to that facility. The Standard covers areas such as physical containment, work practices, training of users, waste disposal, and maintenance of the Register of Organisms where all genetically modified organisms must be recorded. Similarly we heard from Dr John Fraser, Professor of Molecular Medicine at the University of Auckland, who said:

... containment facilities are established to ensure good on-going management, documentation and auditing systems for laboratories handling genetically modified organisms ... It is not uncommon for the University of Auckland Biological Safety Committee [the University’s IBSC] to impose extra controls on applicants to further reduce the possibility of aerosol generation or to ensure the security of facilities. These controls are over and above the two standard sets of controls imposed by ERMA.²⁶

Regulatory and ethics bodies

51. ERMA is established under HSNO and is responsible for granting or refusing approval for:

- importing any genetically modified organisms into containment
- developing any genetically modified organism
- conducting contained field tests (trials)
- releasing any contained or imported genetically modified organism.

52. Some of ERMA’s tasks are carried out in cooperation with other agencies. ERMA and MAF have an agreement that recognises the role of MAF to manage the border control and quarantine issues regarding new organisms, while ERMA exercises the clearance or approval process for any new organism to enter the country.

53. ERMA and the Australia New Zealand Food Authority (ANZFA) have an agreement under which they agree to notify and exchange information about applications to develop or vary a standard allowing the sale of genetically modified

foods or food ingredients in the case of ANZFA, and all applications for approval of genetically modified organisms (excluding development in containment) in the case of ANZFA. They have also agreed, as far as is practicable, to coordinate approvals for the release of genetically modified organisms, genetically modified foods and ingredients derived from genetically modified organisms.

54. Under HSNO, ERMA is required to notify the Department of Conservation of applications for approval of new organisms. ERMA is required to have particular regard for any submissions made by the Department where an application is for approval to import, develop, field test or release a new organism.

55. Under HSNO, ERMA can delegate the power to assess applications for some low-risk new organisms. Most delegations are to research institutions such as universities and CRIs. As mentioned above, a delegated institution must establish an IBSC to assess applications for low-risk genetic modifications. IBSCs assess applications against HSNO and Regulations, advise on containment and procedures for all genetic modification work, and ensure applications involving human genes and animals have appropriate ethical consideration and approvals. Applications to IBSCs that are not low risk must be withdrawn or referred to ERMA for consideration. ERMA visits institutions with delegated authority to review the decisions and processes of their IBSCs. If any delegated institution does not comply with the rules of its delegation ERMA may withdraw the delegation.²⁷ This has happened in the past. The costs involved in losing and regaining their delegation provide institutions with an incentive to comply.

56. The Genetic Technology Advisory Group (GTAC) was established in 1996 as a sub-committee of the Health Research Council's (HRC) ethics committee. It reviews proposals involving the introduction of nucleic acids, genetically manipulated microorganisms, viruses or cells into human subjects for purpose of gene therapy or gene marking, their use to stimulate an immune response against the person's own cells, or the use of genetically modified vaccines to treat cancer.

57. The HRC's Standing Committee on Therapeutic Trials (SCOTT) is responsible for the assessment of the scientific validity and safety of clinical trials in accordance with the Medicines Act 1981. In particular, SCOTT considers aspects of a proposed clinical trial such as whether there is a control group, how the trial compares new with existing treatments, whether investigators have the ability to conduct the trial, whether they have recruited sufficient subjects, and drug toxicity. The most common problems with clinical trials identified by SCOTT are definitions of endpoints, inadequate compliance, and incomplete trial design or protocol preparation. The majority of applications reviewed by SCOTT are for clinical trials sponsored by the pharmaceutical industry.

58. SCOTT will only approve clinical trials once they have been approved by the appropriate ethics committee. All medical trials, whether or not involving genetically modified organisms or their products, and whether in the private or public arena, must be approved by SCOTT at each phase of the trial, before proceeding to the next phase.

59. In phase 1 trials all research is laboratory based. If New Zealand does not participate in phase 1 trials, we might forfeit involvement in the multi-centre phase 3 trials. In phase 2 the new treatment is tested on small numbers of affected patients. In phase 3 many more patients and healthy volunteers are involved. Often large numbers of patients may be required to identify rare adverse reactions to the new treatment. For this reason collaboration is initiated with large international companies and the phase 3 trial is carried out in countries with large populations such as the United States. In phase 4 trials commercial availability of the treatment is concurrent with continued wider research over a longer time frame. This is a form of conditional release. In general New Zealand patients cannot access the new treatment until the trial moves to multi-centre trials in phase 3 or wider monitoring in phase 4, and they may go overseas to access drugs and treatments still in phase 2 trials.

60. The HRC is the major government-funded agency responsible for purchasing and coordinating health research and fostering the health research workforce in New Zealand.²⁸ The HRC Ethics Committee (HRCEC), a statutory committee, requires that ethics approval must be obtained from an accredited ethics committee before HRC funding for any research proposal may commence. HRCEC considers and makes recommendations to the HRC on ethical issues in relation to health research, especially those emerging through the development of new areas. Where funding applications involve issues of national importance or great complexity, HRCEC makes an independent ethical assessment. HRCEC may delegate authority to accredited regional or local institutional ethics committees to review research funding applications.

61. These committees, which are usually defined in terms of their relationship to animal research or human research involvement, are accredited by HRCEC. A number of accredited regional health ethics committees and some institutional ethics committees have been granted delegated authority to review applications for HRC.

62. The Animal Welfare Act 1999 provides the basis for review of animal ethics. HRCEC has delegated authority to institutional animal ethics committees under guidelines set by the National Animal Ethics Advisory Committee (NAEAC). These committees provide ethical review of all funding applications that involve

animals or animal tissues. Committee membership includes a veterinarian and members of the public.

63. In mid-2000 ERMA discovered 191 experiments involving genetic modification that had not been authorised under HSNO. An audit revealed that all non-compliant projects were being conducted safely in containment and that the situation had arisen largely through a lack of awareness of the requirements of the new regulations.

64. Dr Basil Walker, Chief Executive of ERMA, discussed this event during his presentation to the Commission:

The regulatory agency, ERMA, moved promptly and strongly to deal with the situation, with full support from the science institutions I should add, and the rude shock administered has not resulted in a single known instance of non-compliance since.

Moreover, the investigations at the time showed that there wasn't a single instance of deliberate non-application of containment standards, and certainly no evidence of any release or breach of containment.²⁹

Although understandably this event caused a great deal of disquiet, the Commission is satisfied that ERMA handled the situation appropriately.

Anomalies in the regulatory system for contained research

65. The Commission heard considerable evidence about the practicalities of working with HSNO, and its implications for research in New Zealand.

66. There was widespread agreement that HSNO provided a good framework for the regulation of genetic modification research, and that there was a continuing need for a rigorous process of assessment and approval as carried out by ERMA. For instance, the New Zealand Biotechnology Association [IP47] recognised:

... that [ERMA] is the appropriate regulatory body to manage GMO developments in New Zealand, and that ERMA must administer a regulatory framework that considers the safety of researchers, the general populace and the environment.³⁰

67. The main focus of submissions about ERMA related to the practicalities of working with the current regulatory processes. Strong views were expressed about the high and, in the view of many submitters, unnecessary compliance costs related to approval processes, problems with definitions and coverage of HSNO. Emeritus Professor George Petersen, speaking as the immediate past President of the Academy Council and of the Royal Society of New Zealand [IP77a], stated:

The Society supports retaining statutory regulation of GM as an essential part of maintaining public confidence in the use of this technology. However, there is strong dissatisfaction among experimental biological scientists with the wording of the HSNO

legislation, and the consequent constraints it imposes on laboratory-based research in New Zealand. The regulations devised to try to get around the deficiencies of the Act are not in accord with international practice and have placed New Zealand scientists at a disadvantage relative to their overseas counterparts, while other deficiencies of the legislation which cannot be remedied by regulation (eg the rules governing the importation of low-risk GMOs into containment) threaten to undermine international research collaborations.³¹

68. The Commission is aware that, in the United Kingdom, Australia and the United States, developments of genetically modified organisms that clearly meet PC1 criteria are exempt from requiring approval for development. In New Zealand, development of these organisms requires an application to the IBSC for approval. Many professional and research organisations³² suggested that all low-risk research conducted at PC1 level be exempt from approval by either ERMA or an IBSC. These organisations pointed out that the containment laboratory in which the research is carried out must be registered and all containment laboratories are audited by MAF. There were also submissions that research at PC2 level should continue to be approved by the local IBSC.³³ The Royal Society of New Zealand [IP77a] defined the problem created by the numbers of novel microorganisms that are developed daily in containment laboratories:

Because of the way HSNO defines a ‘new organism’, a scientist carrying out standard recombination experiments will continually create ‘new organisms’, each of which legally requires a separate application.³⁴

69. The Malaghan Institute said:

Development of low risk organisms should be exempt from the regulations and for other research, the regulations should be altered so that the research project rather than the specific organism is approved.³⁵

70. The University of Otago also submitted that “applications to develop genetically-modified organisms in containment ... be assessed on a project rather than organism basis”³⁶ and ERMA called for a change to the definition of a new organism from “species” to “type”.³⁷

71. The Commission agreed that some changes are necessary. While it is important that IBSCs continue to have the opportunity to alert researchers to the cultural and ethical issues in their research, it is also appropriate to reduce and streamline the approval processes where levels of risk are low. The Commission recognises the current anomalies in the regulatory systems for contained research to PC2 level.

Recommendation 6.1

that applications to develop genetically modified organisms in PC1 and PC2 containment be assessed by the Institutional Biological Safety Committees on a project rather than organism basis.

72. Professor Alison Stewart, an expert on fungal biocontrol agents from the Fungal Molecular Biology Laboratory at Lincoln University [IP8], expressed confidence in her witness brief in the current regulations, but pointed out to the Commission some anomalies in the regulations for containment facilities. The containment regulation AS/NZS 2243.3 was written originally for microbiological laboratories:

The current containment regulations do not differentiate between classes of organisms eg mammals, plants, viruses, bacteria and fungi. As the aforementioned organisms have diverse methods of reproduction and dispersal, specific protocols need to be made for these in PC2 regulations. Small changes are therefore required, specifically where it relates to containment of different types of organisms.

73. Professor Stewart provided a specific example of this problem, citing an excerpt from AS/NZS 2243.3 Section 3.5.2 (g) which states “where the laboratory is provided with opening windows, flyscreens shall be fitted”. She added that:

Whilst the flyscreens will prevent insects accessing the laboratory it will not prevent the escape of fungal spores which are designed to be wind dispersed.³⁸

74. The submission from Physicians and Scientists for Responsible Genetics supported Professor Stewart’s claim that these regulations need to be reviewed in the light of the rapid development of this technology. Irrespective of amendments to HSNO arising from our recommendations, the Commission considers it is time to review these 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.

75. In particular, there is currently a single application form (Form 3) for approval to develop in containment any genetically modified organism, which covers all research from PC1 to field test.

Recommendation 6.3

that a separate, simplified form be developed for low-risk (Categories A and B) applications to Institutional Biological Safety Committees.

76. It may be possible in the light of future guidelines developed by the Toi te Taiao : the Bioethics Council (we propose the establishment of this Council in chapter 14) for low-risk research in containment involving flora and fauna larger than microorganisms for approval by IBSCs to be in the form of retrospective audit of whether guidelines are being followed.

Importation versus development of genetically modified organisms in containment

77. The Malaghan Institute pointed out that currently there is no provision for a delegated authority (IBSC) to consider an application to import a transgenic mouse or a genetically modified microorganism into containment. However the IBSC may approve the development of the same organism in containment in New Zealand. The time and cost of applying to ERMA to gain approval for the importation of previously characterised genetically modified organisms may be greater than that of developing a similar organism here. Submitters argued that low-risk genetically modified organisms should be treated in the same way whether they are imported or developed. ERMA also considered that the delegations to IBSCs could be extended to cover importation of low-risk genetically modified organisms.

78. The University of Otago submission was concerned by the illogical nature of the current situation:

At present, importation of organisms into containment must be approved by ERMA whereas development of the same organisms in containment in New Zealand can be delegated to IBSCs. This is clearly illogical as the level of risk associated with a genetically-modified organism must be the same wherever it is developed. Delegating to IBSCs the power to approve importation of low-risk genetically-modified organisms into containment, and exempting demonstrably low-risk organisms from requiring prior approval, would result in significant cost-savings both in terms of dollars (as there would be no ERMA processing fee) and time. Importation would still require a MAF importation permit and associated quarantine measures and, as part of this, the importing laboratory must be part of a registered containment facility.³⁹

79. The New Zealand Association of Scientists [IP92] suggested “that both importation of GM organisms into physical containment and development of these organisms be handled by a single delegated authority”.⁴⁰ Transgenic Animal Users strongly urged the Commission to recommend the relaxation of

the regulations for importation of transgenic animals, and their development in containment.

80. The Commission agrees that change is required.

Recommendation 6.4

that the Hazardous Substances and New Organisms Act 1996 be amended to allow for the efficient importation of low-risk genetically modified organisms, through delegation of the approval process to the Institutional Biological Safety Committees.

81. ERMA also pointed out that the “HSNO Act does not at present deal specifically with the holding or breeding of a genetically modified organism, once developed or imported”.⁴¹ They suggest that approvals to develop and import organisms should also cover holding and breeding. We agree.

Recommendation 6.5

that approvals to develop or import genetically modified organisms be deemed to cover their holding and breeding.

HSNO coverage of cell cultures

82. ERMA pointed out the difficulty with genetic modification of human cell cultures:

It is unclear in HSNO whether genetic modification of human cells and related tissues is covered by the Act or not. It is evident that genetic modification of humans [and of human organs] is excluded, but the boundary of what should be covered is not clear. This can lead to situations where experiments involving, for example, monkey cells would be covered by HSNO, but the same experiments involving the equivalent human cells would not, yet these human cell experiments would not be covered by the Genetic Technology Advisory Committee or the HRC Ethics Committee either.⁴²

83. We agree that research using human cell lines should not avoid oversight.

Recommendation 6.6

that the Hazardous Substances and New Organisms Act 1996 be amended to clarify that research involving genetic modification of human cell lines or tissue cultures is covered by the Act.

84. Another issue raised was the current approval processes for research involving genetically modified animal cell cultures or cell lines. The Biotechnology Association requested that, along with work requiring PCI

containment, work using animal cell culture lines be exempt from approval unless they harbour agents of sufficient toxicity to put laboratory workers at risk. It pointed out that:

Animal cell culture lines do not survive outside of laboratories and do not regenerate to whole organisms ... Current good laboratory practice is such that all cell lines, whether genetically modified or not, should be handled in PC2 containment hoods to protect from the possibility of adventitious agents in the cultures. This handling procedure ensures that animal cell cultures are already contained.⁴³

85. We agree that research with genetically modified animal cell cultures will normally be in category A regarding risk, while recognising that, because of the requirements for survival of the cell cultures, the work will often take place in PC2 facilities.

Recommendation 6.7

that approval for development of genetically modified animal cell lines be delegated to the Institutional Biological Safety Committees.

High-risk contained research and field tests

86. The Australia/New Zealand Standard 2243.3, “Safety in Laboratories, Part 3: Microbiology” defines the conditions required for working with hazardous organisms in PC3 and PC4 containment laboratories. These research facilities are audited by MAF, and genetic modification of high-risk organisms requires a full application to ERMA. The Commission did not hear of any problems associated with research involving genetic modification in PC3 and PC4 laboratories.

87. Many witnesses, although accepting the need for a rigorous regulatory process, argued that it is often appropriate and necessary to continue with research outside strict laboratory containment. Some research, such as that with large mammals, is logistically difficult in strict containment, and knowledge of environmental impacts can sometimes only be gained through field trials.

88. Field trials are an essential part of risk/benefit analysis prior to any release into the wider environment. Without field trials it is not possible to assess safety. ERMA has approved a number of field trials, including research with genetically modified sheep, cows, tamarillos, brassicas and pine trees. For further detail see chapter 7 (Crops and other field uses). As noted previously, this is still “containment” under the HSNO definitions. Trials have specified containment conditions. For instance, the animals are contained with double fencing or electric fencing and there are provisions for the avoidance of pollen release by removal of

reproductive structures from the pine trees. In addition, it is possible to tag the animals electronically to monitor their whereabouts.

89. Such work, it was argued, can be carried out safely, based on previous research and forms of biological containment. The safety of field trials and the adequacy of methods to contain risk, can be adequately assessed and dealt with through risk management programmes by ERMA. As noted in paragraph 45, any heritable material involved in a field test must be removable.

90. We heard from Dr Daniel Cohen of HortResearch that he was carrying out a field trial of transgenic tamarillos at HortResearch's Northland Research Station. We heard considerable public doubt about the adequacy of the containment of this trial.⁴⁴ The Commission considers that this public concern was justified.

91. In light of concerns that have arisen this year in connection with horizontal gene transfer (HGT) we consider that rigorous monitoring of field trials is essential and that all material associated with the trial must be removable from the site.

92. ERMA argued that:

... it would be helpful if HSNO permitted it to require, particularly for field trials, that the research be extended to encompass matters which might show the degree or type of risk which would have to be considered if there were a subsequent application to release the organism concerned; or which might identify risks and hazards that might eventuate in different field trials. The more knowledge available to the Authority and to applicants, the more likely are they to be able to eliminate uncertainties.⁴⁵

93. In other words, ERMA recognised that field trials provide an opportunity for other work that will be required in future applications.

94. It is important to note that no one argued for completely unregulated research. Even the most enthusiastic supporters of genetic modification were clear that it was vital that research was conducted within a context of a robust regulatory framework, and that risks should be carefully managed.

95. There is additional discussion in chapters 7 and 9 of aspects of research beyond containment and the issues as they apply to release of genetically modified organisms and the use of genetic modification in health, including some aspects of research and innovative clinical practice, such as gene therapy.

Conditional release

96. ERMA and other submitters⁴⁶ asked that HSNO be amended to provide for a further class of approval between development and import of genetically

modified organisms in containment, and release. Under the current provisions of the Act, release is defined as full release with no restrictions or controls other than those provided for under the Biosecurity and Conservation Acts.

97. The submission from New Zealand Vegetable and Potato Growers' Federation/New Zealand Fruitgrowers' Federation/New Zealand Berryfruit Growers' Federation [IP75] stated:

We believe the current regulatory processes of ERMA need to be extended to include provision for post approval monitoring and control of GM Organisms to be implemented and enforced. Whether post release monitoring or control is required at all and the degree of post release monitoring and control should be decided as part of the ERMA case-by-case consideration of applications for trial and release.⁴⁷

98. Dr Lin Roberts, an ecologist, director of Business and Environment Consultants and former manager at the Ministry for the Environment [IP101], said under cross-examination:

What I ... think ... we were missing at that time [the stage of first applications to ERMA], was other types of controls. And, I think, in the context of hindsight, the ability to have monitoring and research controls, ... that allowed us to gain knowledge from the releases that were made, and also things like risk to other farmers in terms of spread of GM pollen, for instance, being a problem for those who wanted to keep their crops GM-free.⁴⁸

99. ERMA identified this as a weakness in the Act, since applications may only be approved or declined and ERMA has no ability to set controls or conditions on releases. Some examples ERMA provided of situations where such an ability might be used were:

- to enable the progress of the release to be monitored, which may include the spread of the organism, the incidence of adverse effects and the effectiveness of any “controls” set in place
- in the case of animals released for farming, the separation of these animals to prevent interbreeding
- in the case of crops, limitations on the location and extent of plantings.

100. The Commission supports the addition of a class of approval for release with conditions or controls, after a contained field test. This would allow ERMA to impose conditions on the release, which might include the number of organisms released, the location and extent of the release and the auditing of environmental or health impacts. Conditional release would be analogous to the clinical trials that have been part of medical research for decades.

Recommendation 6.8

that the Hazardous Substances and New Organisms Act 1996 be amended to provide for a further level of approval called conditional release.

The rapidly evolving research environment

101. ERMA pointed out that the Act is currently structured in a very prescriptive manner, which has not always anticipated technological developments:

The boundaries are being perpetually pushed. As one result of this ERMA New Zealand is compelled to invest considerable time and effort in the interpretation of the Act, in order to accommodate technological change within a framework which did not contemplate such changes.⁴⁹

102. Techniques used in mammalian cloning such as nuclear transfer and cell fusion are examples where new technologies have had rapid uptake. ERMA also said that while “the potential risks from such techniques are similar to risks from modifications that are covered by the Act”,⁵⁰ currently this work falls outside the legislation. However, these techniques could provide a means by which new organisms could be created. In our view, this is clearly an area which should be covered by ERMA, and we recommend that the Act be amended to achieve this.

Recommendation 6.9

that the Hazardous Substances and New Organisms Act 1996 be amended to cover procedures used in mammalian cloning, such as nuclear transfer or cell fusion.

103. The New Zealand National Commission for UNESCO [IP90] pointed out it was important for any future legislation dealing with the genetic modification of humans or the use of human embryonic cells (for example, the Human Assisted Reproductive Technology Bill and the Assisted Human Reproduction Bill both currently before the House) to be consistent with HSNO and any existing ethical and safety requirements for genetic research.

104. It is likely that as research further expands our knowledge, additional areas not clearly covered by HSNO will emerge. It is also possible developments will emerge falling outside any of the current regulatory structures.

105. Thus, structures and procedures should be put in place anticipating some of those changes, identifying gaps, and responding appropriately to developments. In chapter 14 (The biotechnology century), we propose the appointment of a Parliamentary Commissioner on Biotechnology, one of whose functions will be to monitor developments in biotechnology and provide recommendations.

Ethical and cultural issues

106. A number of researchers discussed the ethical review of research, and the Health Research Council [IP27] provided evidence of the requirements for review of research involving human participants and the use of their tissue.

107. We heard nothing that made us question the adequacy of the current ethics committee structures for the work that they do. Indeed, we heard evidence that there is an insistence for rigorous ethical review and appropriate consultation. For instance, Dr Garth Cooper, Professor of Biochemistry and Clinical Biochemistry at the University of Auckland, who also identified himself as a member of Te ORA (the Maori doctors' organisation), said:

My experience in this area has to do with the cloning and sequencing of the genes from Maori themselves. And, in that area there are regulations ... that govern ethical research within the country. And so, for example, one has to get permission from the RHA Ethics Committees, again through the standard procedures, and then in addition to that the Ethics Committee has an expectation that you will undertake and have evidence of having undertaken appropriate consultation with the iwi groups on whom ... that type of work is to be performed.⁵¹

108. However, there are two areas of concern additional to the work of ethics committees requiring more attention: consideration of cultural issues that fall outside their domain, and provision for generic policy decisions.

109. Some Maori cultural issues are not considered by ethics committees, including those arising in areas of research such as transgenics and the use of indigenous flora and fauna.

110. We were made aware that some research had proceeded without appropriate consultation with local iwi. For instance, Bevan Tipene Matua (Ngai Tahu, Kahungunu) told us at the Christchurch hui that the delegation of approval of low-risk genetic modification research to IBSCs:

... resulted in the last two years in GM work on the kokako, the saddle back, the tuatara, pipi, kuku, tio, toheroa, a native gecko, tuere, tuangi and others. Those are the ones we know about ... only two of those we knew about before they even went through. We found out ... about six months after they were approved.⁵²

111. In his judgment in the *Bleakley* case⁵³ (discussed in chapter 11: Te Tiriti o Waitangi), Justice McGechan noted that the application to the IBSC for (delegated) approval of the initial creation and storage of the genetically modified embryos did not require public notification. The Judge described this as “a quirk of the legislation”.

112. It would be superfluous and add unnecessary expense and delay to require every low-risk application to be publicly notified. However, IBSCs should be alert to applications having the potential to cause concern or offence on cultural or ethical grounds, which will require appropriate consultation notwithstanding the absence of significant physical risk.

113. Dr Mere Roberts, Associate Dean (Maori), Faculty of Science, University of Auckland, appearing for Nga Kaihautu Tikanga Taiao, the Maori advisory committee of ERMA, discussed these difficulties, emphasising the need to develop consultation mechanisms. She suggested:

... that all research institutions should be encouraged to set up a consultative committee to develop long-term relationships with Maori and to engage in constructive dialogue on research issues of concern to Maori. I believe this is an area much broader than that of solely genetic engineering. There is not enough consultation between scientists and the Maori community, and I don't believe our institutions do enough to deal with that.⁵⁴

114. She acknowledged the need to develop models that address those situations where national consultation is required, and where different iwi may expect to be included in consultation.

115. The timing of that consultation is also important. Often low-risk research is lodged under the rapid assessment procedure, and the researcher may leave consultation until after the application has been lodged, when insufficient time is available. Dr Roberts stated:

I think the emphasis I want to make here, is that scientists must be encouraged to engage in this dialogue before they lodge the application, and if it takes them two years to walk up and down the country and talk to every hapu, so be it.⁵⁵

116. We agree it is important that scientists engage in this dialogue before they lodge an application. But we also think it is in everyone's interest to find more effective ways to carry out the consultation. If the costs, in time and money, of consultation are too high, scientists will move the focus of their research away from areas, such as conservation genetics, that are of interest to Maori and the wider community. Indeed, scientists may leave the country for less restrictive work conditions. If for Maori the difficulties of consultation are too great, they will be unable to respond quickly or authoritatively.

117. Work in this area has begun. In addition to the initiatives of Nga Kaihautu Tikanga Taiao, some research institutions have taken steps to create better relationships with Maori communities and to develop appropriate mechanisms for consultation. These steps can both resource Maori for the demands of consultation with researchers, and better manage the workload of researchers developing the

research. For instance, Dr Ian Smith, Deputy Vice-Chancellor, presenting evidence for the University of Otago, told us:

... the way that the University is doing this to facilitate the consultation is ... to pay to Ngai Tahu enough money for them to devote a full half time position from a person to work with the senior members of the iwi who have to be consulted to make the decision. And I think that that work load is one of the major issues, and I think that often the consultation work load, or the scientists feel that it's a lot of work for them, I think they sometimes need to remember that there might be 70 applications, and so the people sitting on the other side of the table have at times as much work to do in the consultation. So, we made the decision to allocate some money from our research budget towards this process in the hope of building a long-term relationship with the two-way understanding, which will make it more efficient.⁵⁶

This relationship seems to work, as we heard from tangata whenua and the Maori representative at the Dunedin regional hui held at Otakou kaik.

118. The resource issue was also recognised by Dr Andrew Pratt, the Chair of the University of Canterbury's IBSC, who told us when speaking as a witness for the University:

... Maori are not resourced to deal with these issues, they don't have financial support to deal with their responsibilities of – under consultation, they're working out of good faith, ... We believe that the resource issue has not been properly addressed... there's an ad hoc development of policy which in several years time will evolve in a reasonable policy ...⁵⁷

119. The resourcing of Maori to be able to contribute this expertise to the approval process extends beyond the immediate costs. We also became aware of the need to resource the training of more Maori so that they will have not only cultural but also scientific expertise to contribute to the process.

120. We note that the authority delegated by ERMA to IBSCs requires that they carry out ERMA's responsibilities to consult with Maori with manawhenua. It is important that IBSCs understand the nature and extent of the consultation required, and indeed ERMA should not delegate to IBSCs unless it is satisfied that the IBSC has the capacity to consult appropriately.

121. Dr Oliver Sutherland, Deputy Chair of ERMA, told the Commission as a witness for ERMA that "in the middle of last year we required any IBSC that was dealing with native species, transgenic work with native species, to include a Maori member from the local iwi on that IBSC". The Commission is aware that not all IBSCs currently have Maori membership. This may raise questions about how they consult Maori over applications. A further issue is that of ensuring consultation is carried out with Maori who have manawhenua for an area, and have the mandate

to speak on behalf of the relevant Maori community. We referred to these matters in more detail in chapter 3 (Cultural, ethical and spiritual issues).

122. We are of the view that local IBSCs, with their delegated authority from ERMA, are responsible for advising researchers when consultation is required. In addition, it is important that research institutions both understand the resource requirements on local communities with whom they consult, and take responsibility to develop the relationships between the research institution and those communities. We discuss an appropriate model of consultation in chapter 11 (Te Tiriti o Waitangi).

Recommendation 6.10

that Institutional Biological Safety Committees include at least one Maori member, appointed on the nomination of the hapu or iwi with manawhenua in the locality affected by an application.

123. During our deliberations it became clear that some cultural and ethical decisions needed to be addressed at a generic level, rather than on the case-by-case approach currently taken by ethics committees. Examples are germ line gene therapy, and the use of human genes in animals.

124. To this end, as mentioned earlier, we are proposing the establishment of Toi te Taiao : the Bioethics Council to which issues can be referred by ethics committees, ERMA or Government. We discuss this further in chapter 14 (The biotechnology century: three major proposals).

Research funding

125. In New Zealand research funding is a combination of public funding and private investment. In the 2000/2001 Budget, Government allocated \$474 million to research. The principal distributors were:

- \$383 million: Foundation for Research, Science and Technology (FRST) [IP21]
- \$26 million: Marsden Fund, Royal Society of New Zealand
- \$40 million: Health Research Council.

126. In its submission, FRST estimated that of the \$383 million it allocates, \$130–135 million (approximately 35%) is invested in research directly involving genetic modification technology. HRC estimated that \$16 million (40%) of its allocation was assigned to research involving the use of genetic technologies.

127. Of the \$383 million allocated by FRST, key areas of expenditure relevant to the work of the Commission identified were:

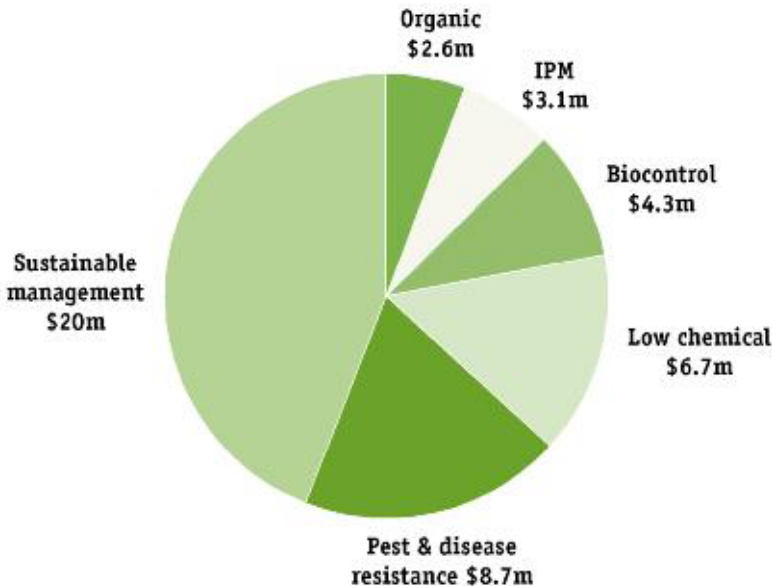
- \$171 million: research for industry to improve competitiveness
- \$51 million: New Economy Research Fund for leading-edge research capability to underpin new and emerging industries and enterprises
- \$84 million: environmental research.

128. The Commission received no evidence about the amount of private research investment involving genetic modification.

129. When asked to compare their research funding allocation to genetic modification as compared with the organic industry, FRST estimated that its expenditure of \$214 million on biologically related funding was assigned as follows:

- \$35 million for research where genetic modification is a key technique
- \$95 million may use gene technology tools
- \$45 million for organic industry outcomes.

130. The \$45 million is described in the following chart based on information supplied by FRST.



131. FRST made the point that clear differentiations are not possible because much research underpins more than one production system. Research in sustainable management, for example, benefits conventional as well as organic farmers. Pest control is likewise of benefit to all production systems. The point was also made that differentials in the dollar amounts allocated do not necessarily mean one industry is valued more than another. Industries vary according to size, and research in some areas carries greater costs than in others.

132. Some submitters expressed the view that there is a need for greater investment in research in New Zealand, and/or a redistribution of the funds available to provide greater emphasis and support to some areas of research. In addition to the need for research to support societal needs for knowledge, greater investment in research and a stable regulatory environment are necessary to attract and retain high quality staff.

Compliance costs

133. There was a strong view among researchers and companies that the current ERMA processes result in unnecessary and burdensome compliance costs for low risk areas of research, and that the approval process ought to differentiate between low-risk and high-risk genetic research.

134. For instance, the Biotechnology Association said:

The process required regarding the release of GM organisms or products is appropriate, but for routine containment the science involved does not warrant the justifications required. ... The present cost structure for university laboratories is not sustainable. In some instances research projects have been changed because the compliance cost to ERMA is more than the grant received from the government to do the work.⁵⁸

135. Dr Pratt described the current situation as unworkable:

It is inordinately difficult to do some of this work here because of the nature of the regulations. In fact, it's easier to go overseas and perform the research overseas and return to New Zealand and pay all the attendant costs, than to go through the regulatory compliance. Because even for experiments that overseas would require no formal risk assessment, it's cheaper to go to America where the regulations accept that the proposed experiments are of negligible risk. To do the experiments in America and then return here – and in fact that type of activity is already ongoing – it's a huge disincentive and we would contend it's a misuse of resources.⁵⁹

136. Genesis Research and Development submitted:

... that the regulations for control of every experimental GMO made in ... a containment facility be amended to decrease the bureaucratic load on scientists and that the oversight of laboratories as containment facilities be rigorously monitored.⁶⁰

137. The University of Canterbury was of the view that HSNO had led to an overly regulated environment for low-risk work, which established serious disincentives to biological research without improving safety. The New Zealand Forest Research Institute [IP2] agreed with this view and in addition thought that the cost of compliance with HSNO needed to be budgeted into the funding portfolios related to FRST-funded projects.

138. Federated Farmers of New Zealand [IP34] expressed the view that the high costs of the ERMA process could provide perverse incentives for people to import organisms illegally. They cited the recent New Zealand experience of biosecurity breach by illegal importation of the rabbit calicivirus.

139. MAF agreed the cost of compliance had been a key driver in recent reviews of regulatory regimes they administered. MAF submitted that:

New Zealand's isolation and border control activities ensure one of the world's highest levels of biosecurity protection, but the border is not impenetrable. While it is illegal to import unapproved GM organisms into the country, border control alone could not prevent accidental or deliberate introductions of GM organisms. MAF could take actions under the Biosecurity Act to manage any GM organisms that were declared to be 'unwanted organisms'.⁶¹

Recommendation 6.11

that the funders of research portfolios be resourced to include the costs of compliance with the Hazardous Substances and New Organisms Act 1996.

140. Together with recommendations earlier in this chapter, this should have the effect of reducing compliance costs for contained research.

Priorities for funding

141. The Commission identified particular areas of research as in need of greater research investment. These were the environmental impacts of genetically modified plants (including the nature and extent of horizontal gene transfer), organic and integrated pest management methods of sustainable agriculture, and the social, cultural and ethical aspects of genetic modification.

Environmental effects

142. Little is yet known about the environmental impacts of genetically modified organisms, and in particular in New Zealand “on the potential adverse effects, or risks of such effects, on the indigenous biota”.⁶² Landcare Research reported on two small studies it has underway, and AgResearch has established a Public Good

Science Fund programme entitled Environmental Impacts of New Technologies. While FRST had called for tenders for work in this area, Landcare Research:

... believe that this level of funding [for environmental impact research] is inadequate for researching such risks. It is far below the levels of funding invested in other risks to indigenous biota such as vertebrate pests (\$6.8 million), invasive weeds (\$2.7 million), or invasive invertebrates and microbes (\$2.6 million). Landcare Research believes that a significantly greater investment is required in research to assess the risks of adverse effects on indigenous biota from GM crops and other GM products released into the environment.⁶³

143. Others affirmed the importance of funding such research. For instance, Dr Stephen Goldson, for AgResearch, argued that such research would benefit the public through increased understanding of the activity of genetically modified organisms. Referring to such research taking place in the laboratory, he suggested:

such work would alert the public and commercial companies to any potentially damaging impacts of GMOs before expensive development costs are incurred and field releases take place. Only opportunists seeking rapid returns from untested technologies would be disadvantaged.⁶⁴

144. There is a particular and specific need for further research to be carried out on horizontal gene transfer. While it is established that pathways exist for gene transfer between species, it is not known under what conditions gene flow occurs and with what possible impacts. We heard evidence of some research in this area, but there are some significant gaps in knowledge on which to base risk assessments for field trials or release of genetically modified organisms. As Dr Jack Heinemann, an expert in horizontal gene transfer from the University of Canterbury, said under cross-examination:

... the current state of events or affairs with horizontal gene transfer is that it's a very interesting natural phenomenon we have to follow. We're informed by doing this kind of work, but gene transfer itself is not risk. It's a natural process. What we have to understand is whether or not there will be a risk from a recombinant event.⁶⁵

145. While international research will increase our knowledge in this area, there is also a need for research specific to the New Zealand environment.

Recommendation 6.12

that the Environmental Risk Management Authority require research on environmental impacts on soil and ecosystems before release of genetically modified crops is approved.

Organics and sustainable agriculture

146. Several submitters called for more funding for research into organics and sustainable agriculture. For example, the Green Party of Aotearoa/New Zealand [IP83] in its written submission said:

New Zealand should increase science funding and capacity building in areas of research that will support organic production, sustainable land management and fundamental understanding of ecosystems, both natural and farmed.⁶⁶

147. We also heard concern about the distribution of public research funding across different areas of work, and that research involving genetic modification may be getting an inappropriately high level of support, to the detriment of other important areas which are also of economic and environmental importance.

148. For instance, Seager Mason, the Chief Organic Certification Inspector for BIO-GRO New Zealand [IP58], said:

We would dearly love some percentage, 50% even would be lovely, for organic research ... [of] research monies that are being put into genetic engineering.⁶⁷

149. New Zealand Worm Federation [IP94] asked that “the New Zealand government spend as much money on organic agricultural research as that on agricultural genetic modification research”.⁶⁸

Recommendation 6.13

that public research funding be allocated to ensure organic and other sustainable agricultural systems are adequately supported.

Social science and research

150. There was a call for further economic research. As the Organic Product Exporters Group [IP53] wrote:

There has been only a modest amount of research investigating potential negative economic impacts on other sectors like organics, Integrated Pest Management (IPM) systems (like KiwiGreen which reject the use of GM technologies), conventional producers not using GMOs, or other sectors like tourism. The negative impacts that might be felt by other industries need to be matched against the potential economic gains from GMOs.⁶⁹

151. The New Zealand Catholic Bishops' Conference [IP38] linked the need for economic research with any balancing of individual rights and the common good:

The extent of individual rights in relation to the common good cannot be determined without sound and neutral research to resolve competing claims about the effects on the New Zealand economy of allowing or not allowing the use of GM.⁷⁰

152. There was also a call for more research into the social effect and acceptability of genetically modified organisms, and the ethical, moral and spiritual issues that arise at the interface between science and society. There were two aspects to this. For instance, SAFE (Save Animals From Exploitation) [IP85] maintained that:

There is a widening gap between society's technological gains and the gains of ethical science (understanding/practical wisdom). This is related to the fact that 'hard sciences' like biotechnology are significantly funded by commercial interests and government research funding, whereas social sciences are not.⁷¹

153. Landcare Research, which is mainly publicly funded, added:

Social research is invaluable in defining some of the uncertainties about the likely use of particular GM products, and hence the specifications that a GM product will need to meet. We strongly believe that ongoing research on attitudes, social learning and public acceptance will be essential.⁷²

154. ERMA pointed out that:

... if the question of the "acceptability" of genetic modification is considered to be important, it is essential that more is known about how our society forms those types of judgements and how acceptability can be measured. That requires properly designed and targeted research.⁷³

155. While FRST has had one tender for work in this area, AgResearch submitted that more funding is required for work that "is clearly in the public interest and in the interest of industry supply chains delivering products to consumers".⁷⁴

156. We also heard calls for research on the bioethics of genetic modification. For instance, the Catholic Bishops' Conference wrote:

Sufficient resources need to be provided for research and teaching in bioethics and similar disciplines, to allow them to contribute more fully to the debate about new biotechnology.⁷⁵

157. Research involving genetic modification is one area that requires support, but it is not the only one, and funding decisions need to address the total social and economic context.

Recommendation 6.14

that public research funding portfolios be resourced to include research on the socio-economic and ethical impacts of the release of genetically modified organisms.

chapter |

7



Crops and
other field uses

7.

Crops and other field uses

Key issues:

- The effect of genetic modification on our unique environment and biodiversity
- Whether the risks associated with genetically modified crops can be minimised
- Can we provide a strategic framework that allows for organics, conventional farming, IPM horticulture and genetically modified crops?

Introduction

1. Much evidence was presented to the Commission on the use of genetic modification in food crops. Non-food applications of genetic modification were also discussed, including uses in forestry, pest and weed control, bioremediation and bioreactors.
2. This chapter discusses, among other things, the use of genetic modification in food crops in New Zealand. Food consumption and medicines are dealt with in separate chapters. Here we consider for the first time the release of genetically modified organisms and products into the environment.

Crops, fruit and vegetables

Applications and benefits

3. Genetic modification of crops is generally undertaken to:
 - incorporate pest or viral resistance into plants
 - incorporate herbicide tolerance
 - increase yields or improve nutritional quality
 - slow ripening in fruit and flowers by inhibiting the actions of certain genes
 - change colours in fruit and flowers, again by inhibiting the actions of certain genes.

4. Genetic modification can lead to crop improvements more quickly than classical breeding, by efficiently identifying and transferring the desired trait. That characteristic alone is propagated.¹ Balanced with such benefits are the potential risks that genetic modification introduces, such as the ability to cross the species boundary and the uncertainty and potential for harm this introduces.²

5. Currently there are no genetically modified food or other crops approved for open field release in New Zealand. New Zealand's current crop production systems include traditional or conventional farming, IPM (Integrated Pest Management), and organic farming. IPM was defined by Dr Hugh Campbell, social geographer and witness for the Organic Products Exporters Group [IP53], as "an internationally recognised movement in which scientists attempt to create crop and livestock management systems that reduce reliance on broad spectrum chemical interventions and promote more ecologically integrated solutions to pest control"³ IPM production systems are more environmentally friendly and are closer to the organic system of production than to conventional farming. They have been fostered in New Zealand by the pip fruit, kiwifruit and wine industries.

6. The fact that genetically modified crops are not commercially grown in New Zealand is not clearly understood, as the Commission's survey shows. The survey results showed that 680 of respondents believed genetic modification was currently being used in commercial crops in New Zealand, with 58% disapproving of such use. There is also confusion in the public understanding of the path between experimental work and commercial release. To date, genetic modification has only been used as a research tool in New Zealand's primary industries. Research is being undertaken to understand how plants, trees and animals grow, to develop new varieties of plants and animals, alter the production efficiency or quality of food, crops and fibre, and develop new products.⁴

7. The Ministry of Agriculture and Forestry (MAF) in its public submission told us that "genetically modified crops have been rapidly adopted by farmers in some overseas countries, but genetic modification is mainly used as a research tool in New Zealand"⁵ MAF noted that China was the first country to grow genetically modified crops commercially in the early 1990s, with the United States establishing widespread commercial plantings of soybean and corn crops in 1996. MAF stated that genetically modified crops are grown in 12 countries and occupy close to 40 million hectares (approximately 1.5 times the area of New Zealand). Internationally, most genetically modified crops are grown in the United States (72%), Argentina (17%) and Canada (10%), with minor plantings in China, Australia, South Africa, Mexico, Spain, France, Portugal, Romania and the Ukraine.⁶

8. In New Zealand the first contained field trials of genetically modified organisms were conducted in 1988 and since that time more than 50 approvals

have been granted for further contained field trials.⁷ Genetic modification field trials in New Zealand have taken the form of small-scale experiments with a range of organisms. MAF lists these as: pasture plants (clover), fruit (apple, kiwifruit and tamarillo), vegetables (asparagus, broccoli, potato), field grains and crops (barley, canola, forage brassica, maize, peas, sugar beet), ornamental crops (*Lisianthus*, *Petunia*), animals (goats, sheep, cattle), trees (*Pinus radiata*) and microorganisms (bacteria).⁸ Trials have not been conducted on soy or wheat crops in New Zealand.

9. The modifications in these trials were described as resistance to herbicides, viral, bacterial and fungal diseases, insects, and improvements in crop performance. Some examples were:

- peas, to test for pea mosaic virus which decreases yields
- tamarillos, to test for resistance to a virus which causes black spotting of the skins, decreases yields and shortens tree life
- potatoes, to test for resistance to potato tuber moth and to herbicide, to confer bacterial and insect resistance, and to improve the nutritional and cooking qualities of harvested tubers
- petunias, to alter form or colour and assess field performance.

10. As discussed in chapter 4 (Environmental and health issues), a research trial to develop salmon with additional growth hormone genes, with the ultimate aim of full release, has also been conducted in New Zealand. Concern was expressed about the standard of containment of the transgenic fish. The Environmental Risk Management Authority (ERMA) [IP76], responsible for the project from part way through its term, imposed significant improvements in the containment of the research. However when deformities developed in the fish, the research was terminated.

Economic benefits

11. Evidence identified likely economic benefits from genetically modifying crops as building agricultural expertise by making commodity production more competitive; the development of niche markets; expanded opportunities in New Zealand's knowledge economy; and decreased chemical use. The National Farmers' Federation of Australia, in a report on the Australian Gene Technology Bill 2000, listed production benefits from crops derived from gene technology as:

- increased resistance to pests and diseases
- associated reductions in pesticide and herbicide use, input costs and adverse environmental impacts
- reduced labour and energy costs
- improved yields and quality

- adaptation to industry and consumer requirements
- better accommodation to environmental and climatic factors (such as water shortages, salty soils and drought)
- incorporation of nitrogen fixing ability into crops, thereby promoting soil nutrition and enhanced productivity
- accelerated breeding of plants with improved characteristics, leading to productivity gains, such as faster growing trees and higher quality grains.⁹

Pasture crops

12. Dr Derek Woodfield, a plant breeder and geneticist at AgResearch [IP13], described research to develop white clover resistance to porina moth larvae,¹⁰ and also high-energy white clover and perennial ryegrass. He saw among the benefits of such applications:

- the need to use less chemical pesticide
- improved energy yields from pasture plants (in turn leading to higher milk production and longer lactation in cows, greater weight gain and wool growth in animals, and reduced ammonia and methane pollution)
- improved yield and quality of pasture plants
- new knowledge of biological processes.

13. Similarly, Warwick Green, President of the New Zealand Plant Breeding and Research Association and an executive of Wrightson [IP3], outlined benefits of the genetic modification of ryegrass, noting there was potential to modify ryegrass pollens to eliminate the allergic response in humans and to improve animal health by reducing the nitrate toxicity level of greenfeed crops.

14. Genetic modification might also have the potential, through modification of grasses such as ryegrass, to develop deeper root structures that could stabilise high country soils. Genetically modified crops with improved uptake of nutrients might also be developed, requiring less fertiliser and in turn reducing nutrient run-off into waterways and the subsequent over-production of weeds.

Seed production

15. New Zealand is internationally recognised as a producer of high quality seeds and has a national seed certification scheme. Neil Barton, a Canterbury seed farmer and chairman of the Grains Council of Federated Farmers a witness, for Federated Farmers of New Zealand [IP34], provided evidence about the counter-season seed production opportunities in New Zealand. He noted that the ability to adopt genetic modification technologies created further potential to develop a large-scale and profitable seed multiplication industry in this country. Mr Barton said that the production of seed crops here during the northern

hemisphere winter enabled plant breeders and seed multipliers to double their annual production volumes and increase the rate of genetic gain in plant varieties. Similarly, Aventis CropScience [IP14] stated locating seed production and evaluation trials in New Zealand allowed two seasons in a single year for field trials, and such benefits had been recognised here by major seed companies such as Pioneer, Pacific Seeds and Wrightson Research.

Horticulture

16. HortResearch [IP5] mentioned in its submission that in its research and development programmes, genetic modification technologies were used in relation to plant breeding, crop production and post-harvest handling. Dr Richard Newcombe, plant molecular biologist for HortResearch, said these included HortResearch's initiation of a genomics project to discover and determine the function of genes from New Zealand's key horticultural crops, including apples and kiwifruit.

17. New Zealand Vegetable and Potato Growers' Federation/New Zealand Fruitgrowers' Federation/New Zealand Berryfruit Growers' Federation (Vegfed, Fruitgrowers, Berryfed) [IP75] said in its submission it had previously supported a trial to produce potato plants with genetically modified resistance to the potato tuber moth, the major insect pest of potatoes in many parts of the world. A trial to produce genetically modified resistance to alfalfa mosaic virus (AMV) in peas had the potential to reduce the economic impact of the disease on growers.

18. Vegfed, Fruitgrowers, Berryfed also supported a HortResearch project to introduce resistance to tamarillo mosaic virus (TaMV) into tamarillo plants, which has the potential to increase tamarillo exports:

Most tamarillo plants in New Zealand are infected with this virus. TaMV remains a barrier to tamarillo exports because infection is obvious and fruit quality is reduced.¹¹

19. HortResearch's genomics programme has benefits for Vegfed, Fruitgrowers, Berryfed. The programme includes gene discovery efforts across a number of target areas, such as the genes involved in the synthesis of secondary metabolites, including antioxidants and vitamins, known to be present in abundance in apples, kiwifruit and berryfruit. The HortResearch project will generate a number of product opportunities using marker assisted selection. This method, referred to as 'smart breeding', uses genetic identification at the level of seeds or young plants to identify desired traits, rather than waiting years until the plant matures and has seeds or fruit of its own. The time taken for breeding is condensed. Dr Sue Gardiner of HortResearch, who uses smart breeding to develop new apple varieties, stressed the trees themselves were not genetically modified.

20. Dr Adolf Stroombergen, economist, Infometrics Consulting Ltd, appearing for New Zealand Life Sciences Network [IP24], noted in his witness brief that genetic modification could be used to provide disease resistance to apples, “notably resistance to black spot and powdery mildew”, and that, while there may be some output benefit in terms of higher quality apples, the main benefit was on the input side:

The annual cost of spraying for black spot and powdery mildew is \$43 million. World-wide the spraying programme is estimated to be worth \$6 billion per annum. Thus a successful product would also generate income from intellectual property and gene patents, plus royalties and licence fees from new plant varieties.¹²

21. Peter Corish, a farmer and Chairman of the Australian Cotton Industry Council, who was called by Federated Farmers, told us about his experiences growing Bt cotton. On his farm Mr Corish had been growing Ingard cotton, a Monsanto product with a Bt gene fused into a conventional cotton variety. The Bt toxin used in Ingard cotton is target-specific to the heliothis caterpillar, a major pest in Australian cotton crops. The principal benefit that Bt cotton provides is the reduced use of pesticides. Mr Corish estimated where he has Ingard cotton plantings his usage of pesticide has been reduced by 50%:

The use of Ingard cotton has allowed us to reduce our pesticide usage by 50% and in some cases more than 50% in the areas where Ingard cotton is grown. That means it’s easier to manage in sensitive areas, for example, around houses, waterways, roads, where some of those public issues really come to the fore.¹³

22. Mr Corish said that Ingard cotton was introduced into Australia in 1996 and had been readily accepted by growers. He noted that consumer issues around Bt cotton had not generally arisen: “I would suggest that one major reason for that is that people wear cotton, they don’t actually eat it.”¹⁴ In Australia, conditions had been imposed on the use of Ingard cotton, requiring that no more than 30% of a planted crop could be Ingard cotton, so that the chances of the heliothis caterpillar developing resistance were minimised.¹⁵

Managing risks

23. Many of the environmental risks that might be generated by genetically modified crops have been addressed on a general level in chapter 4 and chapter 6 (Research).

24. The Commission considers that more research is needed into the environmental risks that genetically modified crops and non-food uses might pose for the ecosystems into which they could be released.

Bt modified crops

25. *Bacillus thuringiensis* (Bt) is a bacterium that creates its own insecticide. Bt plants have been modified to produce this substance in their leaves and/or pollen all year round. Insects that eat the plant die, so the plant is protected. Molecular geneticists designed these crops to help farmers sustain better yields using fewer sprays. Overseas, Bt has been incorporated into many genetically modified plants to protect plants from insect pests.

26. The Department of Conservation in its public submission commented on the impact that Bt bacteria might have such as

- risks to native insects related to the pest being targeted
- Bt plants might hybridise and threaten the integrity of indigenous species
- adverse effects on ecological processes in indigenous ecosystems
- modified plants hybridising with weeds in the conservation estate.

27. The Commission heard from organic producers about their use of the Bt microorganism as an insecticidal spray and their fear that the continued presence of the toxin in Bt plants would increase the risk of Bt resistance developing in the local insect population, and ruining one of their defences against insect attack. Home gardeners also use Bt spray.

28. Bt-modified crops are usually restricted to a proportion of the total crop in order to provide “refugia” for beneficial insects. As noted, Peter Corish told us in Australia Bt-resistant cotton has a post-release condition limiting it to 30% of the total cotton crop planted. The Commission agrees that Bt resistance is to be avoided and considers that New Zealand needs to develop a strategy to manage the use of this insecticide whether incorporated in plants or used as a conventional spray. This is to delay the inevitable emergence of insect resistance.

Recommendation 7.1

that, prior to the release of any Bt-modified crops, the appropriate agencies develop a strategy for the use of the Bt toxin in sprays and genetically modified plants, taking into account:

- **the concept of refugia**
- **limitations on total planted area**
- **home gardener use.**

Increased weediness through outcrossing

29. A number of witnesses presented material to the Commission stating that genetically modified plants would take over and result in the development of super weeds. Whether or not a crop will develop as a weed depends on the

characteristics of the plant. Professor Klaus Ammann, a Swiss botanist called by the Life Sciences Network, provided a list of the characteristics of weeds in his witness brief. The Royal Forest and Bird Protection Society of New Zealand [IP79] also noted that some plant species become weeds more predictably than others. Plant species that exhibit easy cross-pollination traits are most prone to weediness, including floriculture plants and crops such as oats, barley, ryegrass, sunflowers, and oilseed rape (canola).

30. The problem of outcrossing was often raised by submitters. Outcrossing is the term given to cross-pollination with compatible relatives.

31. We heard evidence from various parties that some crops posed higher environmental risks than others. Professor Ammann provided the Commission with a risk assessment framework for genetically modified crops that identified whether the crop was invasive as a weed and whether it would hybridise with wild relatives. He used three indicators that determined the chances for successful gene flow: the dispersal of pollen, the dispersal of diaspores and the frequency of distribution of wild relatives. Using these codes Professor Ammann had developed five categories of risk probability for gene dispersal from transgenic crops to wild flora, ranging from no gene flow effect through to substantial and widespread effects. The Swiss analysis found that crops such as fescue, alfalfa and ryegrass would have substantial and widespread risk, but other crops such as potato, maize and tomato would have no effect as they had no wild relatives in Europe and had little risk of weediness.¹⁶ Dr Cohen stated in his evidence that in New Zealand very few introduced plants were able to hybridise with native flora and very few crop plants had weedy relatives here, apart from weedy brassicas. These weeds were accidentally introduced with crop seeds and are not native to New Zealand.

32. Dr E. Ann Clark, a pasture-grass scientist from Canada called by the Green Party of Aotearoa/New Zealand [IP83], reported in a research paper¹⁷ that outcrossing with weedy ancestors is not a problem with genetically modified crops if there is no wild relative or weedy ancestor for the crop in the vicinity. Professor Ammann also provided evidence supporting this view, as did Dr Michael Berridge, the Acting Director of the Malaghan Institute and a witness called by the New Zealand Association of Scientists [IP92]. Dr Berridge stated, in relation to pollen drift from genetically modified plants, that “many plants used for food production purposes do not have weedy characteristics and have no wild relatives in New Zealand”.¹⁸ He commented that selective breeding for food purposes has essentially ring-fenced most crop plants by reducing fitness to survive in the wild and that “terminator technology” could be applied where there might be a threat to native flora or where weedy characteristics were present. Terminator technology is one of the sterility technologies discussed below.

33. The Commission heard no evidence that genetic modification increased invasiveness of weeds. Certainly canola can become a weed pest in certain environments, but genetic modification of this plant does not appear to increase its weediness.¹⁹ Several witnesses provided examples of situations where canola had developed as a weed. Percy Schmeiser, a canola farmer from Saskatchewan, Canada called by Bio Dynamic Farming and Gardening Association in New Zealand [IP61], told the Commission that canola had become a major noxious weed in Canada and could be seen in towns and along roadways.²⁰ Nelson GE Free Awareness Group [IP100] also commented that crops of canola in the South Island had resulted in the appearance of canola weeds.²¹

34. Dr Beatrix Tappeser, Head of the Department of Risk Assessment of Genetic Engineering at the Institute for Applied Ecology at Freiburg, Germany, and a witness called by the Pacific Institute of Resource Management [IP84], said experience and data pointed to a high probability that canola populations would prevail outside cultivated areas, as well as to the possibility of gene flow to non-transgenic populations and to wild herbs. Dr Tappeser cited an example where under field conditions canola had proven capable of hybridising with wild turnip, wild radish, wild mustard and a variety of other mustard species.²² Dr Anthony Connor, a plant geneticist with Crop and Food Research [IP4], said,

In our recent extensive report on “Ecological risks and managerial consequences of Roundup Ready oilseed rape in New Zealand” it was concluded: Artificial and natural field hybridisation studies, and current geographical distributions of casual escape, naturalised, indigenous and endemic species in the large Brassicaceae family, reveal that field hybridisations between oilseed rape and most other Brassicaceae species are highly improbable. Hybridisation of oilseed rape with wild turnip (*B. rapa* ssp. *silvestris*) and *B. juncea* is, however, likely to occur, but the hybrids will be largely confined to the land growing the oilseed rape where they will readily succumb to the methods currently employed for controlling volunteer plants of conventional non-transgenic rape.²³

35. A study undertaken in the United Kingdom aimed to find out whether transgenic plants would be likely to persist in the wild if they dispersed from their cultivated habitat. The study involved four transgenic crops (canola, potato, maize and sugar beet) grown in 12 different habitats over a 10-year period. The study results indicated that “in no case were the genetically modified plants found to be more invasive or more persistent than their conventional counterparts”.²⁴ Virtually all transgenic plants had died out within two to four years.

Pollen dispersal

36. Dr Phillip Salisbury, Senior Plant Breeder and Researcher from the University of Melbourne, called by the Life Sciences Network, Monsanto New Zealand [IP6] and the New Zealand Feed Manufacturers Federation/Poultry

Industry Association of New Zealand/Egg Producers Federation of New Zealand [IP35], stated in his evidence that canola pollen is transferred by wind and insects, especially honeybees, and that pollen counts decline steeply with distance from the crop. He noted that the vast majority of canola pollen travels less than 10 metres, although in extreme cases it can disperse by wind up to 1.5 kilometres, and by insect transfer up to 4 kilometres. Dr Daniel Cohen, a plant scientist with HortResearch, said, when looking at pollen movement, factors needing to be considered included how far the pollen can travel, how long it remains viable, the receptivity that a plant stigma has to the pollen and the concentration of competing viable pollen. Dr Cohen told the Commission that wind-borne pollens from some plants such as pine trees were light and could be dispersed over large distances, whereas other pollens like those from maize were heavier and fell within a metre of the plant.

37. Robert MacDonald, a witness for Aventis CropScience, discussed the pollen dispersal of canola, saying that some pollen grains might be transported by wind over distances of 32 metres, but around 75% of the total pollen was captured within 6 metres of the parent plant. He also cited other pollen monitoring studies that showed pollen had dispersed up to 400 metres from large release areas of transgenic canola. Mr MacDonald is the Global Product Safety Manager for Oilseed Rape (Canola) from Saskatchewan, Canada, and provided evidence that seed loss and dispersal from harvesters and grain transport trucks represents the main mechanism for the long-range dispersal of canola, regardless of its transgenic nature.²⁵

Herbicide use

38. Herbicide resistance in genetically modified crops has been promoted to farmers as a means of reducing the need to use herbicides to control weeds. The Forest and Bird Protection Society stated in its written submission that a range of issues arose with the development of herbicide-resistant crops, including the development of resistance to the herbicide, effects on non-target species and the possibility of the transgenic crop becoming a weed.

39. Although several witnesses claimed that planting herbicide-resistant crops would lead to reduced herbicide use, evidence was also presented that some herbicide-resistant plants were double or triple stacking resistance to a range of herbicides, resulting in the need for an alternative, and potentially more toxic, herbicide to control volunteer self-seeded plants. Dr Lin Roberts in her background paper prepared for the Commission on *The Environmental Aspects of Genetic Modification*, cited evidence²⁶ that the herbicide resistance modification increased the use of herbicides, giving examples of increases in glyphosate usage in the United States.

40. Lavern Affleck, a witness called by the Bio Dynamic Farming and Gardening Association in New Zealand [IP61], referred to problems arising from the use of genetically modified Roundup Ready canola. Mr Affleck, a cropping farmer from Saskatchewan in Canada, gave evidence by video link, telling us that he did not mind being indoors as the outside temperature was minus 20 degrees. He chose not to plant Roundup Ready canola as he was aware it could result in herbicide-resistant volunteers (self-seeded) establishing themselves as weeds. However, because of contamination from neighbouring fields of Roundup Ready canola, Roundup-resistant seeds had transferred to his land, with the result that he could no longer rely on Roundup alone as a weed control agent. Mr Affleck did not attribute this to carelessness on anyone's part: "There is just no practical way of keeping it out of our fields."²⁷ Mr Affleck acknowledged Monsanto's help in spraying with 2,4-D but said that once the Roundup Ready crop "escaped", despite best efforts it was impossible to control. He spoke of volunteer canola that was resistant to three herbicides, and that some suspected of resistance to 2,4-D was now showing up as well. He noted that in his experience crops and weeds were spread in many ways: by wind, waterways, and farm machinery and trucks. He commented that some degree of genetically modified crop contamination was now present across the entire Canadian prairie.

41. It appeared to the Commission that Mr Affleck raised some important concerns. We consider that there are potential risks involved in planting genetically modified crops on a large scale, and that sufficient consideration should be given to the dangers involved and the controls that ought to be put in place.

42. Roundup Ready crops on the market include many not currently important to the New Zealand agricultural economy, such as soya beans, canola for oil and hard maize for animal feeds. These commodity crops are profitable when grown in large quantities, for example on the plains of Canada. The Commission believes that the so-called first wave of genetically modified crops has little to

Percy Schmeiser and Monsanto

Percy Schmeiser and his litigation with Monsanto had become familiar to the Commission long before his appearance as a witness for the Bio Dynamic Farming and Gardening Association. Anti-genetic modification campaigners mentioned his case as exemplifying the perceived evils of genetically modified crops and multinationals in the genetic modification business. In the event the Canadian court held that Mr Schmeiser had knowingly used genetically modified seeds without authority, thus infringing Monsanto's patent. Although we mention the case because of the frequency with which it was brought to our attention, the Commission does not consider it helps solve any of the issues before it.

offer New Zealand, apart from small, specific applications such as counter-season seed multiplication (Wrightson) or specialised pure seed production (Aventis CropScience).

43. Having regard to the evidence on the use of herbicide resistance genes, including the resulting dependency on herbicides for weed control and the possibility of an increase in herbicide resistance in weed plants, we do not consider that these limited uses justify the environmental risk to New Zealand, until more is known about the size and management of that risk. We acknowledge production of pure unmodified seed might provide an economic opportunity.

44. While this is a matter for ERMA the Commission considers crops using herbicide resistance genes should not be approved for release (conditionally or otherwise) until (a) it is clear there is no trend indicating either increased use or increased toxicity of herbicides, and (b) research indicates there is no increase in the weedy outcrossing involving herbicide resistance genes.

Biosecurity and seed certification

45. MAF commented that New Zealand's isolation and border control activities had ensured that we had one of the highest levels of biosecurity protection in the world. However, our borders were not impenetrable, as recently evidenced by the illegal importation from Australia of the rabbit calicivirus (RCD), a viral haemorrhagic disease, in an attempt to control rabbits throughout the country. The Hazardous Substances and New Organisms Act 1996 (HSNO), covering the importation of new organisms, and the Biosecurity Act 1993, covering exclusion, eradication and effective management of pests and unwanted organisms, were in force at the time.

46. A difficult question arising for New Zealand's biosecurity is how to tell whether crops or products imported into New Zealand have been genetically modified. Government is aware some imported seeds may contain a small proportion of genetically modified contaminants and has therefore stepped up security measures to include testing of all imported seed. MAF stated in its written submission that even with the X-ray machines at our international airports some high-risk goods such as seeds are difficult to detect because of their size and shape. It noted seeds are often brought in with passengers or sent in the mail. MAF also commented there is no generic test to detect for genetically modified goods coming into the country and that it relies on importers obtaining the appropriate approvals from ERMA. We therefore acknowledge it is difficult to keep all genetically modified organisms out of the country.

47. Warwick Green, the President of the New Zealand Plant Breeders' Research Association and a witness called by the New Zealand Arable-Food Industry

Council [IP56], said that New Zealand had a voluntary seed quality assurance scheme, administered by MAF as the regulatory authority. Mr Green said “the seed certification scheme can provide an assurance of purity for GM cultivars just as it has done for conventionally bred cultivars for the last 80 years”.²⁸ The Arable-Food Industry Council believed an industry code of practice was required for management of genetically modified crops, similar to codes that operated in countries such as the United Kingdom. Neil Barton commented in his written evidence for the Council that

the New Zealand MAF Seed Certification Scheme is recognised world-wide, and provides purchasers of New Zealand seed with an assurance of high quality product that is true to type, and free from disease and weed contamination.²⁹

48. Mr Barton told the Commission that the grain and seed industry in New Zealand has “an industry recognised protocol for isolation distances for crops to ensure that we don’t have cross-contamination problems, particularly for vegetable seed brassica”.³⁰ Mr Barton said that the protocols were voluntary and to a large extent neighbours worked together, notifying each other of crop locations, to achieve the isolation distances. He commented that where farmers signed a contract to grow a variety of seed vegetables, they had to give an assurance that they could achieve the isolation distances.

49. Dr Morgan Williams, the Parliamentary Commissioner for the Environment [IP70], advised the Commission that to handle genetic modification issues such as pollen drift New Zealand would need more formal systems, and not rely on informal agreements between neighbouring farmers, particularly if it moved toward a more corporate system of farming.³¹

50. Later in this chapter we discuss and make recommendations on the use of buffer zones and separation distances to facilitate coexistence. As part of the Commission’s coexistence strategy, we also recommend in chapter 13 (Major conclusion) that communication networks be developed between different farming interests.

Ornamental and nursery plants

51. Research is currently being conducted to genetically modify petunia and lisianthus plants. An ERMA approval was granted to Crop and Food Research in 1999 for tests to assess the field performance of genetically modified petunias with altered form or pigmentation. When questioned by Greenpeace New Zealand [IP82] about the likelihood of pollen escaping from the petunia field trial, Dr Oliver Sutherland, Deputy Chair of ERMA, said that a requirement of the trial was that all flower buds be removed before they opened.

52. Flowers may be the first genetically modified organisms to be commercially released in this country, as they are not required to undergo evaluation for human health implications and will have a shorter pathway to approval.

53. The genetic modification of flowers and garden plants is likely to be directed towards novelty features or colourings and changes to growing cycles that will allow “out of season” flowering plants to obtain the best prices in high-value niche markets overseas.

Environmental impacts

54. Genetic modification of exotic rather than indigenous plant species reduces the likelihood of outcrossing problems with native species. However, in its written submission Federated Farmers stated that of the 240 naturalised invasive plants that were pests of the conservation estate, around 180 were brought into New Zealand as garden ornamentals. Examples of exotic garden plants that have escaped into the wild to become weeds include lupins, morning glory, Californian poppy and the ginger plant.

55. ERMA documentation³² supplied to the Commission for the petunia field trial showed that the environmental assessment undertaken as part of the application involved investigation of gene transfer to other plants including natives, non-modified petunia plants and a species of wild petunia. The assessment also looked at whether the modified petunia might establish a self-sustaining population. Control mechanisms proposed for the petunia field trial included buffer zones of non-modified petunias and location of the trial site away from residential areas.

56. The risk of a plant becoming a weed could be reduced by the use of sterility technology. This would accelerate the approval of an application to genetically modify a flower or garden plant since potential problems of pollen transfer by bees and insects would be reduced.

Labelling

57. Labelling of propagative material in order for producers to exercise choice was an issue raised by Vegfed, Fruitgrowers, Berryfed:

We believe that labelling of seeds, nursery stock and other propagative material with their GM status is required. This is key to ensuring that information is passed down the production chain and vital in terms of producers being able to exercise choice about whether or not they grow GM crops.³³

58. The Commission is aware of the number of developments in progress in this area and considers that some system of identification needs to be established.

Recommendation 7.2

that the appropriate agencies develop a labelling regime to identify genetically modified seed, nursery stock and propagative material at point of sale.

Bees

59. The principal issues affecting bees and bee products raised in evidence before the Commission included the potential for bees to:

- pick up pollen from genetically modified crops, whether in field trials or grown for production, and cross-pollinate non-genetically modified crops
- produce bee products, such as honey, which could not be guaranteed to be 100%-free from genetic modification.

60. Honeybees, through their pollination activities, are important to agriculture and the environment. Bill Bracks, Board Chairman of Comvita New Zealand [IP74], noted that honeybees are especially vulnerable to any effects of genetic modification of crops, as they rely almost exclusively on pollen as a food source. He also said there was a lack of publicly available evaluations of the effects of genetically modified crops on honeybees.

61. Comvita stated it was New Zealand's largest manufacturer of therapeutic bee products, exporting to more than 20 countries, and last year became a totally genetic modification-free food and dietary supplements company.³⁴ Comvita was therefore opposed to growing genetically modified food crops in New Zealand, as the company would suffer market resistance if its products, particularly manuka honey, could not be guaranteed genetic modification-free. Supporting this view, Dr Doreen Stabinsky, Science Advisor on Genetic Engineering for Greenpeace, said consumers in Europe were increasingly demanding honey sourced from areas where genetically modified crops had not been grown.

62. Comvita referred to honeybees being “free range” as they “can never be excluded from obtaining honey, pollen and propolis resources from any commercially produced outdoor crop”.³⁵ Dr Stabinsky also noted that honeybees were natural pollinators. She commented that bees liked the strong smell and the sweet nectar of canola and that the pollen grains from canola were sticky and could stay on a bee to fertilise plants with pollen on subsequent foraging trips. She cited evidence from the United Kingdom where six beehives located 0.5–4.5 kilometres from a farm-scale trial were found to contain genetically engineered canola pollen.³⁶ Dr Woodfield, a plant breeder and geneticist for AgResearch, spoke of experiments that looked at gene flow of white clover pollen from

transgenic to non-transgenic pastures. These experiments showed that 99% of pollen spread by bees was deposited within 24 metres of the pollen source and only a very small proportion (<1%) was transferred a greater distance.³⁷ Conversely, Jane Lorimer, Executive Member of the National Beekeepers Association of New Zealand, Poverty Bay Branch [IP62], said that bees flew distances of 6.5 kilometres to gather nectar and pollen and that bees would fly as far as 13.7 kilometres to a food source if no other sources were closer to the hive.³⁸ Dr Salisbury cited research by Ramsay and others (1999) that found most honey bee colonies foraged up to two kilometres from their hives, indicating potential to transfer pollen and fertilise crops up to four kilometres away.³⁹

63. Other evidence suggested it was possible to provide control mechanisms for bees and genetically modified crops. Neil Barton said that, with bee-pollinated crops such as brassica, farmers tended to put hives beside the crop to keep away bees from further afield and avoid contaminating it. He noted that farmers employed isolation distances to prevent the bees from contaminating other farmers' crops.

Recommendation 7.3

that the Ministry of Agriculture and Forestry develop a strategy to allow continued production of genetic modification-free honey and other bee products, and to avoid cross-pollination by bees between genetically modified and modification-free crops, that takes into account both geographical factors (in terms of crop separation strategies) and differences in crop flowering times.

Forestry

64. No genetically modified trees have been commercially released into the environment in New Zealand to date. The forestry industry is important to our economy, with forestry products valued at \$3.11 billion, or 13% of total exports, for the year to June 2000.⁴⁰

65. ERMA's documentation showed that small-scale applications have been approved for genetic modification field trials to test for resistance to herbicide in *Pinus radiata* (Monterey pine) and *Picea abies* (Norway spruce) trees. These trials are likely to take seven to nine years to complete and will be conducted in containment, meaning in this instance that the experiments will be conducted in contained laboratories and glasshouses. In those rare situations where they are grown outside glasshouses, the reproductive structures will not be allowed to mature, or have pollen or seed develop.

Potential benefits

66. Forestry industry companies and a variety of other organisations provided information to the Commission on specific potential benefits of genetic modification in forestry. Such benefits included:

- the ability to produce faster growing trees so that increased productivity could be achieved from the same land area in a shorter time frame. (This may have implications for the use of marginal land and for the conservation of native forests.)
- the ability to make trees infertile so that they produced more wood and less pollen. (Evidence presented at the public meeting held in Rotorua indicated that an infertile tree could produce up to 30% extra wood compared with a tree that was fertile.)
- the ability to produce trees with specific characteristics, including trees for efficient paper production and reduced downstream environmental effects from wood pulp processing. At the national hui in Ngaruawahia, Grant Hawke (Ngati Whatua) graphically commented on current paper production pollution saying that “to get white paper you get black rivers”.
- the potential to produce by-products from currently under-utilised parts of trees, for example pharmaceuticals from tree bark.

67. Carter Holt Harvey/Fletcher Challenge Forests [IP17] gave evidence about additional benefits of genetically modified trees including the potential for new forestry products (such as a tree that might reduce the amount of energy consumed in paper production), the ability to improve the environmental performance of forestry by using genetic modification in pest management, and the ability to create social benefits such as high technology jobs in the forestry sector.

68. Dr Patrick Moore, a former Director of Greenpeace, Canada and of Greenpeace International, who is now involved in promoting sustainable forestry options, spoke for Life Sciences Network. He said that genetic modification of trees could lead to species that were faster growing, disease resistant, had better wood quality and would allow for the expansion of both native and exotic forests. The faster growth of plantation tree species would, he believed, make the industry more profitable. Environmental benefits outlined by Dr Moore included faster carbon uptake by the trees leading to a “reduction in net greenhouse gas emissions, better protection of soils, clean air and water, and the provision of more renewable fuel and material for the economy”.⁴¹

69. Genesis Research and Development Corporation [IP11] also commented on a range of benefits that genetic modification would provide for the forestry

industry in New Zealand. The main ones cited were to landowners, from increased growth rates of trees, wood quality and tolerance of stress conditions; and to the environment, from improved biodiversity, bioremediation uses, reduced pollution and an increase in conservation lands.⁴²

Environmental impacts and concerns in forestry

70. Potential impacts of using genetic modification in forestry that were brought to our attention included:

- greater areas of monocultural land use
- further loss of biodiversity in pine forests because of reduced undergrowth and seed spread
- dominance of one species over others that could lead to weediness as has happened with wilding pines⁴³
- the potential impacts on insect and bird life of sterile trees if no flowers or seeds are produced
- the potential effects on soil nutrients and the water table from faster growing pines
- the potential risk of horizontal gene transfer from modified tree roots to soil microflora with impacts on soil ecology.

71. Additional concerns raised about genetically modified forestry in cross-examination of Carter Holt Harvey/Fletcher Challenge Forests related to the potential for:

- cross-pollination of genetically modified forest trees into neighbouring plantations certified as non-genetically modified
- pleiotropic or unintended side effects of genetic modification of forest trees
- the risk that side effects of genetic modification of forest trees might not be discovered for many years.

72. In response to issues raised about outcrossing or gene flow by pollination, the New Zealand Forest Research Institute [IP2] submitted that pine trees, as well as other plantation forest species used in New Zealand, had no botanically close relatives among New Zealand's indigenous flora and as result there had been no hybridisation of exotic with indigenous plant species. The Institute also commented that, although pollen from pine trees is able to travel large distances by wind, insect or animal vector, it can only pollinate other *Pinus radiata* or *P. attenuata*.⁴⁴ This gene flow risk was reduced further in current field trials for genetically modified radiata pine by removing any reproductive structures as they formed. Dr Moore stated that using sterility technology such as a “terminator

gene” in order to make plantation trees sterile would avoid further encroachment of exotic tree species into native forests.⁴⁵

73. Monocultures of pine trees exist now in New Zealand. Genetic modification technologies may affect the area of land planted with pine trees as silviculture becomes a more viable economic option for land use.

74. In its submission, Greenpeace discussed the economic risks of genetic modification in forestry. Greenpeace noted that more and more consumers were demanding wood products that were certified and labelled as coming from forests that were managed in an environmentally appropriate, socially responsible and economically viable manner. Such forests could obtain Forest Stewardship Council (FSC) certification, but not if genetically modified organisms were employed. In New Zealand, Fletcher Challenge had recently obtained FSC certification, hoping this would provide significant marketing opportunities. Greenpeace noted that if genetically modified pine trees established themselves in FSC certified forests through pollen spread or wild seeding this would breach FSC certification principles and could lead to decertification.

75. Dr Stabinsky provided evidence for Greenpeace on hazards specific to genetically modified trees in New Zealand. With respect to gene flow and wilding pines, she noted that wilding pines were an invasive exotic species in New Zealand that were widely distributed by wind and established easily. Dr Stabinsky commented that pine pollen could be transported by wind for distances of up to 1000 kilometres, which meant that pollen from genetically modified pine trees could pollinate pine trees in other plantations, as well as wilding pines, up to 1000 kilometres from the original tree. Dr Stabinsky also noted that the planting of some genetically modified trees with higher growth rates had resulted in unintended side effects and that fast growing trees tended to use up nutrients faster, so that chemical fertilisers might need to be applied, thereby disrupting soil fertility.⁴⁶

Recommendation 7.4

that, in connection with any proposal to develop genetically modified forest trees, an ecological assessment be required to determine the effects of the modification on the soil and environmental ecology, including effects on soil microorganisms, weediness, insect and animal life, and biodiversity.

76. The Commission regards sterility technology as one valuable tool in a genetic modification strategy for forestry, especially in the case of those genetically

modified trees more likely to cross-pollinate with non-genetically modified trees in the New Zealand context, such as pine trees. A recommendation on the use of sterility technology appears with others in chapter 13 (Major conclusion).

77. Use of genetic modification in forestry also raises cultural issues, for instance if particular trees were chosen to have their characteristics altered. This “cultural gate” to development would arise if there were a proposal to make native trees grow faster so that additional native wood supply could be provided or so that native timbers could be grown on a commercial basis. Te Runanga o Ngai Tahu [IP41] pointed out that the Ngai Tahu Act 1995 identified 53 taonga species of native plants, in addition to other birds, marine mammals, fish and shellfish species that are also taonga.⁴⁷ Te Runanga o Ngai Tahu submitted that to allow genetic modification into New Zealand that might affect taonga species was to ignore Article 2 provisions of the Treaty of Waitangi. (Issues relating to native species and genetic modification are also discussed in chapter 3: Cultural, ethical and spiritual issues, and chapter 10: Intellectual property.)

Bioremediation

78. Bioremediation is the use of plants or microorganisms to clean up or minimise the presence and effects of known pollutants. Bioremediation involves using the natural activity of living organisms or their products, such as enzymes, to help degrade environmental contaminants, either by breaking them down into non-toxic contaminants or by accumulating the chemicals. Bioremediation also includes the use of plants to improve the environment, such as plants that can grow in salty soil. Genetic modification can enhance plants’ natural abilities or alter them in such a way that they can grow in adverse conditions. Particular environmental problems that bioremediation is aimed at include the removal of toxic pollutants in soil, sludge, industrial waste-water and open water bodies. Specific transgenic trees and plants with the ability to accumulate heavy metals such as lead, nickel, gold and cadmium can also be used to remediate degraded or contaminated environments by taking up dioxins, PCBs and heavy metals.

79. However, it is likely to become an important application of the technology. It is probable that in future, commercial uses will develop where private companies are legally required to clean up contaminated sites or where governmental bodies cannot identify a solvent, liable polluter. In terms of the safety of using genetic modification technology for bioremediation, the use of genetically modified plants may be preferred over the use of genetically modified bacteria as the organisms are likely to be easier to contain.

80. Landcare Research [IP12] stated in its submission that bioremediation offers the potential for cost-effective clean up and that genetic modification would be a powerful tool in its development. For example, Landcare Research is undertaking research on the potential for genetically modifying free-living bacteria so that they could help remediate New Zealand soils from the effects of DDE contamination (a DDT degradation product).⁴⁸ Dr Andrew Shenk, a witness called by Genesis Research and Development, told us of the bioremediation of sites damaged by chemical hazards such as mercury by planting trees genetically engineered to accumulate the metal. Dr Shenk mentioned the potential for using genetic modification to develop forestry for environmental recovery applications, such as where soils have elevated salinity levels. He noted that rising salt levels in soils were an increasing agricultural problem worldwide, exacerbated by over-use of irrigation.⁴⁹

81. Professor John Mattick, the Foundation Professor of Molecular Biology at the University of Queensland, Australia, a witness called by Auckland UniServices [IP23], stated that genetic modification had enormous potential for bioremediation and reclamation of polluted and degraded environments using genetically engineered microorganisms. For instance, he identified soil salinity as a significant problem in Australia and said that, by engineering trees to become salt tolerant, salt-affected lands could be reforested.

82. Biomining, which is similar to bioremediation, is another non-food application of genetic modification. Biomining involves using genetically modified or unmodified plants and concentrating the metal so that it can be harvested. The Commission did not receive any evidence on biomining but is aware that it is being researched at Massey University and overseas and might have potential for uses in New Zealand among gold tailings or in soils rich in heavy metals.

Environmental impacts of bioremediation

83. Several submitters, such as the Royal Forest and Bird Protection Society, Nelson/Tasman Branch [IP43] raised the issue of sites in New Zealand that require bioremediation, such as the Mapua chemical site where organochlorine pesticides (eg, dieldrin, DDT, lindane and PCBs) were used. In its oral evidence, the Forest and Bird Protection Society expressed concern that if genetic modification applications, mainly genetically modified bacteria, were used to clean up sites of this kind, such “experimental” applications might have unforeseen outcomes leaving the taxpayer or ratepayer to meet even more expense. They questioned the ultimate fate of products metabolised by the genetically modified organism in bioremediation and whether any transfer of

recombinant DNA would occur from the genetically modified organism into the food chain. The Forest and Bird Protection Society also stressed the need for a contingency plan to allow for unexpected events such as flooding if genetically modified organisms were to be used for bioremediation.

84. Dr Stabinsky was sceptical about many of the claims made for genetic modification's potential in bioremediation. She commented on problems with microorganisms not persisting long enough to perform the clean-up task, potential risks such as the inability to stop the spread of the microorganisms in open water situations and the possibility that bacteria could escape into the water system when used in sludge and waste treatment.

85. Maanu Paul of the New Zealand Maori Council [IP105] spoke about the health problems people had experienced from the use of dioxins in processing timber at the former Whakatane sawmill. He highlighted concerns about long-term and unintended effects that genetic modification might have, likening it to the effects of 2,4,5-T and 2,4-D, and of sawmill processing, which were not understood at the time of early use.⁵⁰

86. Bioremediation is likely to become a more urgent matter in the future, and the Commission considers that as genetic modification technology develops it may become viable.

87. However, consideration of alternatives to using genetically modified plants or organisms would appear to be important in assessing applications for genetically modified organisms for bioremediation. Plants and trees that are not genetically modified, such as willows, also have the capacity to bioremediate.

Bioreactors

88. The term “bioreactor” can encompass the use of genetically modified microorganisms, plants or animals to produce medicines or specific proteins, including vaccines. Bioreactors are part of a larger process known as biomanufacturing.

Plant bioreactors

89. The Commission received little evidence that research on plant bioreactors was in progress in New Zealand. However Dr Jeremy Levin, a witness for Auckland UniServices, stated:

We are using plant cell culture to produce naturally occurring compounds that have therapeutic value, such as the chemotherapeutic agent taxol,⁵¹ a compound found in yew trees.⁵²

90. Professor Mattick said that crops such as canola can be genetically modified to produce oils with an altered bond structure that make them suitable as raw materials for plastics production. Fergie Sumich, the Manager of DuPont New Zealand [IP1], noted that new processes such as genetic modification could produce textiles and plastics from renewable resources like corn. Similarly, HortResearch stated in evidence that, in future, plants might be used as “factories” to produce large quantities of biopolymers such as bioplastics.

Cell bioreactors

91. Many of the protein products we use every day, from the enzymes in our washing powder to the chymosin enzyme used in the manufacture of some cheeses, are produced from genetically modified bacterial or yeast strains which are grown in large fermenters containing a nutrient broth. An increasing number of medicines, such as recombinant human insulin, are also produced in this way (see chapter 9: Medicine). The microorganisms are modified to produce large quantities of specific proteins, which are secreted into the broth or medium and which can then be purified for use. The resulting proteins do not contain DNA.

92. Many of the human proteins needed for the treatment of disease cannot be produced in a biologically active form by microorganisms. These proteins need to be made in mammalian cells, which can shape and modify the protein correctly. In this case large, industrial-scale cultures of genetically modified animal or human cells produce the product required, in a similar manner to the example described above for the production of taxol. In order to coerce the cells to grow and divide continuously, the cells are often transformed to free them from the normal constraints on replication.

93. The Green Party made it clear to the Commission that the production of genetically modified products from mammalian cell cultures in containment was ethically and environmentally more acceptable to them than the use of transgenic animals such as cows.⁵³

94. However, use of large-scale fermenters in an industrial setting can lead to the production of small quantities of very toxic contaminants, as happened with the production of L-tryptophan (see chapter 4). In addition, large-scale fermenters have major waste management and disposal issues. Associate Professor Michael Eccles, a biomedical researcher called by Lysosomal Diseases New Zealand [IP99], spoke of mounting evidence that the use of bioreactor transgenic farm animals or transgenic plants would be cleaner and more environmentally friendly than the large fermenters of microorganisms or cell cultures (cell bioreactors). He said that the broth from the cell bioreactors had to be treated with either disinfectants or other noxious substances before disposal.

Animal bioreactors

95. The use of animals as bioreactors is currently a highly capital-intensive undertaking. We cannot see our current farming being supplemented by large, unconstrained herds of pharmaceutical-producing goats, sheep and cattle in the near or medium future. However, bioreactor animals may form a small, high-value niche market in our mixed, diversified economy.

96. Dr Robert Welch, a witness called by the New Zealand Cooperative Dairy Company [IP88], provided evidence on a range of commercial applications around the world where transgenic animals such as mice, sheep, cattle, goats and rabbits had been used to produce proteins in milk.⁵⁴ He stated that the proteins so derived had been used only to a limited extent in clinical trials and that there was not yet any conclusive evidence of adverse effects of the proteins on human health.⁵⁵

97. PPL Therapeutics Plc, one of the world's leading transgenic technology companies, is currently using genetic modification technology to breed transgenic sheep that can produce very high levels of a human protein (alpha-1 anti-trypsin) in their milk. New Zealand was chosen as a site for this experiment because of its skilled animal husbandry workforce, equitable climate and freedom from bovine spongiform encephalopathy (BSE) and sheep diseases such as scrapie. This protein is used in the treatments of emphysema and cystic fibrosis. Yields produced from using the transgenic sheep are estimated to be one thousand times higher than those achieved using animal cell culture techniques.⁵⁶ We heard from Basil Wakelin, Regional Manager (Industrial) of Sinclair Knight Merz, giving evidence for Biotenz [IP25], that currently the milk from bioreactive sheep in New Zealand is shipped to Scotland for extraction of the active proteins.⁵⁷

98. ERMA has also approved the development of a field trial for 200 transgenic cows. This field trial involves inserting a basic human protein into cattle embryos to produce a protein for researching treatments of multiple sclerosis. ERMA's decision was challenged in a High Court appeal on numerous grounds (the *Bleakley* case),⁵⁸ but the High Court set the approval aside solely for the reason that ERMA did not follow the prescribed methodology in coming to its decision. At the time this report was being completed, the field trial was continuing.

99. As mentioned in the research chapter, the use of animals as bioreactors gives rise to animal welfare issues. In its submission New Zealand's national animal rights/welfare organisation SAFE (Save Animals From Exploitation) [IP85] raised concerns about using animals as "machines" to produce products.⁵⁹ SAFE expressed the opinion that current animal welfare legislation and regulations did not adequately protect animals that might be subjected to genetic

modification applications.⁶⁰ It noted that such animals would require protection from bacteria, parasites and the elements, and as a result intensive indoor farming might develop.⁶¹ SAFE was opposed to genetic modification of animals on ethical grounds. However, when asked if animals could be bred to produce more animals all containing the same modification (so that they produced the same protein in their milk) but without cloning or undergoing the original genetic manipulation, Dr Michael Morris, Senior Lecturer, Shibaura Institute of Technology in Japan, for SAFE, indicated he would not see a problem with that.

100. Many submitters who noted the use of animals as bioreactors had great concern that these animals should be prevented from entering the food chain. If possible it would seem preferable to give priority to using animals not usually used for food as bioreactors in order to lessen the possibility of human health impacts and the associated anxiety over the potential for affecting food sources. For example, goats rather than sheep could be used for human protein production as less goat meat is eaten in New Zealand.

101. Care has to be exercised to prevent animals that have been modified as bioreactors from entering the food chain, for two reasons. First, these animals are likely to contain human genetic material and their consumption as food would therefore be unacceptable to many. Second, the meat from bioreactor animals would not have been certified as safe to eat by the Australia and New Zealand Food Authority (ANZFA).

102. To assist with biosecurity and help prevent them from entering the food chain, bioreactor animals should be electronically tagged for identification. Other methods of stopping these animals entering the food chain should also be explored. The Commission does not foresee open release of bioreactor flocks in New Zealand, as these animals are likely to be subject to conditional release.

103. The Green Party contended there would be no need to use animals as bioreactors, since all genetically modified products could be synthesised by microorganisms.⁶² However, as mentioned previously, Lysosomal Diseases called evidence in rebuttal that microorganisms were not effective producers of the complex enzymes found in mammals. For example lysosomal enzymes were found only in animal cells and many animal proteins could not be modified correctly by microorganisms. Transgenic animals were therefore more likely to produce medically useful proteins. We accept Lysosomal Diseases' rebuttal evidence and are satisfied that it will not always be possible to use vats to produce the pharmaceuticals required.

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.

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.

Pest control

104. Genetic modification has potential applications for pest control and consequent protection of New Zealand's unique environment and biodiversity. In terms of public acceptability of the use of genetic modification for crops and non-food uses, the Commission's public opinion survey showed 54% of respondents approved of the use of genetic modification for pest control; 65% thought that genetic modification was currently being used for this purpose.

105. Evidence was provided by Landcare Research that genetic modification offered more precise and better targeted ways of addressing pest problems than the current methods employed.⁶³ Applications of genetic modification technology being considered by Landcare Research were possum fertility control, stoat and wasp control, biosensors and bioremediation. The public submission from the Possum and Bovine Tuberculosis National Science Strategy Committee noted that similar research was being conducted in Australia for control of Australia's three major mammal pests – the mouse, the fox and the rabbit.⁶⁴ In particular, Landcare stressed the desire to reduce New Zealand's current reliance on large scale use of broad-spectrum poisons for pest control that left New Zealand exposed to substantial health, environmental and trade risks.

106. Dr Phil Cowan, programme leader for research into mitigating the impacts of mammalian pests at Landcare Research, noted that the biotechnological approach to pest management by fertility control was equally applicable to other pests, such as stoats and wasps.

107. As a result of concerns about the continued use of poisons and the potential effect on New Zealand's trade, increased research is under way looking at biological control options for possums. The public submission from the Possum and Bovine Tuberculosis National Science Strategy Committee reported that,

The potential of genetic modification applications for possum control⁶⁵

The Australian brushtail possum (*Trichosurus vulpecula*) was introduced to New Zealand in the 1850s from Australia to establish a fur trade. Since that time possums have become New Zealand's number one vertebrate pest in economic and ecological terms because of the damaging effects they are having on New Zealand's biodiversity, bird life, forestry, horticulture and primary production sector. In addition, possums also spread tuberculosis to cattle and deer, and carry diseases that have human health risks. Currently the principal control methods for possums are leg hold traps and poison baits.

New Zealand Crown Research Institutes, such as AgResearch and Landcare Research, are investigating new methods of possum control employing genetic modification. Landcare Research is looking at genetically modified fertility control, which acts by immunising female possums against proteins from sperm and eggs so that fertilisation is blocked and no young are born. Delivery of the immuno-contraceptive may involve the use of transgenic carrots or potatoes expressing possum proteins or may be by a transgenic possum-specific parasite such as an intestinal worm, being developed by Dr David Heath of AgResearch, Wallaceville. Dr Heath, who presented for the New Zealand Association of Scientists [IP92], stated his belief that biological control was the only method that offered effective control of possums in New Zealand. Roger Wilkinson, a social scientist employed by Landcare Research, told us that the public was frequently sceptical that any form of biological control could provide a complete solution to the possum problem.

Dr Phil Cowan of Landcare Research said there were now around 70–90 million possums in New Zealand spread over 95% of our land area. However, he noted that with the increase in controls over the last five years possum numbers might have reduced by 10–15 million.

Dr Cowan told us that \$50 million was spent each year controlling them, with the total cost of both possum control and damage estimated at between \$80 and \$100 million per year.

He said that the main poison used in New Zealand for possum control was 1080 (sodium monofluoroacetate) and that each year New Zealand released about two and a half tonnes of this poison into its environment, comprising 90% of the world's use. Concerns had been expressed over the dangers of poisons used for possum control, such as environmental contamination and risks to non-target species, particularly native birds, and that the massive expenditure on possum control was unsustainable. The reliance on 1080 poison could also have trade implications if New Zealand's major trading partners were to find the continued use of this poison unacceptable.

during the year 1999–2000, \$5 million was spent on research into new control technologies for possums.

108. Dr Williams, the Parliamentary Commissioner for the Environment, said there was a need for knowledge about the effects that possum biocontrols might

have on New Zealand's unique biodiversity, on non-target species or the broader environment, and on physical taonga. Dr Williams said his research report "Caught in the Headlights: New Zealanders' reflections on Possums, Control Options and Genetic Engineering" (October 2000) stated most possum control methods currently being researched involved identifying a biological control agent suitable for genetic modification to be a delivery system for possum control. Dr Williams said this "significantly increases the levels of public unease and perceptions of the potential risks of these technologies".⁶⁶ The report noted that, although genetically modified possum control technologies showed promise, they were still some years away from being ready for application in New Zealand.

109. In its public submission the Department of Conservation also expressed support for research into the potential for genetically modified organisms to be used for biological control of possums, but took a cautious approach to the introduction of new organisms. The Forest and Bird Protection Society did not support the spread of any genetically modified organism for possum control.⁶⁷ Principal concerns raised by the Society included the potential for the biocontrol to invade Australia where possums are protected as an indigenous species, the lack of testing of the carrot bait proteins on other animals, and the propensity for resistant possum populations to multiply if sterilising controls were not 100% efficient.

110. We heard evidence about the range of benefits of fertility control of possums. Those listed by the Possum and Bovine Tuberculosis National Science Strategy Committee in its public submission included:

- a reduction in the threat to non-target species
- a reduction in the amount of toxins used for possum control
- fewer problems with bait and poison shyness
- vaccines that were expected to be humane
- assistance from vaccines in helping reduce dependence on toxin
- greater public acceptance of a contraceptive rather than an exterminatory approach.⁶⁸

111. The research report referred to by the Parliamentary Commissioner for the Environment identified fundamental criteria for acceptability of biocontrol technologies, including:

- specificity to possums as the target species
- effectiveness
- humaneness
- rigorous long-term testing of adverse effects on the environment
- consistency with the principles of the Treaty

- the development of the technology through a process fully transparent to the public.⁶⁹

112. Similarly, the public attitude research undertaken by Roger Wilkinson found the two most important criteria for acceptability of genetic modification-based fertility control were that it was specific to possums and that it was humane.⁷⁰ The Parliamentary Commissioner for the Environment’s research showed that, of the potential biocontrol methodologies, non-genetic modification methods such as hormonal control were most favoured, immunocontraception was regarded as generally acceptable, immunosterilisation of adult animals was considered a higher-risk option than contraception, and reducing possum numbers through infant mortality (such as through interfering with possum lactation) was considered inhumane.⁷¹

113. Mr Wilkinson’s research found that some participants were wary of supporting genetic modification in possum biocontrol applications, considering it “a Trojan horse or thin end of the wedge”, with one respondent stating “GE for possum control is about getting the foot in the door for GE for food, to reassure us it’s safe”. Another respondent in this research commented:

When you allow GE for possum control, that says to the New Zealand public, “Look at this wonderful tool for controlling possums,” they think perhaps it’s not so bad if we have it in our food, or crops grown in the environment.⁷²

114. The benefits of controlling possums by either genetically modified immunocontraception using carrots or possum-specific parasites would be negated, if even some dairy cows showed decreased fertility. In summary, we consider that genetic modification technology offers significant potential for the control of possums in New Zealand and understand that it is likely to form part of a management strategy that might integrate genetic modification techniques with conventional controls.

Biofuels

115. Given the finite and decreasing reserves of fossil fuels, there is great commercial interest in growing replacement fuels. However, we are not aware of any research into genetically modified biofuel products in New Zealand.

116. Biofuels may be synthesised from conventional, unmodified crops, but genetic modification may increase the likelihood of commercial yields of fuel from plants. Biofuel products are likely to become highly valuable and may raise issues of security or industrial espionage. Gary Goldberg, Chief Executive Officer of the American Corn Growers Association, a witness called by BIO-GRO

New Zealand [IP58], said that most genetically modified maize was being used in the United States for ethanol production as well as livestock feed.⁷³

117. The use of genetically modified microorganisms such as *Klebsiella planticola*, a lactose-fermenting bacterium that converts agricultural waste into alcohol from crop residues, was described by Dr Roberts in her background paper prepared for the Commission on the Environmental Aspects of Genetic Modification. She quoted a study which found that crops grown in soil containing genetically modified *Klebsiella planticola* died. Dr Elaine Ingham, a Canadian soil scientist and author of that study, and a witness called by the Green Party, referred to a potential catastrophe from this use, claiming that the level of alcohol per gram of soil produced by the engineered bacterium could kill all terrestrial plants.⁷⁴ However, soon after this evidence was presented, the Green Party withdrew the essential parts, accepting that Dr Ingham's assertions went beyond the published literature. We do not give any credence to Dr Ingham's evidence.

Bioprospecting

118. Another application of genetic modification technology brought to the attention of the Commission was bioprospecting. Submitters claimed New Zealand's biodiversity represents a pool of untapped opportunity, with scientists estimating that only 30,000 out of an estimated potential 80,000 indigenous species have been identified so far.⁷⁵ In its public submission the Department of Conservation defined bioprospecting, or biodiversity prospecting, as "the exploration of biological material in order to provide chemical components, genes and their products for potential use and development in pharmaceutical, agrochemical, biotechnology, cosmetic and other applications".⁷⁶ The Department noted that using genetic resources of indigenous species for bioprospecting would raise ecological, commercial, cultural and ethical issues. They also noted there is no statutory management framework for bioprospecting in New Zealand at present. Genetic modification of indigenous plants or resources, such as modification of flax or manuka products, raises cultural risk issues for Maori. In particular, issues arise relating to ownership of indigenous resources and the as yet unresolved WAI 262 claim. This matter is discussed in greater detail in chapter 10 (Intellectual property).

Biodiversity issues

119. Biodiversity relates to the variety of all biological life; to plants, animals, fungi, and microorganisms, the genes they contain and the ecosystems they live

in, whether on land or in water.⁷⁷ Concerns about reducing biodiversity levels include concerns about the maintenance of the diversity of ecosystems and species in New Zealand and the retention of a resource of genes that may be important in the future.

120. New Zealand has a unique physical environment. The Department of Conservation, in its public submission, noted that New Zealand was isolated from other land masses for 80 million years, resulting in the evolution of unique biota. The Department stated that pre-settlement New Zealand lacked mammals, excluding bats, and as a result animals and plants had developed traits making them vulnerable to predation and browsing by introduced mammals such as rats, stoats, possums and goats. New Zealand's unique environment is also a product of recent settlement, the introduction of exotic species (including pests and weeds) and landscape changes for farming, forestry and settlement. In addition, on an international scale New Zealand has a remarkably high level of indigenous species.⁷⁸ We have a range of distinctive ecosystems and New Zealand's biological world has provided inspiration for our national icons: the kiwi, the silver fern and the koru.⁷⁹

121. The decline in New Zealand's biological diversity was noted as New Zealand's most pervasive environmental issue in a *State of the New Zealand Environment* report prepared by the Ministry for the Environment in 1997. In particular, the pressures on biodiversity included insufficient habitat in lowland areas, declining quality of land and fresh water habitats, impacts of pests and weeds, and impacts on some marine species and ecosystems. The *New Zealand Biodiversity Strategy* (February 2000) says exotic species have had a dramatic impact on New Zealand's indigenous biodiversity and that invasive pests are recognised as the greatest single threat to our remaining natural ecosystems, habitats and threatened native species. It was estimated that about 1000 of New Zealand's known animal, plant and fungi species were now considered threatened, including three-quarters of our bird species.⁸⁰ The *New Zealand Biodiversity Strategy* says that, in the last 700–800 years in New Zealand, humans and pests have made extinct:

- 32% of indigenous land and freshwater birds
- 18% of all sea birds
- three of seven frogs
- at least 12 invertebrates, such as snails and insects
- one fish, one bat and perhaps three reptiles
- possibly 11 plants.

122. New Zealand is a party to, and has ratified, the Convention on Biological Diversity, which requires New Zealand’s legislation and international actions to be consistent with the Convention’s principles. In order to meet obligations under this Convention, the Biodiversity Strategy was developed by the Department of Conservation, the Ministry for the Environment and other government departments and was released in March 2000. In New Zealand, responsibility for the protection of biodiversity rests principally with the Department of Conservation. The Biodiversity Strategy is aimed at halting the decline in New Zealand’s indigenous biodiversity as well as conserving the genetic resources of important introduced species. The Strategy also acknowledges the special holistic view that Maori have of the environment and biodiversity that arises from their belief system that all components of ecosystems are linked and possess the spiritual qualities of tapu, mauri, mana and wairua. The Biodiversity Strategy is now Government policy.

123. The Department of Conservation noted that in June 2000 Government announced a funding package of \$187 million over five years to implement the key actions of the Biodiversity Strategy. This included \$57 million for pest and weed control on public conservation lands. However, the Department commented that, despite this funding, the proposed expenditure would be insufficient to maintain indigenous biodiversity across all public conservation lands. As a result pest control would be restricted to priority areas until new techniques for pest control could be developed.

124. As discussed above, genetic modification may be used to benefit biodiversity, as it could assist in controlling pests, help with biodiversity restoration projects or reduce toxic chemical use. Landcare Research stated that, through the Biodiversity Strategy, Government had identified pest management as the principal means of protecting New Zealand’s biodiversity. Landcare noted that protecting New Zealand’s biodiversity was a national imperative and an international obligation that would call for a “full management toolbox”⁸¹ including genetic modification technology.

125. We also heard evidence about the possibility of using genetic modification for conservation genetics, for example to characterise species, to possibly recreate extinct species such as huia, to grow genetically modified native plants to protect the conservation estate. However, these proposals generate significant cultural issues.

126. The development of seed-saving groups for heritage seeds forms an important part of improving our biodiversity. The Koanga Gardens Trust [IP72], a heritage seed-saving group from Northland, outlined how they were establishing and maintaining a collection of New Zealand heirloom plants. This was done to

ensure their survival for future generations as a resource for cultivation and genetic diversity, and as taonga for the public of New Zealand. Other seed-saving groups operate on a regional basis around New Zealand.

127. Information about potential long-term effects of genetically modified organisms on the environment and on biodiversity is still sparse. The Department of Conservation said there is no consensus as to the seriousness, or even the existence, of any potential harm from genetic modification technology.⁸² As there is limited knowledge of the long-term effects of genetic modification, the Department asked whether decisions relating to releasing genetically modified organisms into the environment should be postponed until there is more information on their effects on New Zealand's environment and biodiversity.

128. The threat of genetic modification to biodiversity was a strong theme that emerged in the analysis of public submissions. Key issues raised by submitters included the potential that genetic modification would result in: the extinction of some species; the creation of new and dangerous organisms such as super weeds; the contamination of the environment from genetic modification activities (for example where organisms escaped from field trials or laboratories); and the irreversibility of genetic modification releases.⁸³

Development of monocultures

129. The Commission heard that genetic modification technologies encouraged the development of monocultures, leading to a reduction in biodiversity, both in the gene pool within species and in the variety of species planted. Questions arose whether genetic modification actually exacerbated the development of monocultures or whether the loss of biodiversity occurring now was more a result of increasing agricultural intensification. There is evidence of this happening in New Zealand with the increased areas of *Pinus radiata* planted, and overseas with extensive plantings of wheat, rice and maize. It would appear that arguments over reduction in biodiversity tend to be more against increased agricultural intensification rather than against genetic modification technology itself. The Commission considers that, with regard to monocultures, genetic modification in crops and other field uses brings no new issues, other than of scale.

130. Dr Vandana Shiva, a theoretical physicist and philosopher of science, and a witness called by the Pacific Institute of Resource Management, wrote in her witness brief that genetic engineering was narrowing the genetic base of agriculture to only a few crops and accelerating the expansion of monocultures. This in turn led to the destruction of on-farm biodiversity through the use of broad-spectrum herbicides like Roundup and threatened survival of species

through the use of crops which have had bacterial toxins (such as Bt) added to allow them to produce their own pesticides. She said:

Genetic engineering maintains and deepens the monoculture paradigm of the Green Revolution and industrial agriculture that focuses on single functions of single species, and fails to take yields of diverse species and diverse function into account.⁸⁴

131. Anuradha Mittal, Co-director of the Institute for Food and Development Policy in Oakland, California, appearing by telephone link for Greenpeace, said that genetic engineering was based on the same principles as industrial agriculture: those of monoculture, technology and corporate control. She believed problems were likely to be exacerbated in countries that lacked stringent procedures for dealing with environmental problems caused by the release of genetically modified plants into the environment. She said that under “Green Revolution technology, farmers were encouraged to produce massive monocultures of the same high yielding crop” and that although high yields could be achieved the seeds were vulnerable and required heavy input of chemical fertilisers and pesticides.⁸⁵

132. Ms Mittal said the Green Revolution caused short-term rises in production in many Asian and Latin American countries, followed by ecological collapse, farmer debt and increased hunger. The “miracle yielding” crops of the Green Revolution had also led to erosion of the genetic base of most crops. She said that “according to the FAO, 75% of genetic diversity in agriculture has been lost in the last century”.⁸⁶ She also noted that monocultures had increased pest attacks on crops, as planting the same varieties year after year encouraged pests to build up and made plants vulnerable to attack by new viruses.

133. A range of witnesses told the Commission that the development of monocultures should not be encouraged because of the heavy input of chemical fertilisers and pesticides needed by hybrid seeds and the increased vulnerability of crops to disease and pest attacks. However, most of the evidence presented related to overseas experience. The Commission is more concerned with the need to pursue a strategy for New Zealand that will preserve the variety of land uses and the range of agricultural practices currently employed here, as well as providing for flexibility in future developments.

Compatibility with other production systems

134. The principal environmental risk in releasing genetically modified food and other crops into the environment is the physical contamination of other production systems.

135. The Commission heard evidence from a range of farming organisations on the perceived risks of establishing genetically modified crops near to organic, conventional or IPM-based horticultural crops and the potential for outcrossing. Organic farmers expressed concern about the potential for loss of organic certification if their farms were to be “contaminated” by genetically modified crops. They did not feel confident buffer zones of specified distances would ensure protection. The international organics movement sees no place for genetic modification in organic agriculture.

136. The Green Party stated that “the release of genetically modified crops and organisms into the New Zealand environment would represent a major and very serious threat to the organics industry in this country”.⁸⁷ Similarly, Noel Josephson, the Managing Director of Ceres Enterprises Limited (a distribution company for biodynamic and organic food) called by the Bio Dynamic Farming and Gardening Association, said “the release into the environment of genetically modified organisms is to the disadvantage of those people associated with the industry that has built up around biodynamic and organic farming”. Mr Josephson pointed out that cross-pollination could not be controlled once a genetically modified crop was commercially released into the environment. He said:

A biodynamic or organic farmer in the area is then susceptible to cross-pollination of the same crop. Biodynamic and organic standards specifically exclude genetically modified material and therefore any cross-pollination would render a biodynamic or organic farmer’s crop unsaleable as biodynamic or organic. As their farm is set up to perform to these standards the investment is lost and their livelihood under threat.⁸⁸

137. The Green Party cited an opinion poll commissioned by the meat company AFFCO (dated May 2000) which found that “70 percent of farmers and commercial growers believed the future of New Zealand agriculture was with organic production”. The same survey found that 15% of farmers and commercial growers believed the future was with genetically modified production and only a small proportion (4%) saw the future involving a combination of the two systems.⁸⁹

138. The Commission asked MAF to prepare information⁹⁰ on the compatibility of genetic modification and organic agriculture. MAF stated that “if organics standards allow the possibility of accidental contamination, then coexistence is possible. If standards demand zero tolerance for accidental GM contamination, then coexistence may not be possible”.⁹¹ MAF was unaware of any study that had looked at compatibility between farming systems in any country, but knew of studies of separation distances between crops to manage cross-pollination.⁹² MAF added this was an issue of importance to plant breeders prior to the introduction of transgenic crops. MAF mentioned the countries with the largest

areas of transgenic crops (United States, Argentina and Canada) had commercially successful organic production sectors.

139. The New Zealand Dairy Board [IP67] in its written submission commented that determining whether organics and genetic modification were compatible depended on how the term “organic” was defined. The Board noted that some definitions (such as the Codex Alimentarius Committee definition) did not necessarily prevent aspects of genetic modification becoming part of organic farming systems in the future. It expressed the opinion that compatibility might be possible if certification of organic produce allowed for some tolerance of genetic modification and if isolation distances from genetically modified crops permitted organic production to continue.⁹³

Effects on organic certification

140. Governments or growers’ organisations set a variety of standards for organic certification internationally. New Zealand has several. The principal standard used here is BIO-GRO. The Demeter standard is stricter and meets the BIO-GRO standard, in addition, the Agri-Quality standard has been developed in consultation with growers. These three standards do not allow for any genetic modification contamination of organic crops. Both BIO-GRO and Agri-Quality standards are accepted internationally.

141. At present there is no one accepted international standard for organic production, but there is a move to harmonise standards. Dr Salisbury, stated in his evidence that:

... to ensure successful coexistence of organic and GM0 canola crops, all growers need to accept similar standards of purity to those currently used for canola seed production worldwide, allowing, for example, a threshold of up to 1% off-types (Moyes and Dale, 1999). Such thresholds are currently being considered by organic growers in Europe.⁹⁴

First release issues

142. Dr Campbell gave evidence relating to research on the potential first release of genetically modified organisms in New Zealand food production. He saw the three principal industries that might be affected by physical contamination from genetically modified crops production as honey (both conventional and organic production methods), organic farming and IPM-based horticulture. Dr Campbell provided a quantitative analysis of New Zealand’s production options and advocated a position that would keep our options open. He noted that despite growth in organic exports the total volume was still small compared with IPM-based horticultural exports. Recent research estimates that IPM-based exports from New Zealand were valued at between NZ\$900 million and

NZ\$1 billion in the year 2000. He also cited figures showing the international growth in the market for organic products, saying that average growth rates were 30–35% in new markets and 20–25% in mature markets. According to Dr Campbell there were three important drivers in global markets for organics and IPM produce, each affecting the demand for or access to genetically modified food:

- trade/regulatory barriers such as “green protectionism”
- retailer strategies, with some retailers avoiding genetically modified foods
- consumer responses, with wealthy consumers tending to show a demand for organic foods and a rejection of genetically modified foods.

Future systems of production

143. Federated Farmers said “conventional production is likely to continue to be the dominant production system in New Zealand”.⁹⁵ It noted that production systems needed to become more transparent, with a need for trace-back mechanisms and farm-to-plate assurance systems to compete in world markets. Farmers would have to weigh up the opportunities that genetic modification technology might offer, against potential losses in market share. Although there was disagreement as to where New Zealand’s competitive advantage lay, mixed strategies were preferable “as they spread risk from cycles in market demands and consumer preferences”.⁹⁶ Witness Neil Barton expressed the opinion that the various production systems could exist alongside genetic modification in New Zealand. He stated:

The ability to continue production of organic or specialist non-GM crops, can continue without threat, should novel genetically modified plant varieties be grown in our cropping districts. This would occur in exactly the same way as different crops co-exist now.⁹⁷

144. Dr Campbell looked at the issue of whether genetic modification could be used in the organics industry and cited research that suggested “an involvement of GM in organic production is unlikely”.⁹⁸ He put forward reasons such as a strong market association between organic produce and being genetic modification-free and considered that the importation of genetic modification technology into the organics industry could seriously threaten the market niche it currently held. In addition, Dr Campbell noted that international organic agriculture movements were opposed to using genetic modification technologies in production. However, he said there had been no comprehensive research conducted in New Zealand to calculate the negative economic impact of genetic modification on organic production.

145. The Life Sciences Network argued that “coexistence of GM, conventional and organic agriculture is possible through appropriate use of management (stewardship) protocols (eg separation distances)”.⁹⁹ Life Sciences also argued “coexistence is a farmer responsibility”.¹⁰⁰ Tom Lambie, an organic dairy farmer and a witness called by the Dairy Board, spelled this out:

As much as it is possible we seek to keep the effects of our activities within our own boundary. The farming community will accept a degree of external effect but these are tolerated only within “normal” standards. Should I demand a higher standard, I expect to internalise the cost of paying for that standard. For instance, if I don’t like the colour of my neighbours shed I can plant a hedge or construct a fence to block the vision. If my neighbour traditionally uses conventional sprays I can plant hedges to act as a barrier and maintain a buffer zone to satisfy myself that there is no risk from any unintentional spray drift. Equally, I expect my neighbour to internalise the costs of his preferred production regime by taking action to prevent spray drifting across my property. The steps the neighbour can take include the maintenance of a buffer zone.¹⁰¹

146. While we agree and encourage this type of cooperation and self-reliance the Commission considers there also has to be an element of government regulation to develop and maintain coexistence.

Managing the risks and preserving the opportunities

147. The key impacts likely to result from genetic modification in crops and non-food uses associated with the release stage are the control of environmental effects such as cross-pollination, horizontal gene transfer and seed dispersal.

148. The United Kingdom Advisory Committee on Releases to the Environment (ACRE) has produced guidance notes¹⁰² on best practice in the design of genetically modified crops to be released into the environment, including a wide range of techniques to reduce environmental risks. The guidance notes put forward three ways to reduce the exposure and therefore the risk from transgenes and their products: avoiding the inclusion of superfluous transgenic sequences, minimising the expression of the transgene, and minimising the dispersal of the transgenes into the environment. Examples of methods to minimise transgene dispersal in the ACRE guidance notes include:

- considering whether plants actually need to be released into the environment. (Some crops such as high value bioreactors might be grown effectively in containment.)

- choosing plant species that are appropriate recipients for the transgene. Since expression of pharmaceutical genes in food crop plants or plants with wild relatives might not be desirable
- exploiting differences in flowering times between plants, and using or breeding varieties that have flowers which are unattractive to insects, by altering flower colour, shape, scent or the production of pollen
- producing transgenic plants that either cannot produce pollen or produce sterile seed.

149. Some possible control mechanisms to which ERMA could give consideration are outlined in the following subsections.

Choosing which plants to modify

150. One method of managing risk related to genetically modified crops is to identify those posing the greatest risk in terms of outcrossing, ban them and allow less risky crops to be grown. The use of a risk assessment framework, such as the one provided by Professor Ammann, referred to earlier in this chapter, would help identify which crops would carry substantial and widespread risk.

151. No native species in New Zealand outcross with the major crops grown in this country. The risk assessment approach is obviously being considered by ERMA, as demonstrated in the assessment of wild relatives undertaken for the petunia trial application. A table for New Zealand similar to Professor Ammann's could be formulated that would help researchers identify high risk plants early and institute an appropriate methodology. Such an approach would enable those crops most at risk of outcrossing in the New Zealand environment to be identified. The Commission notes that Professor Ammann's analysis identified ryegrass as particularly prone to gene transfer through outcrossing.

Risk management for high-risk plants

152. Evidence was presented on a range of management options for growing both genetically modified and non-genetically modified crops that could help reduce the risks associated with genetic modification. A number of such methods are outlined below.

Physical barriers

- spatial barriers – where plants grow in different areas or where there is no common pollinator
- temporal barriers – which occur when plants flower at different times of the year

- biological barriers – which reduce the chance of cross-fertilisation between species by preventing fertilisation or seed development.¹⁰³

153. Barriers of time as well as space could be used, for example crop rotation where certain crops were not planted for a specified time after harvest, or where different crop species rotate on the same parcel of land. Time barriers already apply to some crops where purity is an issue. For example, a minimum of four harvest seasons is required between growing different white clover cultivars in the same field.¹⁰⁴

154. A United Kingdom Ministry of Agriculture, Fisheries and Food (MAFF) report¹⁰⁵ provided examples of other types of barriers that can affect the transmission of pollen to a receptor crop including:

- woods and hedges – which can act as a barrier to both wind-borne pollen and flying insects
- topography – wind velocity and airflow are affected by topography and this can influence the amount of pollen delivered to the receptor
- barrier crops of the same species as the crop – either planted around the crop emitting the pollen or around the receptor crop. Both of these systems mean that the pollen has a greater distance to travel and that insects might be more likely to visit the barrier plant.

Buffer zones and separation distances

155. MAF provided information¹⁰⁶ to the Commission on buffer zones in countries where genetically modified crops are grown. It noted buffer zones to mitigate the dangers of cross pollination were a requirement for seed production and that the OECD standard for maize seed was a buffer zone of 200 metres, adhered to in both the United States and the European Union. MAF noted this zone was imposed for reasons of seed purity rather than because of genetic modification or organics. MAF commented there did not appear to be specific rules, as distinct from standards, relating to buffer zones, apart from in the United Kingdom.

156. The Arable-Food Industry Council noted that an industry group in the United Kingdom, the Supply Chain Initiative on Modified Agricultural Crops (SCIMAC), had produced an industry code of practice for genetically modified crops. The Arable-Food Industry Council submitted that an industry code of practice for genetically modified crops, similar to the United Kingdom model, should be developed for New Zealand. The Council believed that such a code should be developed by cross-industry agreement and operated along similar lines to the seed certification production scheme.

157. MAF cited the MAFF (UK) report¹⁰⁷ noted above, which looked at separation distances used in agriculture that are intended “to secure desired levels of crop purity by limiting cross pollination between different varieties or types of the same crop”. The guidelines seek to avoid pollen contamination between genetically modified and other crops. The main crops to which these guidelines relate are maize and sweetcorn, canola (*Brassica napus*) and turnip rape (*Brassica rapa* ssp. *silvestris*). The separation distances for each crop are set in relation to threshold levels of contamination from cross-pollination, for example for canola the separation distance for 1% contamination is 1.5 metres; for 0.5% contamination the distance is 10 metres; and for 0.1% contamination the separation distance is 100 metres.

158. Mr Barton gave evidence of isolation distances varying from 100 metres for ryegrass to 700 metres for kale,¹⁰⁸ and Dr Salisbury said “isolation distances of 100 to 500 metres were generally considered sufficient to prevent outcrossing and maintain seed purity for basic and certified seed”.¹⁰⁹ Dr Salisbury noted further the isolation distances were not intended to prevent outcrossing entirely but to reduce outcrossing to an acceptable level. Dr Salisbury cited Hoyes and Dale (1999) who found that when appropriate isolation distances were used no contamination above the allowable thresholds was reported.

Recommendation 7.7

that the Ministry of Agriculture and Forestry develop an industry code of practice to ensure effective separation distances between genetically modified and unmodified crops (including those grown for seed production), such a code:

- **to be established on a crop-by-crop basis**
- **to take into account**
 - **existing separation distances for seed certification in New Zealand**
 - **developments in international certification standards for organic farming**
 - **emerging strategies for coexistence between genetically modified and unmodified crops in other countries**
- **to identify how the costs of establishment and maintenance of buffer zones are to be borne.**

Sterilising technology

159. Various techniques make crops infertile and allow the harvesting of the crop but prevent reproduction. The ACRE report¹¹⁰ provides an excellent summary of the current research status of sterilising techniques. The technologies incorporate genes into the plants that stop the seeds germinating or the female flowers being fertilised. Some such genes have been called “terminator” genes and encode enzymes or similar products that confer sterility.¹¹¹ Professor Martina McGloughlin, Director of the Biotechnology and Life Sciences Informatics Programmes at UC Davis University in California and a witness called by the Life Sciences Network, commented on more recent ways to limit gene flow:

There are strategies to reduce the ... risk of gene flow from transgenic crops. One possibility is the use of male sterility plants, which works well but is limited to a few species. For many crops in which chloroplasts are strictly maternally inherited, which is to say not transmitted through pollen, transformation of the chloroplast genome should provide an effective way to contain foreign genes. Henry Daniell and colleagues at Auburn University introduced a gene for herbicide resistance into tobacco, showed that it was stably integrated into the chloroplast genome, and demonstrated that transgenic plants contained only transformed chloroplasts. This result advances the potential for chloroplast transformation to be an effective strategy to manage the risk of gene flow.¹¹²

160. Objections to “terminator” or “traitor” technology have been expressed by many organisations, such as the Pacific Institute of Resource Management, which noted that “over 30 patents have been issued for Terminator and Traitor technology, which is designed to make farmers chemically dependent and prevent them from saving their own seed”.¹¹³ Traitor technology requires the use of a proprietary spray, usually involving hormones, to turn on the genes of interest. Dr Stabinsky expressed concern in her evidence regarding the use of sterility technology in pine trees in New Zealand, noting that it could have a negative impact on organisms that rely on pine pollen as a food supply. The Commission considers the use of sterility technology in commercial forestry trees should be investigated, as it has the potential to reduce pollen production with its associated allergenicity problems and prevent wild pine escape. However, a full assessment, based on field trials, of the effects of genetically modified sterility on the ecology of the forest would be required.

161. The Commission considers an increasing variety of techniques is available to limit the effects of genetically modified crops on the environment and to control the escape of the modified genes.

chapter |

8



Food

8.

Food

Key issues:

- Is genetically modified food safe to eat?
- Are the current food safety standards satisfactory?
- Can people choose whether or not to eat genetically modified food?

1. From the submissions received and the statements made at the public hearings it was clear genetically modified food was one of the issues that dominated the discussion. This was no surprise. Food is a matter of personal importance to individual New Zealanders. As food production for domestic consumption and for export contributes significantly to the economy, it is also of national importance.

2. Some submissions questioned the need for genetically modified food. To some people, the genetic modification of food and food crops is part of globalisation and the free trade agenda, another avenue for multinational corporations to exploit developing economies. To others, developments in food, such as Golden Rice, have the potential to provide part of the solution to third-world hunger and poverty.

Golden rice¹

Rice is the staple food for two billion people. It is usually milled to remove the outer seed layers to prevent their high oil content causing spoilage. The remaining grain is low in β -carotene (Vitamin A). Some 400 million people worldwide suffer from vitamin A deficiency and over 3.7 billion people are iron deficient. These deficiencies lead to poor development and increased susceptibility to disease. Vitamin A deficiency causes five million deaths annually, and blindness in a further 500,000 people, while iron deficiency causes anaemia and birth defects.

Golden Rice is a transgenic crop created by Dr Ingo Potrykus and his colleagues to improve the nutritional quality of rice, by increasing the quantities of β -carotene, the precursor to vitamin A and improving its iron content. Several genes have been inserted into the rice

genome, including a daffodil gene, allowing the endosperm (the part that remains after milling and polishing) to produce β -carotene. Additionally a phytase gene (which produces an enzyme to release chemically bound iron), a gene to increase organic iron and a gene to aid iron absorption in the digestive tract have been added. The presence of β -carotene in the endosperm of the transgenic rice gives it a golden colour. The Golden Rice project is trying to achieve the strategy of the FAO and WHO to “ensure that sustainable food-based strategies are given first priority particularly for populations deficient in vitamin A and iron, favouring locally available foods and taking into account local food habits”. The research was funded by the Rockefeller Foundation, the Swiss government and the EU.

The Golden Rice project hopes to provide a cheap form of vitamin supplementation to help prevent these deficiencies. It is not the product of profit-seeking companies. When viable, the rice was to be freely distributed with no patents blocking access to it. Dr Potrykus stated that he was somewhat surprised when it was found that in the creation of his Golden Rice there were 70 intellectual property rights belonging to 32 different companies and universities for which he needed free licences to be able to establish a “freedom to operate” situation. Currently, intellectual property issues are being resolved.

Some believe that Golden Rice is being over-hyped, because it allays public fears about genetic modification, and that it is not the best solution to the nutritional problems in developing countries. They point out that, despite all the time and money spent on Golden Rice, it is not yet available to those it was designed to help, and in fact is several years away from commercial production. They have also pointed out new agreements with AstraZeneca and Greenovation mean that, though the companies will donate seeds to developing countries, only farmers earning less than \$10,000 annually from the sale of the rice will be exempt from paying royalties.

It is also argued that problems with malnutrition have little to do with the nutritional value of the food consumed. Rather the problems are:

1. *Food distribution.* Malnourished people often come from countries with food surpluses. Golden Rice is a high yield crop and may be grown for export rather than for local supply. If this happens, people who are too poor to buy food will not be aided by Golden Rice.
2. *Food preferences.* Because of cultural preferences people may choose not to eat Golden Rice, despite its nutritional benefits.
3. *Food variety.* Vitamin A deficiency rarely occurs in isolation, but rather with other vitamin and mineral deficiencies. Since many species of plant contain β -carotene, it would be better to diversify crops and encourage people to eat a wider range of foods rather than rely on Golden Rice as a single major source of the vitamin.
4. *Effects on agriculture.* There are fears about the possible associated effects of the technology itself on human health and on farming practices in developing countries.

3. The Commission's Warrant, however, confines our considerations to issues relating to genetically modified food in New Zealand. Although diverging views about the value of genetic modification to developing and developed countries are important in the overall debate about the use of the technology, issues such as Golden Rice are not material to our inquiry. We have included an information panel about it only because the subject was mentioned so often.

4. The need for genetically modified food was also questioned on the grounds that New Zealand is self-sufficient in food.² The importance of imported food to the New Zealand population, however, was identified in the submission from the New Zealand Grocery Marketers Association [IP54]. The submission pointed out that New Zealand now has a higher proportion of imported processed food than any other country in the western world.

5. The Association suggested that there were two reasons for this high rate of importation. First, the New Zealand climate limited the foods that could be grown here and, second:

... a very high dependence on pre-processed food imports is associated with that of economies of scale. With a domestic population of 3.8 million people New Zealand cannot sustain high volume sophisticated (manufacturing) plants just to supply the domestic base.³

6. The submission also referred to the importance of international companies in the food production sector in New Zealand. As the Commission listened to submissions from organisations such as the New Zealand Dairy Board [IP67], we could not but become aware of the importance of international trade to the New Zealand companies, growers and food producers who are involved in the export market. Again, the Grocery Marketers Association explained:

New Zealand's economy is dependent on the food industry. It contributes 42% of the country's export earnings (the exports for the year ended June 2000 were \$24.746 billion of which food contributed \$10.336 billion). In addition the processed food industry contributes \$11 billion to the domestic economy.⁴

7. For reasons we will set out, the Commission does not accept that it is a viable option to ban the production, importation or sale of genetically modified food in New Zealand. It considers, however, to ensure the health and safety of the public, the food industry must be subject to rigorous standards enforced and monitored by competent and careful regulatory bodies.

The current status of genetic modification in food and food processing in New Zealand

8. Genetically modified food may have been on the New Zealand market for as long as a decade. The Grocery Marketers Association stated that the first food products modified by gene technology were a yeast used in baking, which was approved for use in the United Kingdom in 1990, and chymosin, the enzyme used in cheese making, which was approved for use in the United States, also in 1990. The Flavr-Savr tomato, which was the first whole food produced using gene technology, received approval in the United States in 1994. Transgenic soybeans, corn, cotton and potato, from which many ingredients are now derived, were approved overseas during the 1990s.⁵ These foods could have come into New Zealand as ingredients in imported food.

9. It was difficult to establish the nature and range of the genetically modified food available on the New Zealand market. The Australia New Zealand Food Authority (ANZFA) is required to conduct a scientific assessment process prior to genetically modified foods being released. At the time the Commission's inquiry began, there were a number of genetically modified foods on the New Zealand market that had not completed this process. This was because, during the time that Standard A18: *Food Produced Using Gene Technology*, which regulates the sale of genetically modified food, was being developed in 1996 and 1997, a number of genetically modified foods entered the Australian and New Zealand markets legally without being assessed by ANZFA. These were largely components of imported processed foods. Subject to certain conditions, these foods were allowed to remain on the market while they went through the ANZFA system for assessing compliance with Standard A18. At the hearing before the Commission, ANZFA was questioned further on this matter. (See paragraphs 129 to 202.)

Processed food

10. The submission from the Grocery Marketers Association stated there are “no whole genetically modified foods on the market” in New Zealand. At the time of the Commission's hearings, therefore, all genetically modified foods were used as ingredients in imported foods. The Association provided a list, reproduced overleaf, of examples of the products that might be present in foods currently available in New Zealand. The Association pointed out, however, that it is not possible to state the extent to which the products listed are used in New Zealand.⁶

Ingredients derived from genetically modified crops

Genetically modified organisms	Ingredient, additives and processing aids	Used in following foods
Soybean	soybean flour	soy drinks, soy sauce, tofu
	soybean protein	processed meats/sausages/salamis
	hydrolysed vegetable protein	bread
	textured vegetable protein	dairy – drinks, yoghurts, desserts, ice cream
	soybean oil	baked goods – cakes, pies, pastries, biscuits
	lecithin	soups and sauces
	additive and flavour carriers/diluents	cooking oils, salad dressings
	tocopherols – vitamin E	margarines and spreads, peanut butter confectionery, savoury snacks, infant food
Corn/Maize	flour	bread
	corn starch	dairy products – drinks, yoghurts, desserts
	corn oil	baked goods – cakes, pies, pastries, biscuits
	corn protein and isolates	soft drinks and cordials
	corn syrups	soups
	modified starches	sauces, pickles and chutneys
	dextroses	cooking oils, salad dressings
	maltodextrins	margarines and spreads
	glucose syrups	confectionery, fruit flavoured spreads
	humectants, food acids	savoury snacks
	additive and flavour carriers/diluents	herb and spices (through carriers and diluents)

Ingredients derived from genetically modified crops *continued*

Genetically modified organisms	Ingredient, additives and processing aids	Used in following foods
Canola	canola oil lecithin	baked goods – cakes, pies, pastries salad dressings cooking oils margarines and spreads confectionery
Cotton	cotton seed oil	baked goods cooking oils salad dressings margarines
Sugar beet	sucrose mono sodium glutamate (MSG)	dairy products – drinks, yoghurts, desserts bread baked goods – cakes, pies, pastries, biscuits soups sauces fruit drinks, soft drinks and cordials jams and preserves confectionery savoury snacks
Potato	potato potato starch modified starch	soups sauces, pickles and chutneys confectionery savoury snacks

Microorganisms

11. The Grocery Marketers Association told the Commission that, in addition to the genetic modification of whole plant foods, microorganisms could be designed to improve the efficiency of fermentation and other primarily enzymatic processes, and be used in the production of ingredients. The Association listed these uses as being:

- microbes to produce amino acids for the synthesis of aspartame
- plant cells grown in fermenters to produce flavours such as vanilla
- chymosin, a replacement for calf rennet, overseas supplies of which are inadequate to meet needs
- alpha-amylase, which is used in the production of high fructose corn syrups
- lactase, which is added to milk to reduce the lactose content for persons with lactose intolerance
- bakers' yeast modified to provide faster carbon dioxide production, which improves dough characteristics
- brewers' yeast with an ability to degrade starch and for use in making reduced calorie beer.

Grains and cereals

12. The first generation of genetically modified crops were the important grain and cereal crops, tomatoes and some niche products, such as papaya. Traditionally, most of New Zealand's supplies of these products have been imported and no genetically modified crops have yet been approved for commercial cultivation in New Zealand.

Fresh produce

13. The submission from the New Zealand Vegetable and Potato Growers' Federation/New Zealand Fruitgrowers' Federation/New Zealand Berryfruit Growers' Federation (Vegfed, Fruitgrowers, Berryfed) [IP75] pointed out that very few genetically modified fruit cultivars or species are being traded on world markets, possibly because the development of genetically modified fruit has been of lower priority than mainstream agronomic crops. No genetically modified fresh fruit or vegetables are currently imported into New Zealand. Any fresh produce would require ANZFA approval before it was released on to the New Zealand market, and any produce that contained viable seed or provided propagation material would also require approval from the Environmental Risk Management Authority (ERMA).

Meat

14. We heard no evidence of products from genetically modified animals, either raised in New Zealand or imported, being available on the New Zealand market. Both would require ANZFA approval. Dr Phil L’Huillier, a scientist with AgResearch [IP13] at Ruakura, informed us of research currently underway into myostatin knockout sheep to increase musculature and, as a result, to improve meat quality. The submissions from both Meat New Zealand [IP31] and the New Zealand Game Industry Board [IP33], however, confirmed that neither organisation would sanction the entry of transgenic products into the food chain without strong public support. The same view was expressed by a number of primary industry sector representatives.

Dairy products

15. We understood from the evidence that, at present, there is only limited use of genetic modification in the New Zealand dairy industry. The New Zealand Dairy Board said that, as a result of public attitudes towards the use of gene technology, policy decisions had been taken in at least two instances not to make use of the available technology. It confirmed that the industry does not take milk from cows that have been treated with injections of bovine somatotropin (bST), and does not use genetically modified bacterial cultures in cheese making. The Dairy Board’s submission also confirmed that no pasture plants or dairy cattle used in the production of milk were genetically modified. It said that “apart from some well-known and approved additives and processing aids” no foods derived from genetically modified organisms are used in any of the range of food products manufactured from milk.⁷ There was limited use of the enzyme chymosin, produced by genetic modification, in cheese for overseas markets.

Animal feed

16. At the hearing before us, the New Zealand Feed Manufacturers Association/ Poultry Industry Association of New Zealand/Egg Producers Federation of New Zealand [IP35] confirmed that poultry in New Zealand was fed a combination of modified and unmodified soy meal.⁸ Meat New Zealand advised that, while genetically modified soy products are being used in animal feeds, they do not appear to be being used in the red meat industry in New Zealand. We discuss the safety of genetically modified stock feed in paragraphs 121 to 126.

Future developments

17. We heard evidence that, while the first wave of genetically modified food was seen as having benefit primarily to commercial interests, the second wave would have clear consumer benefits in addition to those for food growers and manufacturers.

18. Many of the references to the future developments of genetically modified food were general in nature. There were claims that the use of gene technology in relation to food will have the following benefits for the food industry:

- improved productivity with increased efficiency, sustainability and cost-effectiveness
- improvements to food safety; for example, use of the technology to detect food-borne pathogens, toxins and chemical contaminants
- improvements to storage properties, such as by extending the shelf-life of foods
- the use of gene technology for checking alterations in product quality and checking for temperature abuse.

19. Benefits for the consumer are expected to be:

- products with improved tastes, textures and keeping qualities
- foods that are less allergenic and contain lower levels of toxins
- new foods with elevated levels of nutrients and bioactive agents
- reduced chemical use during the growing process, with a consequent minimisation of chemical residue
- reduction in pathogens causing harm to human health.

We heard a number of claims that gene technology will result in the development of foods with properties that will have a range of direct benefits for human health. This area of ‘functional’ or ‘nutraceutical’ foods is considered in more detail in chapter 9 (Medicine).

20. The New Zealand Grocery Marketers Association provided a list, as shown opposite, of genetically modified foods currently being developed.⁹

Public perceptions

21. Throughout the Commission’s processes, many people expressed concerns about the safety of consuming genetically modified food. Over 68% of the written submissions we received from the public expressed the view that the use of genetic modification in food production was unacceptable. Many of the Interested Persons who appeared before us at the formal hearings referred to the widely held

Genetically modified foods under development

Genetically modified food	Modification	Potential benefit
Potatoes	Increased levels and better distribution of starch levels	More effective processing, less absorption of fat when frying potatoes
Potatoes	Developed to contain a high volume of proteins	Lower fat absorption. Improved texture. Replacement for non-animal proteins and synthetic protein derivatives
Rice	Enhanced with β -carotene, a precursor for Vitamin A. Improved nutrition	A cure for blindness in third world countries. Improved nutritional value
Corn and soy	Lower levels of saturated fats. Fats higher in oleic acid	Improved nutritional values. Enhanced use
Rice	[Reduce allergenic proteins]	Of advantage to people with rice allergies
Tomatoes	Higher lycopene levels	An antioxidant
Garlic cloves	Higher allicin levels	Cholesterol lowering agent
Strawberries	Higher ellagic acid content	Health benefits
Vegetables, fruits, and seafood	Enhanced flavonoids, carotenoids and omega fatty acids	Improved nutrition and enhanced health benefits. WHO has reported that more than 30% of non-communicable diseases can be prevented by diet. The evidence of the health benefits of flavonoids, carotenoids and omega-3 fatty acids are increasing
Cereal grains	Changes to the structure of the grain	Improves the digestibility of cereal and bakery products with improved control of glycaemia
Milk	Enhanced casein and calcium content	Improved nutritional and health benefits

public uncertainty about the consumption of genetically modified food. Some of the Interested Persons and many of the people who spoke at the public meetings urged caution, largely because of concerns about safety. Some of the Interested Persons, such as GE Free New Zealand (RAGE) in Food and Environment [IP63] and Nga Wahine Tiaki o te Ao [IP64], strongly opposed genetically modified food and sought a total ban on allowing genetically modified food to be either sold or grown in New Zealand. The Safe Food Campaign [IP86] recommended that a “no regrets” approach should be adopted and suggested that:

... in order to prevent harm from occurring rather than manage the risks once harm has occurred, New Zealand should not utilise GM as a strategic option. As an alternative strategic option the Safe Food Campaign supports New Zealand becoming a GM-free zone and an organic nation.¹⁰

22. The Commission’s own survey, conducted by BRC Marketing and Social Research, confirmed that the wider New Zealand public were aware of the use of genetic modification in relation to food and many also had concerns about the technology.

23. Almost all the people who responded to the survey were aware that genetic modification was being used in processed food. Significantly, well over half of the respondents thought that genetic modification was already being used, to a greater or lesser extent, in commercial crops in New Zealand.¹¹ Although there was no direct questioning on the subject, it is possible that some of those people believed that genetically modified food crops were already being grown for sale, rather than just as small research plots within some degree of containment.

24. A significant number of people questioned (69%) saw genetically modified processed food as having more disadvantages than advantages. We were interested to note that over half the respondents who saw genetic modification as being important to New Zealand’s future also thought that genetically modified processed food had more disadvantages than advantages.¹² Clearly, even some of those who were generally positive about the use of the technology had reservations about its use in relation to food. It was not surprising, therefore, that processed food was the area of genetic modification with the highest disapproval rating both by those who saw genetic modification as being important to New Zealand’s future and those who saw it as being unimportant.¹³ Clearly genetically modified food is a source of concern, at times great anxiety, for a significant proportion of the New Zealand population.

25. Submissions received from both the public and the Interested Persons focused mainly on the safety of genetically modified food and on the possible adverse impacts from consumption. In particular, we heard concerns about the

development of allergens and toxic substances in foodstuffs that had hitherto been considered safe to consume, about increasing antibiotic resistance among humans and animals as a result of the use of antibiotic marker genes, and about possible changes to the nutritional and other properties of modified food.

26. People were concerned about not only their personal health but also the possible impact of genetically modified food on their family's health and that of future generations. One public submission we received said:

I wish to claim under the Human Rights Act the right to protect the future gene pool and health of our food and children by banning genetically modified foods from growth or food production in New Zealand. I will be horrendously angry with any government that

Bovine spongiform encephalopathy (BSE)¹⁴

Bovine spongiform encephalopathy (BSE), widely known as “mad cow disease,” is a chronic, degenerative disease affecting the central nervous system of cattle. Worldwide there have been more than 178,000 cases since the disease was first diagnosed in Great Britain in 1986. Although the disease has also been confirmed in native-born cattle in other parts of Europe, over 95% of all BSE cases occurred in the United Kingdom. Epidemiologic data suggested that BSE in Great Britain is a common-source epidemic involving animal feed containing contaminated meat and bone meal as a protein source.

In 1988, the UK Government introduced legislation that required all cattle suspected of suffering from BSE to be destroyed and sent for diagnosis. In 1989 controls were imposed that banned from the human food chain tissues of cattle, sheep and goats known to, or that might potentially, harbour detectable BSE infectivity.

In 1996, BSE was linked with a new variant form of Creutzfeldt-Jakob Disease (CJD).

Classical CJD, which was first diagnosed in the 1920s, is a slow degenerative human disease of the central nervous system which occurs sporadically worldwide, including in Australia and New Zealand, at a rate of one case per one million people per year. On 20 March 1996, the UK's Spongiform Encephalopathy Advisory Committee (SEAC) announced the identification of 10 cases of a new variant form of CJD (vCJD). All the patients developed onset of illness in 1994 or 1995 and the features of CJD in these 10 cases differed from the sporadic form of CJD.

The SEAC concluded that, although there was no direct scientific evidence of a link between BSE and vCJD, based on current data and in the absence of any credible alternative, the most likely explanation at that time was that the cases were linked to exposure to BSE before the introduction of control measures, in particular the specified bovine offal ban that had been imposed in 1989. Research reported later in 1996 and in 1997 found further evidence to support a causal association between vCJD and BSE.

The official report into BSE strongly criticised government ministers and officials for consistently playing down the risk to humans and for failing to coordinate properly a government response.

has neither the foresight or the courage to stand up to the pressure of multinational conglomerates in this matter.¹⁵

27. The submission from the social scientist members of the Royal Society of New Zealand [IP77b] cited evidence to show that international consumer reaction to genetically modified foods is becoming increasingly negative. Dr Hugh Campbell, giving evidence in support of Organic Products Exporters Group [IP53], suggested that, in New Zealand, the public's concern about genetically modified food was a "food scare".¹⁶ Certainly, a number of the people who made submissions to us drew parallels between genetically modified food and BSE in order to illustrate both the hidden dangers of food and an apparent lack of scientific or regulatory rigour. A major outbreak of foot-and-mouth disease in Britain and Europe at the time of the Commission's inquiry served to heighten public awareness of the potential for rapid spread of disease among animals.

28. Although some people clearly have a high level of anxiety about genetically modified food, the Commission is not persuaded that the general level of concern in New Zealand can be described as a "food scare". We agree, however, that there is widespread public unease about the use of genetic modification in relation to food, which should be taken into account by central government and the relevant regulatory agencies when making any decisions relating to genetically modified food in New Zealand.

29. Dr Lynn Frewer presented useful evidence on public attitudes to genetic modification. Dr Frewer, who was called as a witness by Crop and Food Research [IP4], is a psychologist and Head of the Consumer Science Section in the UK Institute for Food Research. In her discussion of international consumer attitudes towards genetically modified food, Dr Frewer suggested that:

... consumer negativity towards genetically modified foods appears to have arisen because of the order of entry of products into the market place. The public perceived that the first genetically modified foods available were of benefit to industry rather than the consumer, which led to increased rejection of products. Research has shown that novel foods with direct and tangible consumer benefits are more acceptable than those from which only industry will benefit or profit. Perceptions of need and advantage (particularly associated with human health, environmental advantages, or animal welfare) will offset perceptions of risk, but only if the claims made about these benefits are realistic.¹⁷

30. The Commission was told that some producers and sellers of foods overseas were responding to consumer preferences by declining to use or sell genetically modified products. Primary sector industries in New Zealand involved in food production indicated they would be cautious of using genetically modified products because of negative public perceptions.

31. In her written brief and at the hearing before us, Dr Frewer commented on the complexity of the causes for public concern and the variability of consumer attitudes towards genetically modified food. Dr Campbell's comments on Dr Frewer's evidence and his own views on consumer attitudes were noted by the Commission. There were significant areas of agreement in their evidence, particularly with regard to the complex causes and variability of public attitudes, and the potential difficulty of changing established attitudes. We agree there is a need for the public's concerns to be taken into account in all discussions about the use of the technology, particularly in relation to food, with which, as Dr Campbell pointed out, humans have an "ongoing ambiguous and paradoxical relationship".¹⁸

32. The Grocery Marketers Association suggested that, while consumers perceive the genetically modified foods and food ingredients currently on the market as having benefit only to corporate and agricultural interests:

In the future, genetically modified foods will have many direct benefits for the consumer. For example, the ability to produce foods with higher nutrient and health qualities such as lower saturated fats, higher vitamin levels and higher antioxidant levels, will have enormous benefit for consumers, particularly as the link between diet and health is becoming increasingly evident.¹⁹

33. Dr Frewer, however, suggested that, while this second wave of genetically modified foods might be more acceptable, attitudes were unlikely to be changed easily where consumers had already formed strong opinions against genetic modification. She said:

Recent information campaigns in Europe, which have emphasised the positive and beneficial aspects of genetic modification, have not convinced consumers that genetic modification of foods is desirable, or even acceptable in principle. Other information provided by pressure groups which oppose the technology, appears to have been more influential.²⁰

34. On the evidence, there is currently a high level of mistrust of genetically modified food. Among some people, possibly the group Dr Frewer described as "being very vocal in providing input into the public debate",²¹ mistrust may amount to acute anxiety about the safety of genetically modified food, while for others there may be simply a level of uncertainty based on a variety of reasons. The Commission's survey, and other surveys of public opinion, suggest that, even though there may be some personal benefit to consumers from the second wave of genetically modified food, there is no certainty it will be acceptable to a significant proportion of the population in the near future.

35. We noted, however, Dr Frewer's opinion that consumer unease about genetically modified food may relate to the lack of public inclusion in the debate

on genetic modification, rather than, or as well as, a lack of confidence in food testing measures.²² We concur in her view that there is a need for communication about genetic modification to take into account public concerns about the use of the technology, and for the public to be included in the ongoing debate about genetic modification, particularly given the increasing use of genetic modification in relation to food crops and products overseas. We consider the debate should extend beyond discussion of the risks and should encompass a broad range of issues relevant to the use of gene technology in relation to food and human health. We suggest that the agencies responsible for regulating the sale of genetically modified food in New Zealand have an important role in this debate. We would encourage regulatory agencies such as ANZFA, the proposed New Zealand Food Administration Authority and the Ministry of Health to take every opportunity for communicating with and for listening to the public. In particular, we commend the establishment of interactive websites that provide accurate, current information on issues relating to the genetic modification of food and food products, and that allow for the public to express their views.

Current New Zealand regulatory responsibilities for food

36. Submissions from ANZFA, and the Ministries of Health, Agriculture and Forestry, Consumer Affairs and Foreign Affairs and Trade provided information on the regulatory framework and international obligations relevant to genetically modified food.

Food standards

37. Food standards, which regulate the quality and composition of the food available on the market, are designed primarily to protect public health and safety. In December 1995, the New Zealand Government entered into the Food Standards Treaty, formally known as the *Agreement between the Government of New Zealand and the Government of Australia Establishing a System for the Development of a Joint Food Standards*. The Food Standards Treaty encompasses primarily food composition and labelling requirements. It does not cover the setting of maximum residue limits, food hygiene (including food safety plans) and export requirements relating to third-country trade. The Food Standards Treaty, together with the Trans-Tasman Mutual Recognition Arrangement (TTMRA), which came into effect in 1998, are part of the economic agreements and arrangements between Australia and New Zealand as a result of the Australia New Zealand Closer Economic Relations Trade Agreement, known as CER,

signed in 1983. TTMRA gives effect to mutual recognition principles relating to the sale of goods and the registration of occupations.

38. The practical implications of TTMRA are that food that can lawfully be sold in New Zealand may also be lawfully sold in Australia and vice versa. In New Zealand, these rights are subject to the Fair Trading Act 1986.

39. One of the key outcomes of the Food Standards Treaty was the implementation of a single set of standards for the composition and labelling of food that applies in both New Zealand and Australia. These standards comprise the Australia New Zealand Food Standards Code (“the joint Food Code”) gazetted in New Zealand on 20 December 2000. This will become the sole food code for both countries in December 2001. Although during the transitional period, New Zealand food businesses have the option of complying with one of the current New Zealand Food Regulations, the Australian Food Standards Code, or the joint Food Code, all food businesses must comply with any “mandatory standards” in the New Zealand Food Standard 1996. Standard A18, which regulates the sale of genetically modified food in New Zealand, is a mandatory standard.

Australia New Zealand Food Authority: structure and role

40. The Australia New Zealand Food Authority (ANZFA), which develops food standards for inclusion in the joint Food Code, is a body set up under Australian law by the Australia New Zealand Food Authority Act 1991. Following the signing of the Food Standards Treaty in 1995, the existing ANZFA Board was expanded to include New Zealand representation. New Zealand has two members and a further representative was appointed as a special member for a limited term at the request of the New Zealand Minister of Health, specifically to assist in the process of transition to the new joint Australia New Zealand Food Standards Code.

41. In response to criticism of the nature of the Board membership, its expertise and understanding of community issues expressed during the course of the formal hearings, Ian Lindenmayer, Managing Director of ANZFA, provided further details. He said:

Six of the ten members are themselves scientists. Two of them have high-level medical qualifications. In fact, both of those two also have a distinguished record in relation to human nutrition and its medical implications. Two others, one from New Zealand and one from Australia, [are] distinguished in the areas of nutrition and dietetics, and two others, again one from New Zealand and one from Australia, have expertise in the areas of food, science and technology.²³

42. The remaining members, he said, were he and three others, including a New Zealand representative, with experience at senior level in government. At the hearing, Mr Lindenmayer advised that the most recent appointment to the Board was:

... herself a Maori and who has worked very closely with that community over more than 25 years. ...²⁴

43. Later, at the Gisborne hui, we heard from the appointee, Hiki Pihema (Ngati Porou), who is the nutritionist at Cook Hospital, about her hope of facilitating communication between ANZFA and the Maori community.

44. The Australian State and Territory governments, the Commonwealth government and the New Zealand government fund ANZFA. Through the Minister of Health, New Zealand enters into an annual Partnership Agreement with the Chairperson of ANZFA. Under these arrangements, New Zealand makes financial contributions to ANZFA's work in developing food standards for both countries, but not to ANZFA functions that lie outside the Treaty. The financial contribution is based on population share.

45. ANZFA conducts risk assessments, initiates and coordinates expert panels and reference groups and undertakes consultation to develop recommended food standards. In reviewing food standards and developing its recommendations, ANZFA seeks advice from the broad community (including industry, consumers and others) and government agencies from both countries. It also receives advice from government agencies in Australia and New Zealand through the Australia New Zealand Food Authority Advisory Committee (ANZFAAC) and a working group of Senior Food Officers. Currently, nominees of the Ministry of Health and the Ministry of Agriculture and Forestry represent New Zealand on both these committees.

46. ANZFA does not have authority to make final decisions to adopt new food standards. These are made through consensus or a majority vote of the Australia New Zealand Food Standards Council (ANZFSC). The council comprises ten Ministers of Health; the New Zealand Minister of Health, the Federal Minister of Health and the Ministers in the eight Australian States and Territories.

Proposed changes to the process for establishing food standards

47. ANZFA's written submission advised that the Authority will be replaced by a new organisation, Food Standards Australia New Zealand (FSANZ). This alteration will require amendments to the Australia New Zealand Food Authority Act and, as a consequence, to the Food Standards Treaty. At the time of writing

this Report, the amendment had been considered by the Australian Senate but had not completed its legislative passage.

48. The proposed changes will affect the membership and function of the new Authority's governing body and the role and responsibilities of the Ministerial Council. It is also possible that the powers of the Australian Federal government in relation to food standards may be increased.

49. Some Interested Persons had reservations about these proposed changes. In particular, there were concerns that New Zealand representation on the governing Board may be proportionately less than it currently enjoys, and that any additional power given to the Federal government would be to the detriment of New Zealand's sovereignty. The proposal that Ministers from portfolios other than Health should sit on the Ministerial Council also gave rise to concern.

50. During the hearing attended by representatives of ANZFA, Sue Kedgley MP, representing the Green Party of Aotearoa/New Zealand [IP83] and the Safe Food Campaign, sought confirmation that changes to ANZFA and the composition of the ANZFSO were being considered under Australian legislation and without any discussion in the New Zealand Parliament. Mr Lindenmayer responded:

The legislation which is currently before the Parliament in Australia is legislation which is intended to give effect to changes which have been developed by a committee, not including my organisation, but a committee representing all ten of the jurisdictions.

Secondly, the advice of that committee has gone to government level, to ministerial level, and I understand there have been discussions encompassing Ministers of New Zealand and Ministers from the Australian side as well.

An intergovernmental agreement was signed in Australia between the Commonwealth Prime Minister and the Premiers and Chief Ministers of the States and Territories, indicating agreement to proceed with the sorts of changes to which you are referring.

My understanding is that, prior to that occurring, there were discussions also with the Government of New Zealand, and there was acceptance that a move – that such a move would be acceptable.

... It was certainly envisaged that the next stages would be a combination of the development and passage of legislation through the Commonwealth Parliament, and discussions between Australian and New Zealand Governments to modify the existing Treaty, and that there would be some Parliamentary process, and I'm not sure of the detail, on the New Zealand side too – as part of that latter process.²⁵

51. Ms Kedgley then pointed out that treaties are not discussed in the New Zealand Parliament. Discussion of proposed treaties by Parliament as a whole is a constitutional issue outside the scope of our Warrant. Negotiations between the

New Zealand and Australian Governments over the proposed legislative changes, and the consequential changes to the Food Standards Treaty, are ongoing. We anticipate, therefore, that there will be debate within New Zealand about the issues raised by the proposed amendments.

52. Until the amending legislation has passed through the Australian legislative process, and the negotiations between the two Governments in relation to the Food Standards Treaty have been finalised, the full impact of the changes cannot be known. The Commission makes recommendations relevant to this matter later in this chapter.

Standard A18 Food Produced Using Gene Technology

53. ANZFA Standard A18: *Food Produced Using Gene Technology*, Division 1, is the standard that regulates genetically modified foods. Standard A18 is incorporated into New Zealand law as a mandatory standard in the New Zealand Food Standard 1996. Standard A18 regulates the sale and labelling of genetically modified foods. The text of the Standard is available on the ANZFA website at www.anzfa.govt.nz.

54. In standard A18, a food produced using gene technology is defined as “a food which has been derived or developed from an organism which has been modified by gene technology”. A food derived from an animal or other organism that has been fed food produced using gene technology is specifically excluded from the definition.

55. Clause 2 of Division 1 of the Standard is a general prohibition on the sale of genetically modified food. Foods that are exempt from the prohibition are listed in the table under clause 2, together with any special conditions the Authority has imposed on them. To be included in the table, a food must have been assessed as being safe for human consumption in accordance with the Authority’s approved safety assessment criteria. Having satisfied the assessment, the food requires the consent of ANZFSC before it is listed in the table.

56. Clause 2A in the Standard is a transitional exemption to the general prohibition on sale. It allows certain genetically modified foods to remain on the market pending ANZFA assessment. This exemption addresses the fact that genetically modified foods were imported into New Zealand and Australia before the Standard came into force in May 1999. Clause 2A(2) permits genetically modified foods to stay on the market where:

- an application was made to ANZFA before 30 April 1999 for the food to be permitted under Standard A18

- there is evidence that the food is lawfully permitted for sale in one or more countries other than New Zealand and Australia, by a national food regulatory agency
- ANZFSC has not become aware of evidence that the food poses a significant risk to public health and safety.

ANZFA process

57. In its written submission, ANZFA stated that, in developing food regulatory measures such as food standards, its objectives (in order of priority) are:

- protecting public health and safety
- providing adequate information relating to food to enable consumers to make informed choices
- preventing misleading or deceptive conduct.

58. In making recommendations on food standards, ANZFA must also give regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence
- the promotion of consistency between domestic and international food standards
- the desirability of an efficient and internationally competitive food industry
- the promotion of fair trading in food.

59. ANZFA outlined the process for developing new food standards or varying existing standards, initiated either on receipt of an application from an external body or through ANZFA's own preparation of a proposal. If, after it has made a preliminary assessment, ANZFA decides to accept an application, submissions are invited from the public. A full assessment report is made, based on a scientific risk assessment, taking account of all evidence received in submissions from interested parties and the public. At the hearing before the Commission, ANZFA representatives provided further details on the scientific risk assessment that is carried out as part of the full assessment, and tabled the extensive documentation related to one such assessment.²⁶

60. On the basis of this full assessment, ANZFA would either reject the application or prepare a draft new standard or a variation to an existing standard. The draft new or varied standard and the full assessment report are circulated to all individuals and groups that made submissions on the matter, and public advertisements seek commentary on the appropriateness of the drafting. Finally, ANZFA makes a recommendation to the ANZFSC based on its consideration of information and comment received in the third stage.

61. Before an ANZFSO decision is incorporated into New Zealand law, the New Zealand Minister of Health must issue an amendment to the New Zealand Food Standard 1996 that recognises the variation to the Australian Food Standards Code. The Minister’s amendment is then gazetted, and the standard becomes law in New Zealand after 28 days.

62. Under the Treaty, New Zealand may opt out of a food standard if it considers the standard to be inappropriate on the grounds of “exceptional health, safety, third-country trade, environmental or cultural factors”. Susie Lees, cross-examining on behalf of the Environment and Conservation Organisations of New Zealand (ECO) [IP102] and Nelson GE Free Awareness Group [IP100] at the special hearing attended by ANZFA, questioned whether, in reality, New Zealand could choose to opt out of Standard A18.²⁷ In a letter responding to questions posed at the hearing, ANZFA confirmed New Zealand could opt out of Standard A18, even after it had been adopted, by initiating a process leading to a decision by the ANZFSO that the standard should not apply in New Zealand.²⁸ However, because of TTMRA, unless exceptional health, safety and environmental concerns exist, a New Zealand variation will not prevent Australian food permitted to be sold under Standard A18 being sold on the New Zealand market. Many submitters considered ANZFA to be predominantly Australian, and saw the determination of food standards by this organisation as an abrogation of New Zealand’s sovereign right to determine its own affairs for the benefit of its citizens.

63. Dr Peter Wills, a witness for Physicians and Scientists for Responsible Genetics [IP107], Greenpeace New Zealand [IP82], Green Party, Friends of the Earth (New Zealand) [IP78], Sustainable Futures Trust [IP51] and Pacific Institute of Resource Management [IP84], expressed the mistrust shared by a number of submitters when he wrote:

Successive New Zealand governments have become parties to a number of agreements affecting citizens who have had no say in the matter. In respect of the safety of our food supply, we are now subject to decisions that are made by an international body (ANZFA) which is dominated by industrial interests. All considerations in relation to these international obligations are dominated by scientific and technical matters and the unique cultural and ethical perspective of New Zealanders is given absolutely no weight.²⁹

64. Understandably, others may share the concern that Australian commercial interests may dominate ANZFA and undermine the Authority’s ability to carry out its functions. The Commission considers, however, that Australia and New Zealand have the same desire to achieve high standards of food safety and we see no likelihood that joint activity in this area will be detrimental to New Zealand’s interests. Moreover, collaboration between the two countries allows New Zealand

to share the cost of a better resourced and equipped safety assessment process than might be possible if a parallel agency were established and funded internally.

Public consultation

65. A number of submissions raised doubts about the nature and extent of public involvement in the development of food standards. In its written submission, ANZFA said that calling for public submissions on food standards applications is a requirement under the Australia New Zealand Food Authority Act 1991. It stated:

Community participation in the development of effective food standards enables:

- the tendering of relevant data not already available to ANZFA
- the views of the community to be presented and understood
- sound decision making following review of all available information
- a form of peer review for scientific and technical matters
- increased accountability and transparency in decision making
- smooth implementation following decision making.³⁰

66. ANZFA's submission advised that it has developed a Community Involvement Strategy "which will provide a framework for improved consultation with the broad range of interested community participants". A consultation strategy for Maori, including the formation of a Maori Reference Group in July 2000, is intended to facilitate greater participation of Maori in the food standard setting process.

67. ANZFA stated that the role of the Maori Reference Group is to provide advice on Maori culture and community processes. The Reference Group will assist in identifying:

- food standards issues of significance to Maori
- strategies for effective communication with Maori
- strategies to involve Maori in food standards issues
- projects and research relating to food standards.

68. We understood from Mr Lindenmayer that the Maori Reference Group, in its meetings to date, has emphasised the significant spiritual role that food plays within Maori communities and the importance of developing effective and meaningful relationships and dialogue on issues.³¹ The Commission considers it essential that Maori are closely involved with the development of food standards because of its fundamental importance to their physical and spiritual well-being. During the course of our inquiries, we heard much said about the loss of traditional Maori food. Cheryl Smith (Ngati Apa, Te Aitanga a Hauiti), in the course of the presentation by Nga Wahine Tiaki o te Ao, emphasised that there is

an active and ongoing dialogue among Maori about changes to food, including changes through genetic modification. She pointed out that:

The issues of kai, for example, and the safety of our kai, and the loss of our kai or of our traditional kai, has been a point of discussion among us from the time colonisation began. Genetic modification, of course, is yet another issue. What's happened is that we're finding more and more a need to protect ourselves in regard to growing our own kai and ensuring the safety of what we actually feed our own children. One of the key motivations for our people to return to growing their own kai at the moment is the issue of genetic modification.³²

Labelling requirements

69. Standard A18 Division 2 regulates the labelling of genetically modified food. ANZFA's written submission said that, under Standard A18 as it stood at the time of the Commission's inquiry, genetically modified foods must be labelled regarding the origin and nature of the characteristic or property modified, where:

- the modification results in one or more significant compositional or nutritional parameters having values outside of the normal range of values for the existing equivalent conventional food or food ingredient
- the level of anti-nutritional factors or natural toxicants are considered to be significantly different in comparison to the existing equivalent conventional food or food ingredient
- the food contains a new factor known to cause an allergenic response in particular sections of the population
- the intended use of the food or food ingredient is different to the existing equivalent conventional food or food ingredient.

70. Following the recommendations of an ad hoc inter-governmental task force, which included New Zealand representatives, the ANZFSC decided to extend the labelling requirements of genetically modified food. From 7 December 2001, food will be required to be labelled as being genetically modified where:

- novel DNA and/or protein is present in the final food; and
- the food has altered characteristics when compared with its conventional counterparts.

71. There will be exemptions in relation to:

- highly refined food where the effect of the refining process is to remove novel DNA and/or protein
- processing aids and food additives, except those where novel DNA and/or protein is present in the final food

- flavours that are present in a concentration less than or equal to 0.1% in the final food
 - food prepared at the point of sale.
72. The amended Standard will allow an ingredient to contain up to 1% of unintended presence of a genetically modified product without requiring labelling. In its written submission, ANZFA stated that this provision is not to be interpreted as a “general threshold”.
73. The New Zealand Ministry of Health, in its written submission, said that this amendment was determined following public consultation in New Zealand and in Australia in which consumers expressed a desire for comprehensive labelling. The Ministry said that, in making a decision about the labelling of genetically modified food, four criteria were used to assess options: meaningful information, cost of compliance, international trade implications and enforceability.³³
74. The labelling requirements will be reviewed three years after they are implemented, in December 2004.
75. Public concerns about the adequacy of the new labelling requirements are discussed later in this chapter.

Regulatory responsibilities in New Zealand

Genetically modified food

76. At the time of submissions to the Commission, two New Zealand Ministries had responsibility for matters relating to food. The Ministry of Health had primary responsibility for managing the relationship with ANZFA, including contributing to, reviewing and commenting on standards developed by the Authority and coordinating responses by New Zealand government agencies on matters related to food standards. The Ministry of Agriculture and Forestry (MAF) reviewed and commented on ANZFA standards affecting primary produce.
77. Both the Ministry of Health and MAF had roles in international forums, with MAF coordinating New Zealand’s input into Codex Alimentarius decisions. MAF also had responsibility for policy advice on primary production and agricultural trade issues and the Ministry of Health provided policy advice on public health issues.
78. The Ministry of Health was responsible for coordinating the enforcement of food standards in New Zealand. Complaints regarding actual breaches of food standards are investigated by designated officers in public health units of hospitals and health services around New Zealand. The Ministry of Health also has responsibility for monitoring public health and responding to and identifying

the causes of outbreaks of ill effects, such as those that occurred as a result of the L-tryptophan incident in the United States of America.

79. Animal feed is regulated under the Animal Compounds and Veterinary Medicines Act 1997. Regulations under that Act come into force in July 2001. Genetically modified animals, if used in the production of food, will be regulated under the Animal Products Act 1999, which had not come into force at the time of the Commission's hearings. The written submission from the Ministry of Agriculture and Forestry stated that the legislative regime under this Act provides a mechanism for secondary processors to switch between risk-based management systems under the Food Act 1981 and the Animal Products Act 1999. It also provides for setting standards for genetically modified animal material or products or ingredients or additives.³⁴

80. In chapter 7 (Crops and other field uses) we considered the use of animals as bioreactors for the production of biopharmaceuticals. In that chapter we recommended that, to avoid such animals entering the food chain, it is preferable that only non-food animals used should be used as bioreactors. Meat from any genetically modified animal, regardless of the purpose for which it has been modified, will require approval by ERMA and ANZFA and will have to satisfy the labelling requirements before it is allowed to enter the food chain.

Food Administration Authority

81. Since the Commission has completed its public inquiry, the Government has announced the formation of a separate food safety agency, under the umbrella of the Ministry of Agriculture and Forestry. Although no details of the new agency have been released to date, we understand it will assume many of the responsibilities for food previously undertaken by the Ministries of Health and Agriculture and Forestry, although epidemiology and other public health issues will remain with the Ministry of Health.

82. The Commission considers that the creation of a separate agency is appropriate. We agree with the frustration expressed by the Grocery Manufacturers Association which said:

Food safety administration and monitoring and enforcement activities of food are undertaken by a myriad of agencies in New Zealand including the Ministry of Health, Ministry of Agriculture and Forestry and local authorities. This has long been of considerable concern to all sectors of the food industry for the following reasons:

- the lack of resources in some situations to carry out the necessary tasks
- inconsistent rulings and interpretations that result from having a multiplicity of agencies involved
- companies can be subject to many audits.³⁵

83. There are a number of responsibilities related to the management and oversight of genetically modified foods in New Zealand that the Commission would want to see the new agency undertake. These responsibilities are identified during the course of this chapter and summarised in paragraphs 208 to 213.

International obligations

84. The written submission from the Ministry of Foreign Affairs and Trade provided information on New Zealand’s international obligations. The Ministry suggested that participation in the international community was important “for a small nation like New Zealand, which has limited ability when acting alone to influence other governments to its advantage”.³⁶ New Zealand is a party to a number of international treaties and agreements.

World Trade Organization

85. The Ministry’s submission included reference to the World Trade Organization (WTO) and focused on two WTO agreements relevant to genetic modification, the Agreement on Technical Barriers to Trade (TBT) and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS). The submission pointed out that the TBT Agreement, which embodies the principle that products from one country should be subject to the same rules as like products imported from another country, or produced domestically, applies to technical regulations, including mandatory labelling requirements. The Ministry commented that the principles under the Agreement were important considerations in the development of the Standard A18 labelling provisions. The SPS Agreement, which allows for a country to impose standards in respect of plant and animal pests and diseases that are necessary to protect a country’s biosecurity (including food safety), also embodies the principle of non-discrimination between countries.

Codex Alimentarius

86. The Codex Alimentarius Commission (Codex) is the United Nation’s joint Food and Agriculture Organization/World Health Organization body responsible for setting food standards. The main purpose of Codex is to protect the health of consumers and to ensure fair practices in food trade. It also promotes coordination of food standards work undertaken by governmental and non-governmental organisations. New Zealand was a founding member of Codex, which now consists of 165 member countries. The submission from the Ministry of Foreign Affairs and Trade advised that Codex comprises a number of committees that consider a range of matters related to standard setting.

Committees with activities on their work programmes that relate to food derived from biotechnology include:

- the Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology
- the Codex Committee on Food Labelling (CCFL)
- the Codex Committee on Methods of Analysis and Sampling (CCMAS)
- the Codex Committee on General Principles (CCGP).

87. In 1978, the New Zealand government directed that, where practical, New Zealand should adopt Codex food standards.

88. Both ANZFA and the Ministry of Health provided information on matters currently being considered by Codex. The Codex process for finalisation of the international documents and standards relating to the safety of foods derived from biotechnology is required to be completed by 2004 and a determination of labelling standards for genetically modified foods may also take as long to be completed. The ANZFA submission appended two draft documents currently being developed by the Codex Taskforce on Foods Derived from Biotechnology, both of which relate to assessing the safety of genetically modified food. The joint submission from Vegfed, Fruitgrowers, Berryfed cited with approval the draft *Guideline for the Conduct of Safety Assessment of Foods Derived from Modified Plants*.

OECD Task Force

89. In its written submission, ANZFA said that it participates in the OECD Task Force for the Safety of Novel Foods and Feeds. The Task Force builds on the work done by the OECD in the 1990s to develop scientific principles for the safety assessment of products of modern biotechnology.

Inclusion in the global community

90. Inclusion in the international community is one of our common values and New Zealand's international obligations are important to the country's economic well-being. Participation in international forums both allows New Zealand to contribute to the debate about genetically modified food and also keeps current the knowledge and understanding of officials charged with protecting the safety of the general public.

91. The Ministry of Agriculture and Forestry and the Ministry of Health held a joint public consultation meeting on 12 February 2001 at Wellington, and invited written submissions from interested parties on the work of the Codex taskforce. Public involvement of this nature in the debate about genetically modified food should be encouraged to ensure that the views of the community are incorporated into New Zealand's responses to the deliberations of international forums.

92. The Commission is aware of the concern among some of the public that membership of international bodies such as the WTO may impinge on New Zealand's ability to exercise self-determination. During the course of cross-examination, the Dairy Board³⁷ spoke of the value of the World Trade Organization and the Board's written submission said:

As a small nation, with little economic and political power, New Zealand is highly dependent upon the international community of nations respecting the framework of legally enforceable rules created by the WTO. Any actions which undermine respect for that system have negative implications for New Zealand.³⁸

93. Greenpeace discussed New Zealand's international obligations and made reference to decisions of the Appellate Body of the World Trade Organization in respect of a number of appeals against restrictions imposed on trade in food. WTO has been instrumental in providing environmental protections and, only recently, New Zealand took advantage of the WTO dispute resolution process to protect important agricultural exports to the United States. We consider that such cases illustrate the value of membership of the international body, even where this may involve relinquishing some degree of national autonomy.

94. Membership of the international community requires reciprocity. Exports, for example, are protected against discriminatory trade practices imposed by other nations by the provisions of the TBT and SPS Agreements. In return, New Zealand must not implement statutory requirements that may be discriminatory against countries from whom we import. The international trading community is very watchful in ensuring this does not happen. The Ministry of Foreign Affairs and Trade, for example, pointed out that New Zealand and Australia, along with the European Union, had been among the first countries to develop comprehensive labelling for genetically modified foods. Approaches to labelling differed among countries, with some countries preferring to avoid mandatory labelling. Assurances had already been sought that the labelling requirement under Standard A18 were consistent with provisions of the TBT Agreement.

Significant issues

Is genetically modified food safe?

95. Many of the Interested Person groups prominent in the campaign against genetically modified food, and many of the people who spoke at the public meetings and workshops, expressed concerns about the risks associated with the consumption of genetically modified food. A number of scientists from New Zealand and overseas gave evidence that the insertion of genetic material into an organism would create unexpected effects that, in food, could have adverse effects

on human health. For example, in her witness brief for the Safe Food Campaign, Ms Kedgley identified most of the concerns shared by submitters when she said:

Scientists warn that food with altered genes could introduce a range of unanticipated health risks to consumers, including increased levels of naturally occurring toxicants, the appearance of new, not previously identified, undetectable toxicants, reduced levels of nutrients, the presence of new allergens, the creation of antibiotic resistance, immuno-suppression and the potential nutritional degradation of foods.³⁹

96. In addition, some submissions also expressed a belief that horizontal gene transfer could transfer recombinant DNA from a modified organism to an unmodified organism, including a mammal. GE Free New Zealand said:

There is also serious concern about the dangers of using genetically engineered viruses as delivery vehicles (vectors) in the generation of transgenic plants and animals. This could destabilise the genome and lead to horizontal gene transfer to other species, including mammals. This risk is known because recent research suggests that disabled viral material used in recombinant DNA techniques can recombine with other viral material in plants or in the human or animal gut to produce new active forms of viral material.⁴⁰

97. Scientific witnesses, such as Dr Beatrix Tappeser, a molecular biologist with the Institute for Applied Ecology at Freiburg and a witness for the Pacific Institute of Resource Management, and Dr Mae-wan Ho, a witness for GE Free New Zealand, as well as members of the Physicians and Scientists for Responsible Genetics, provided evidence about the risks of genetically modified food, including the possibility of horizontal gene transfer to humans through the consumption of genetically modified food. Together with many other submitters, these witnesses stated that, because of lack of experience with modified foods, the risks could neither be known nor predicted. They called for foods to be subject to tests similar to those undertaken in relation to pharmaceuticals and suggested that, until genetically modified food could be shown to pose no risk to human health, all modified foods currently offered for sale should be removed from sale. The view was expressed that, in the absence of adequate testing, humans were being used as “guinea pigs”.

98. One of the more publicised and controversial research projects was that carried out by Dr Arpad Pusztai and Dr Stanley Ewen into the toxic effect of inserting lectin genes into potatoes. Witnesses such as Professor John Mattick of the University of Queensland, a witness for Auckland UniServices [IP23], maintained the study was flawed. Dr Pusztai and Dr Ewen appeared before the Commission as witnesses for Friends of the Earth, and the Commission had the opportunity to ask questions about their research.

Pusztai's Potatoes – the controversy⁴¹

Dr Arpad Pusztai, a senior scientist at the Rowett Institute, Aberdeen, Scotland, came to international attention when he announced to the media that eating genetically modified potatoes depressed rat immune systems and caused changes in their intestinal tract.

Dr Pusztai and his colleague, Dr Stanley Ewen, tested the dietary effects of potatoes genetically modified to contain and express a gene for snowdrop lectin, called *Galanthus nivalis* agglutinin (GNA). Lectin was introduced to potatoes as an insecticidal protein, but is also an antimetabolite, ie it slows down cell growth.

Dr Pusztai and co-workers compared rats fed genetically modified potatoes with those eating non-modified potatoes, with and without added GNA. The genetically modified potatoes appeared to cause changes in the rats' immune response and the structure of the intestinal lining. They asserted that this outcome was the result of the way the lectin gene had inserted into the potato genome, rather than the expression of lectin by the potatoes.

While the experimental design appears to be correct for this type of feeding study, there were difficulties with the use of a raw potato diet. Rats do not like to eat raw potato, and a standard 110-day trial had to be abandoned after 67 days, because the rats were starving. Starvation affects gut histology, and the lining of the gut of control rats eating unmodified potatoes was shown to be abnormal. This led to confusion regarding the significance of Dr Ewen's histological results, particularly to the reported 'over growth' of gut epithelial cells of rats eating genetically modified potato. The presence of other potato toxins could also have had a confounding effect on cells in the intestine, especially since the potato lines were not substantially equivalent:

"... we couldn't come to any other conclusion but this, that the GNA gene insertion into our potatoes induced changes in the levels of all these things ... So we had to say at the end, the GNA GM potato lines were, therefore, not substantially equivalent to the appropriate parent tubers. And I can take it further, that the two lines of genetically modified potatoes were not substantially equivalent to each other".⁴²

It is also noteworthy that evidence used by Dr Pusztai to indicate that the rats had depressed immune systems was not the result of standard immune response tests.

Within the scientific community there is general agreement that the results of Dr Pusztai's experiment are inconclusive insofar as there were flaws in the process, and the project was incomplete. Extensive testing carried out by Chinese researchers, similar to that described by Drs Pusztai and Ewen, has not replicated their results.

99. The Commission, having heard evidence directly from Dr Pusztai and his colleagues, is also of the view that the results are inconclusive. It was unfortunate that the process of peer review was pre-empted by premature media release, thus preventing further scientific assessment.

100. Although evidence was presented about the risks of genetically modified food, we also heard that risks have been overestimated. Many witnesses pointed out that, although genetically modified food had been available internationally for over a decade, there was no evidence it had caused harm. The Grocery Marketers Association considered that:

If very little was known about genetically modified foods, even a suspicion of harmful effects might deter their being marketed. But a considerable amount is known, which has allowed regulatory agencies around the world, such as the OECD, the WHO, FDA, to state that genetically modified foods are as safe as conventional foods.⁴³

101. Dr Brian Jordan, Director of the Nutrition and Health Institute of Food, Nutrition & Human Health at Massey University, a witness for the New Zealand Arable-Food Industry Council [IP56], said:

Of particular concern to the public is the ability of this new technology to supply consistently safe food. This concern has been addressed many times recently by a number of world organisations, such as the OECD, FAO and Codex Alimentarius. The overall conclusion is that there are no credible reports of adverse health effects from consuming GM foods. For instance, the OECD conference held in Edinburgh in March 2000 on “the scientific and health aspects of genetically modified foods” concluded that GM food was not a health risk.⁴⁴

102. HortResearch [IP5] also suggested that there were no risks associated with the genetically modified foods available in New Zealand. Its written submission said:

While everyone should have the choice as to what they eat, there are no known health risks associated with eating GM-sourced foods available in New Zealand under current legislation. ... Most people take a far greater risk every day in eating food potentially containing pathogens like Salmonella or Campylobacter. The apparent high level of public concern about the safety of GM foods is based more on a range of other concerns (such as moral and ethical issues) rather than on the technical risks to food safety.⁴⁵

103. Many of the submissions were concerned about the relationship between antibiotic resistance marker genes and increased human resistance to antibiotics. As discussed in chapter 4 (Environmental and health issues) and chapter 6 (Research), the Commission considers increased antibiotic resistance has resulted from a combination of factors, including the overuse of antibiotics in medicine, other than the use of antibiotic marker genes. However, given the increasing frequency of antibiotic resistance, we would encourage the use of alternative strategies to antibiotic resistance marker genes in the development of transgenic organisms.

104. The Commission was told that food retailers overseas are responding to consumer concerns by refusing to sell produce such as meat, poultry, milk and eggs coming from animals or birds fed on genetically modified feed, and by using positive labelling mechanisms such as “organic” or “GE Free”.

105. None of the organisations involved in the research and development of food crops or in food production and distribution, however, suggested that the safety of genetically modified food should be assumed. They supported ANZFA’s view that, in the absence of a history of safe use:

... a cautious approach is applied to these foods that involves scientific risk assessment prior to their being permitted for sale in the food supply.⁴⁶

106. The Commission considers this to be the appropriate approach to follow. Witnesses said that there may be risks associated with the application of gene technology to food. While we accept that, to date, there has been no evidence of unsafe foods entering the New Zealand market, we are conscious that there is always a possibility of adverse effects from unsafe food. We are aware of the serious concerns about the long-term effects of food on human health raised by the incidence of BSE. At the same time, we are in agreement with the statement made by the New Zealand National Commission for UNESCO [IP90] that:

... if genetic engineering can lead to increased productivity of crops, growth rates and usable plant product; quality of crops including nutritional quality and storage properties, adaptation of plants to specific environmental conditions, a broadening of plant tolerance to environmental stress; increase in disease and pest resistance and less need for the use of agrochemicals; production of substances in food crops of importance to human health and the utilisation of hitherto unused species for human consumption, then these benefits for humanity cannot be foregone.⁴⁷

107. Many witnesses said that the “second wave” of genetically modified foods will have greater direct benefits for consumers. We do not, therefore, consider it would be in the best interests of New Zealand to ban genetically modified food. We do, however, consider that consumers should be protected by rigorous scientific assessment processes and by proactive and effective post-market monitoring systems, and should also be able to exercise their own choice as to whether or not they consume genetically modified food.

108. Organisations such as the Safe Food Campaign suggested that a prohibition on genetically modified food and a thrust to make New Zealand “an organic nation” would lead to increased consumption of organic food with a commensurate improvement in public health.⁴⁸ We have seen no evidence to support this assertion. We acknowledge the importance to people of being free to choose food produced through a process they consider to be safe. Based on the

evidence we heard, we see no reason to assume that the continued presence of genetically modified foods assessed to be safe by the appropriate regulatory body will prevent individuals being able to exercise their choice to eat organic food. Steps should be taken, however, to avoid the contamination of organic food crops growing in New Zealand and this is discussed in chapter 7.

Unapproved genetically modified food

109. Several submissions expressed concern that ANZFA had permitted genetically modified food to remain on sale in New Zealand pending the completion of safety assessments. Sue Kedgley, on behalf of the Green Party and the Safe Food Campaign, cross-examined Mr Lindenmayer on the ANZFA decision not to require these foods to be withdrawn. She questioned whether, in the absence of a safety assessment, ANZFA was meeting the obligation under the New Zealand Food Act 1981 that “food in New Zealand must be safe and must not contain anything harmful to health”.⁴⁹

110. In its original written submission, ANZFA advised it was considering 18 applications for approval for the release of genetically modified foods, covering soybeans, corn, canola, potato, sugar beet and cotton, all but one relating to the introduction of genetic traits designed to improve production characteristics, such as a crop’s insect resistance or tolerance to herbicides. The other application related to changes in the oleic acid content of a soybean. The written submission advised that, on 28 July 2000, ANZFSC approved two genetically modified foods: glyphosate-tolerant soybeans (Roundup Ready soybeans) and oil and linters derived from insect-protected cotton lines 531, 757 and 1076 (Ingard cotton). Ten safety assessments had been completed and sent for final approval to the Council. Assessments for the remaining six “were at an advanced stage” and would soon be released for public consultation.⁵⁰

111. At the time of the written submission, therefore, only two genetically modified foods had been approved under Standard A18, although a number were in the process of being approved. Later, at the hearing before us, Mr Lindenmayer was asked about the foods that might still be on the market awaiting assessment. He said:

My expectation is that 18 of them would be on the market – market still, of which, I think it is seven, have already been approved and are therefore under the ongoing regulatory arrangements. Another group have now gone through the ANZFA Board processes and recommendations are with – or are about to be with the Ministerial Council. And, I think safety assessments have been completed for all but two, and those two are two in respect of which we have been requiring further information from the applicant companies in order to allow us to complete our safety assessment.⁵¹

112. Because most of the foods approved by ANZFA are used as ingredients, a list of foods that have been approved does not give a clear picture of the foods on the supermarket shelves that could be classified as genetically modified. Few if any of these foods were required to be labelled in accordance with the provisions of Standard A18, which is currently being extended. Many submitters, however, suggested to us that the labelling required under the amended Standard A18 will still not provide the level of information about the use of genetic modification in food they think is necessary. We consider this issue later in this chapter.

Compliance with Standard A18

113. Submissions raised two situations in which genetically modified foods that had previously been approved under Standard A18 could cease to comply with the standard: accidental unnotified changes to gene constructs, and contamination by unapproved genetically modified products and changes.

Changes to construction of approved food

114. Ms Lees, cross-examining for ECO and Nelson GE Free Awareness Group, raised with ANZFA the issue of unnotified changes. She questioned whether the Authority regularly tested for changes in gene constructs and suggested that, had there been an unexpected change in the gene construct, it might not have been possible for the applicant to notify ANZFA of this change. She asked whether, in such a situation, ANZFA could assure the safety of that food.⁵²

115. Mr Lindenmayer pointed out that it was ANZFA's responsibility to establish food standards and to amend the Food Standards Code to indicate approval for foods. Once approval had been given, responsibility for monitoring and enforcing standards in New Zealand rested with the Ministry of Health.

Accidental contamination of approved food

116. The StarLink™ incident (see overleaf) was frequently mentioned as an example of how the safety of genetically modified foods could be compromised. Many submitters seemed to see the events as an illustration of the overall lack of safety of genetically modified food.

117. The Commission does not consider that cases of the accidental contamination of human food by unauthorised genetically modified material cast doubt on the safety of all genetically modified food. They do, however, raise issues about the need for vigilance on the part of regulatory agencies. Many submitters discussed the possibility of foods available in New Zealand being accidentally contaminated and were concerned that a complaint would be needed to trigger action from the responsible regulatory agency.

StarLink™ Corn⁵³

In 1998, and subsequently in 1999 and 2000, the US Environmental Protection Agency approved for use as animal feed a corn modified by insertion of the Cry9C gene from Bt encoding for an insecticidal crystal protein endotoxin. The corn was marketed as StarLink™. Because of concern that the protein Cry9C could be allergenic, the Agency could not find that there was a reasonable certainty of no harm to humans. The corn was not, therefore, approved for use as human food.

In September 2000, a coalition of environmental and food safety groups announced that Cry9C DNA fragments had been found in a popular brand of taco shells sold in the United States. In addition, the Cry9C protein was discovered in some non-StarLink™ seed corn. As a result, there was a voluntary recall of corn-derived food products in the United States by manufacturing companies, some of who took steps, such as mandatory testing requirements, to ensure no further contamination.

Late in 2000, a further review of the potential allergenicity of Cry9C, and of mechanisms for assessing suspected allergic reactions to StarLink™ corn concluded that the Cry9C protein had a medium likelihood of proving to be a potential allergen and that seven out of 34 reactions to a meal containing corn products were probably allergic. A definitive conclusion would have required further studies.

The presence of Cry9C protein in seed corn was thought to be a result of physical contamination, although cross-pollination from StarLink™ corn could not be ruled out as the source.

The StarLink incident illustrates a number of issues relating to genetic modification of food and crops:

- The difficulties of restricting a genetically modified food for use for animals or industrial purposes when there are almost indistinguishable unmodified counterparts available for human consumption.
- The difficulty of preventing accidental contamination of human foods by imposing segregation requirements on modified food crops.
- The difficulty of ensuring adherence to separation requirements to prevent cross-pollination of genetically modified and unmodified crop species, and the failure of the companies promoting genetically modified crops to require or ensure proper growing practices.
- The need for appropriate labelling, and for post-market monitoring to identify allergic reactions rapidly and accurately.
- The externalisation to producers and to consumers of costs created by growing genetically modified crops.

118. In New Zealand, enforcement of food standards was, at the time of writing this Report, the responsibility of the Ministry of Health. It is a function that, we assume, will be moved to the proposed Food Administration Authority. Given the level of public concern about the safety of genetically modified food for human consumption, it is important that the Food Administration Authority, when

established and, until then the Ministry of Health, are proactive in enforcing food standards and in providing the public with assurance that the safety of genetically modified food is closely monitored. We are concerned that this appears not to have been done in the past nor was the capability there to do so.

119. The Ministry of Health advised that genetically modified food is not routinely tested to ensure compliance with Standard A18. Once the amended mandatory labelling regime comes into force, the Ministry intends to investigate substantiated complaints of breach of the Standard, as well as undertaking a project to look at compliance with the labelling requirements.⁵⁴

120. It is not sufficient for the Ministry to rely on complaints before initiating an investigation. Testing for the presence of unauthorised genetically modified material in foods is an issue of food safety, not of regulatory compliance. The Commission notes that the Ministry has contracted the Institute of Environmental Science and Research to establish and maintain analytical capability to test genetically modified food. We expect that such tests will be carried out routinely as part of the Total Diet Survey, which already tests for pesticide residues and heavy metals in food.⁵⁵

The safety of genetically modified stock feed

121. The Green Party expressed concern about the possible risks to animal welfare and human health from the use of genetically modified animal feed. It suggested that any products incorporated into animal feed should be required to undergo well-controlled feeding studies in the target animal comparing the new plant variety with the conventional plant.

122. The Feed Manufacturers Association, Poultry Industry Association and Egg Producers Federation were questioned at the hearing on the use of genetically modified soy and corn meal fed to chickens in New Zealand. In response to questions from Tom Bennion on behalf of the Green Party and GE Free New Zealand, John Foulds, speaking on behalf of the Associations, said that he did not know if any assessment or testing was carried out prior to the meal being used in New Zealand. In response to questions on the steps taken to source unmodified feed, the Associations' representatives stated that they experienced difficulty sourcing feed that could be guaranteed to be free from genetic modification because overseas suppliers were unable to give such a guarantee. The Associations also said that, if they were able to source such feed, it would be more expensive.

123. ANZFA acknowledged that concerns were raised from time to time about the human health consequences of the feeding of genetically modified feed to animals. It cited information from the Federation of Animal Science Societies (FASS), an association of three prominent American animal agriculture societies

(the American Dairy Science Association, the American Society of Animal Science and the Poultry Science Association), indicating that no DNA and/or protein could be detected in products such as meat muscle, whole milk, poultry and eggs from animals or birds fed a variety of genetically modified commodities.⁵⁶ In a report prepared recently for the Ministry of Health, Institute of Environmental Science and Research reproduced a review by Dr Marjorie Faust at the Department of Animal Science, Iowa State University, of studies designed to detect any unintended effects in livestock fed genetically modified crops. Dr Faust's review stated that conclusions from the more than 40 animal feeding studies that had been completed or were currently in process had been consistent in finding no detrimental effects in livestock fed genetically modified crops.⁵⁷

124. ANZFA submitted that possible consequences to human health should be assessed on a case-by-case basis, taking into account any potential hazards identified combined with a consideration of the animal feeding practices used for the particular feed in question. The submission suggested that, if any hazards were identified during an assessment of genetically modified animal feed, consideration should be given to the potential human exposure to that hazard through the use of the feed. Genetically modified stock feed will have to meet the regulatory standards that come into force on 2 July 2001. These standards require the importer of stock feed to satisfy the Ministry that the product is safe and fit for stock feeding purposes. The submission from MAF, however, advised that stock feeds that are not genetically modified organisms but are the products of genetic modification may not require an assessment and registration under the Animal Compounds and Veterinary Medicines Act 1997 (ACVM) if they do not trigger any safety or risk thresholds.

125. The Commission noted the call for separate testing of animal feed. With regard to human health, although we heard evidence of potential risk pathways, particularly through horizontal gene transfer, no evidence was presented of actual harm to human health. We do not, therefore, consider a mandatory safety assessment on stock feed should be imposed unless there is evidence of either novel DNA or other potentially harmful novel material being found in the products of animals and birds fed genetically modified stock feed.

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.

126. Products from animals or birds fed on genetically modified pasture or stock feed do not require assessment under Division 1 of Standard A18 because they are not considered to be genetically modified, nor will they require labelling under the labelling provisions to be implemented later this year. It is important that consumers are able to choose to avoid consuming the products of animals and birds fed on genetically modified feed. Where a claim that animals and birds have not been fed genetically modified food can be sustained, labelling that identifies the product as being free of genetic modification will be appropriate. We discuss genetic modification-free labelling later in this chapter. Without such a label, consumers must assume that a genetically modified food may have been used.

Are the current food safety standards satisfactory?

127. Those people who worried about the safety of genetically modified food were also doubtful about the ability of regulatory agencies to identify and manage the associated risks. Nelson GE Free Awareness Group referred to the anxiety of environmentalists and said:

Many are extremely concerned over the lack of adequate testing carried out by the regulatory agencies and multinationals and the rapid introduction of foods from this technology reaching the supermarket. The public wish to preserve their health and understand that their consumption of safe, nutritional food is the best way to ensure continued health.⁵⁸

128. Joanna Gamble referred to the importance of consumer confidence in regulatory agencies in the background paper provided for the Commission on public perceptions of genetic modification. She pointed out that a 1998 study conducted with focus groups by HortResearch revealed that, because consumers were reliant on particular organisations (ANZFA, governmental) to provide them with information on the use of genetic modification, a high degree of trust in those entities was required for the information to be accepted.⁵⁹

129. As the regulatory body most closely identified with responsibility for ensuring the safety of genetically modified food, ANZFA attracted considerable criticism from those submitters who were concerned about the safety of the technology. During the public hearings, and in written submissions, the Commission heard serious allegations about the inadequacy of ANZFA's processes and standards. The Authority was, therefore, invited to appear before the Commission and respond to criticisms. The hearing was open to the public so that not only the Commission but also Interested Persons were able to question the ANZFA representatives. In inviting ANZFA to appear, the Commission

particularly drew their attention to the strong criticism expressed by the National Nutritional Foods Association of New Zealand (NNFA) [IP106]. The submission from the NNFA, and the witness brief from its Executive Director, Ron Law, referred to events relating to royal jelly (a bee product) and said:

The Australia New Zealand Food Authority is an Australian government agency given legal authority to set food standards. ANZFA assures the public that it has vigorously determined the safety of GE product approved to date. The NNFA will provide prima facie evidence that ANZFA has a track record of using false, falsified and even fabricated data to establish food standards.⁶⁰

130. Mr Law also raised issues about the credibility of the Therapeutic Goods Administration (TGA), the Australian equivalent of Medsafe, which is discussed in the following chapter on Medicine. Mr Law said:

Based on the NNFA's experience with the regulatory process, New Zealanders can have zero confidence in ANZFA, TGA or the Ministry of Health regulating GE products in an objective, transparent and equitable manner that is commensurate with good regulatory practice.⁶¹

131. The Commission was able to form its own opinion of ANZFA based on what it heard during the course of the hearing. As will emerge in the conclusions later in this chapter, the Commission does not share Mr Law's views.

132. The doubts we heard expressed about the quality of the safety standards applied to genetically modified food tended to focus on the following issues:

- lack of independent testing of genetically modified foods by ANZFA
- reliability of the scientific data on which safety assessments are based
- reliance on Food and Drug Administration (FDA) approval
- testing standards applied to determine the safety of genetically modified food
- application of a “substantial equivalence” test to determine whether or not a modified food was safe
- adequacy of scientific knowledge of the effects of genetically modifying food.

Lack of independent testing of genetically modified food

133. Concern about the lack of independent testing arose primarily from doubts about the integrity of applicant companies and the reliability of any information they would supply. For example, GE Free New Zealand said:

ANZFA regulations do not contain provisions for independent testing of the safety of novel foods. ANZFA relies on the assessments and submissions provided by the

manufacturers and regulators in the country of origin of the novel foods. This process is open to abuse. It is a highly risky method of assessing safety as the manufacturers have commercial reasons for hurrying their products to market and may cut corners with safety testing and assessment.⁶²

134. ANZFA confirmed that it does not carry out any scientific testing of its own but, in the absence of internationally agreed guidelines, followed an assessment process based on recommendations from internationally recognised organisations such as the OECD.⁶³

135. During the hearing, Mr Lindenmayer pointed out that the cost of testing at product level would be “vast”. Moreover, he questioned whether independent testing would add anything significant to the assessment process. Any testing that would be carried out would be more limited and would:

... raise the question of what more should be tested for than what is already tested for by the applicant organisation in gathering the data for the data packs.⁶⁴

Reliability of the scientific data provided by applicants

136. There was also concern that ANZFA based its assessment on scientific data put forward by applicant companies involved in developing and promoting genetically modified food. It was suggested that the data was not reliable because it had not been peer reviewed or published, nor was it tested by ANZFA. Dr Judy Carman, an epidemiologist and immediate past-president of the South Australian Branch of the Public Health Association of Australia, who appeared as a witness for Pesticide Action Network New Zealand [IP87], said:

one of the concerns of course is that the information that comes to ANZFA now only comes from the applicant company; there are no independent safety assessments done that ANZFA can collect that they can look at. This is a worry because clearly the company is going to benefit financially from the food if it is assessed as being safe, yet ANZFA appear to be accepting their safety evidence without discount, and in the complete absence of produced independent assessments.⁶⁵

137. ANZFA staff provided considerable detail about the scientific data and information used by the Authority in the course of its scientific assessment. Dr Marion Healy, ANZFA Chief Scientist, discussed the scientific information used in carrying out assessments. She stressed that the information requirements ANZFA set out in publicly available guideline documents are indicative only and that ANZFA reserves the right to require additional information if necessary. Dr Paul Brent, ANZFA’s Manager (Biotechnology) advised that:

... of the 18-odd assessments done so far, there wouldn’t be one where we haven’t gone back on many occasions to the applicant and challenged them to clarify bits and pieces of applications, particularly the molecular characterisation.⁶⁶

138. Dr Healy commented that the quality of the data presented with an application was a critical part of the evaluation process. She said that, when assessing the quality, ANZFA took into consideration matters such as:

- the relevance of the data to the hazard, the food and the consumption of the food
- the appropriateness of the methodology: is it up-to-date? has it been validated?
- the adequacy of the study design, including the length and sufficiency of the testing, whether or not there is a dose response curve
- the appropriateness of any relevant statistical analysis
- the reproducibility of the data
- the totality and the weight of the evidence.⁶⁷

139. Dr Healy emphasised that totality and weight were key factors in assessing the safety of a food, rather than individual studies alone. She told the Commission that, in situations where there is scientific uncertainty, a number of additional steps are built into ANZFA's risk and safety assessment process, such as:

- determining whether a pre-market product-by-product assessment should be carried out or whether general permissions should be given
- determining whether case-by-case assessments or generic assessments should be carried out
- the scope and relevance of the data, including issues relating to the veracity of the data, its sources, its production
- the relevance of the data to the target population
- modelling the exposure scenarios.

140. Dr Healy stated that the higher the level of uncertainty, the more conservative would be ANZFA's approach to modelling the exposure scenarios. She also commented that, in determining any appropriate risk management strategies, ANZFA would also be more conservative according to the level of uncertainty in the information.⁶⁸

141. Dr Brent provided further information about the data on which ANZFA based its recommendations. He advised that, as part of the application, the Authority received the raw data from every experiment conducted by the applicant, which, he suggested, allowed for a more rigorous analysis than could be done on the summary data submitted in support of publication of a scientific journal article. Dr Brent also emphasised the quality expected, saying:

... for the data to be accepted as reliable, relevant studies must be conducted using internationally accepted protocols for research, such as good laboratory practice, and they are usually independently audited.⁶⁹

142. Dr Brent advised that data was required on:

- how the food was developed, including the molecular biological data which characterises the genetic change:
 - data on the donor, the host, the method of transformation
 - the full sequence of the gene construct and the vectors
 - regulatory elements, construct maps, number of insertion sites
 - information on the stable inheritance over generations
- data on the composition of the novel food compared to the non-modified counterpart foods:
 - nutritional information
 - potential for toxicity and allergenicity.

143. Following the hearing, Commission members had the opportunity to read documentation presented in support of an application for approval of Roundup Ready Soybeans.⁷⁰ From our reading of these 15 substantial volumes, and also documentation relating to other genetically modified food applications, we conclude that ANZFA required comprehensive studies, including raw data, and did not rely on the conclusions reached by the applicant company’s own employees or contractors. We consider that the ANZFA staff is well qualified to analyse the data and to assess the safety of genetically modified food based on current scientific knowledge.

Provision of false information

144. At the hearing, the Commission raised with ANZFA staff the possibility of false information being supplied by applicant companies. The Commission asked whether the Authority could be certain that false test results had not been given, and also queried whether there was a risk that the applicant might suppress unfavourable test data.⁷¹

145. Dr Healy replied it was not hard for an experienced scientist, knowledgeable in the relevant discipline, to identify a “disjunction” between the data presented and what the body of scientific literature says should occur. In response to the second question, Dr Brent agreed that suppression of unfavourable test results by a company would be difficult to detect. Mr Lindenmayer pointed out that not only were regulatory bodies, such as ANZFA and ERMA, developing systems for exchanging information but also it was likely that such behaviour would become public. He reminded the Commission that companies wished to protect their reputations.

Reliance on FDA approval

146. A number of submitters were particularly concerned that ANZFA had approved the entry of genetically modified food to the New Zealand and

Australian markets on the basis of prior approval by the United States Food and Drug Administration (FDA). ECO said:

ANZFA needs to investigate more fully the actual testing that has been done on the foods approved. They should not rely on FDA testing, as the FDA has been shown to ignore its own scientists' advice and a "revolving door" between industry employees and the FDA has been documented. This calls into question the impartiality of the FDA's decisions. When ANZFA's decisions are contrary to the New Zealand public's wishes, then New Zealand should be free to make independent decisions based on public preferences.⁷²

147. Steven Druker, a witness for the Nelson GE Free Awareness Group, gave further details of the doubts about the FDA. Mr Druker, an American public interest attorney, who was representing nine scientists in a lawsuit against the FDA, related a number of concerns about genetically modified food, and also questioned the soundness of FDA policy, which he described as "irresponsible and immoral".⁷³

148. At the hearing before the Commission, the Authority was questioned on two occasions about its reliance on FDA approvals during the course of safety assessments. Questions from GE Free New Zealand specifically addressed this issue:

MR COLLINS QC: In undertaking the assessment, to what extent was there reliance on FDA prior approvals?

DR BRENT: There was no reliance on the approvals. They don't do a pre-market safety assess, so we've never used any evidence from the FDA as part of our approvals.

MR COLLINS QC: Yet there are many many foods that were introduced into New Zealand and Australia which were approved because they were authorised by FDA?

DR BRENT: No, that's not correct. I think you will find in the interim arrangements we use the words "regulatory authorities".

MR COLLINS QC: Yes.

DR BRENT: And that would include the UK, the EEU, Japan and Canada.

MR COLLINS QC: Not the FDA?

DR BRENT: The FDA has never been in a position – or we have never used the FDA as a standpoint to base our safety assessments. They don't do one.

MR COLLINS QC: So you are able to categorically assure the Commission that there has been no reliance placed on "FDA approval", if I can use that word in quotation marks, in giving approval to a food introduced into New Zealand or Australia as part of that interim regime?

DR BRENT: Not for a GM food, no.⁷⁴

149. Later in the hearing, after a brief discussion on whether the FDA had a voluntary or mandatory notification process, the Commission asked for confirmation of the relationship between FDA and ANZFA approval:

CHAIR: So, whether it was at the voluntary stage or at the more recent mandatory stage, the fact that something has been submitted to the FDA, plays no part in ANZFA's decision-making?

DR HEALY: That's right. Obviously we monitor what's going on at regulatory agencies as well as the scientific literature around the world and we're well aware of the types of products that are being discussed with the FDA, as we are with a number of other regulatory agency. But, the decision, or the kind of discussions that the FDA are having, do not directly at all impact on the sort of decision-making that we at ANZFA have. If they alerted us to a particular problem then obviously we would take cognisance of that information as with any piece of information that we derive from anywhere; regulatory scientist, wherever, to make us look a bit more closely at what the issue was.⁷⁵

150. The Authority went on to state that the fact that a food had been on the market in a country other than New Zealand for a significant period without adverse effects would be one of the factors taken into account in the decision-making process.

151. The Commission was satisfied that reliance on FDA approval does not, on its own, play a role in either the scientific assessment process or the overall process for making decisions on applications under Standard A18.

Standard of ANZFA safety assessments

152. Many of the submissions we received questioned whether ANZFA's safety assessment process was adequate to provide an assurance of the safety of approved genetically modified food. In its written submission, GE Free New Zealand said:

The Environmental Risk Management Authority (ERMA) and the Australia New Zealand Food Authority (ANZFA) are operating case-by-case assessments of biotechnology food products whereby most gene-altered foods are passed as safe with minimal testing and sold to the unsuspecting public without health warnings to identify these novel food risks. The safety assessment procedures involve no long-term health testing of novel foods. Therefore the ERMA and ANZFA regulatory framework is prima facie inadequate to protect consumers from health hazards.⁷⁶

153. Moreover, Dr Carman in her evidence suggested that ANZFA has:

... as a philosophy the idea with genetically engineered foods that they are safe until they are proven to be unsafe.⁷⁷

154. During the course of the hearing, Dr Healy and Dr Brent described in some detail the process ANZFA followed in carrying out safety assessments. Dr Healy described the risk assessment, safety assessment framework within which

decisions on the safety of novel foods are made and the policy considerations relating to decision-making in respect of those foods. She told the Commission that a safety assessment is viewed as a modified form of hazard identification and is a comparative approach, aiming to identify new or altered hazards relative to the comparator and to identify changes relevant to human health in relation to key nutrients. She mentioned that assessments of genetically modified foods also took into account the potential dietary exposure of the foods.⁷⁸

155. In discussing the safety assessment process, ANZFA staff stressed the qualifications and scientific experience of its own staff. There were five staff on the scientific side, in addition to the Chief Scientist. ANZFA also confirmed that it used external scientists for specific assessments. A list of names was included in the additional information the Authority provided in response to criticisms made of it during the course of our inquiries.⁷⁹

156. We were also advised that, before any recommendation is forwarded to the Ministerial Council (ANZFSC) for approval, there is opportunity for comment, including comment on the science, from a range of people with knowledge of food safety issues. These included internal and external peer reviewers, the senior health officials of all the jurisdictions covered by the ANZFA process, and Health Ministers on the Council.

157. Dr Carman stressed the importance of public health expertise in the safety assessment process⁸⁰ and during the course of cross-examination Ms Kedgley questioned the public health expertise of ANZFA staff. Dr Healy responded that, in addition to the staff with molecular genetic qualifications, ANZFA staff had a range of qualifications, including qualifications in nutrition and public health. Mr Lindenmayer confirmed that there were a number of external sources of public health expertise available to the Authority.

158. In response to a question from the Commission, Dr Healy discussed what might constitute scientifically reasonable grounds for withholding approval for a genetically modified food. She identified allergenicity as being a particular ground for withholding approval, as well as evidence of abnormal toxins. She also mentioned that a deliberate nutritional modification might create issues about any consequent alteration to the impact of particular nutrients in the nutrient profile in the context of diet, and confirmed that the Authority would have particular concern about the potential for the production of a protein of unknown function or unknown impact.

Use of “substantial equivalence” as a test for safety

159. Several of the Interested Persons expressed concerns about the use of substantial equivalence as a test for the safety of genetically modified food. The

Safe Food Campaign, for example, said it believed that:

... substantial equivalence testing jeopardises consumer safety by allowing the quick introduction of GM foods into the human diet without adequate testing. We believe that ANZFA should not be approving these recently and relatively developed untested products to be consumed. The lack of safety testing and the labelling of GM foods we believe does not address the risks surrounding GM foods, and does not adequately protect consumers, or provide them with adequate opportunity to avoid GM foods.⁸¹

160. As well as listening to ANZFA's comments on this issue, the Commission considered the views expressed by the Expert Panel of the Royal Society of Canada.⁸² We noted also the discussion of approaches to the nutritional and food safety evaluation of genetically modified foods contained in the report of the meeting of a joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology held towards the middle of 2000.⁸³

161. The report from the Royal Society of Canada explored the uses of "substantial equivalence" within the Canadian regulatory environment. It cited the original OECD formulation of the concept as saying: "If a new food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety."⁸⁴ The Canadian Royal Society pointed out that this could be interpreted in two ways. It suggested that one interpretation was:

... to say that the new food is "substantially equivalent" is to say that "on its face" it is equivalent (ie it looks like a duck and it quacks like a duck, therefore we assume that it must be a duck – or at least we will treat it as a duck). Because "on its face" the new food appears equivalent, there is no need to subject it to a full risk assessment to confirm our assumption.⁸⁵

162. Under this interpretation, the Expert Panel suggested, the concept of "substantial equivalence" functions as a decision procedure for facilitating the passage of new products, both genetically modified and unmodified, through the regulatory process.

163. The second interpretation the report identified was to treat the concept as a standard of safety. In this interpretation, "substantial equivalence" functions as a scientific finding or conclusion justifying an assumption of safety:

This interpretation requires a scientific finding that the new food does not differ from its existing counterpart in any way other than the presence of the single new gene and its phenotypic change. In every other way, phenotypically and in terms of its impacts on health and the environment, it will have been demonstrated to be identical to the existing food.⁸⁶

164. The Royal Society of Canada concluded that, in practice, regulatory agencies, in Canada at least, relied on “substantial equivalence” as a decision threshold. The report recommended that approvals for new transgenic organisms should be based on “rigorous scientific assessment of their potential for causing harm to the environment or to human health”.⁸⁷

165. The report of the joint FAO/WHO Expert Consultation also discussed substantial equivalence and pointed out that:

The application of the concept is not a safety assessment in itself; it does not characterise the hazard, rather it is used to structure the safety assessment of a genetically modified food relative to its conventional counterpart.⁸⁸

166. The report then went on to outline the comparative approach that should be taken to identify any intended and unintended differences between the modified food and its closest traditional counterpart. These differences, the report said, then become the focus for the safety assessment.

167. During the formal hearing process, we heard a number of Interested Persons active in the campaign against genetically modified food state that ANZFA used substantial equivalence as a test to determine the need for further assessment. In the light of the views expressed in the reports from the Royal Society of Canada and the FAO/WHO, the Commission was particularly interested to hear and evaluate the information provided by ANZFA on its application of the concept of “substantial equivalence”. We noted the statement, contained in the written response to criticisms made of ANZFA during the course of the Commission’s inquiries, that:

... they [the Canadian Royal Society] endorse substantial equivalence when it is used in the way that ANZFA uses it, ie when it is used as a starting point for comparison with existing food as suggested by the FAO Expert Consultations.⁸⁹

168. Bearing in mind the findings of the Canadian Royal Society on the application of substantial equivalence by regulatory agencies, the Commission was keen to hear ANZFA’s explanation of the role the concept played in its assessment process. We therefore noted carefully the description of the assessment process given by ANZFA staff during the hearing and their responses to questions in cross-examination.

169. Dr Healy sought to clarify how ANZFA has been using the concept of substantial equivalence. She referred to “the comparative approach” and said:

We do use the approach of comparing food produced using gene technology with conventionally produced food ... it’s well accepted in the community that the conventional food supply has a history of safe use and, if you like, there’s a community standard that we can use as a basis.

In undertaking this comparative approach we're looking for similarities and differences in key constituents between the two foods. The aim of this comparison is to identify the similarities and particularly the differences. And particularly to see whether, in these differences, there may be new or altered hazards that we need to give some consideration to.⁹⁰

170. Mr Law, questioning on behalf of the NNFA, said he presumed that the purpose of a safety assessment of a food produced using gene technology was to confirm substantial equivalence. In response, Dr Healy disagreed with the presumption. She explained that the question of the safety of the food and to confirm it as a food with all the benefits and risks normally associated with food were two separate questions. She said:

... substantial equivalence is a tool to guide decision-making to look for potential new – to look for differences that may – and those differences may be hazardous. You would then go on to analyse whether any of those differences do in fact have an adverse health impact. They may or may not. They may or may not even be biologically meaningful.⁹¹

171. Having listened to ANZFA's description of its assessment process, its discussion of how the Authority uses substantial equivalence in that process and, in particular, having regard to the extensive documentation, consisting of 15 thick files of information, relating to the assessment of food derived from Roundup Ready soybeans (Application A338), we concluded that the concept of substantial equivalence is not used by ANZFA as a decision threshold to determine whether or not a safety assessment of the genetically modified food should be conducted. We accept that the concept is part of a process of comparative analysis that is a springboard for consideration of a range of matters relevant to establishing the safety or otherwise of the food. We are confident that ANZFA does not assume that, just because it looks like a duck and quacks like a duck, it is a duck.

Adequacy of scientific understanding of the effects of genetically modifying food

172. Issues raised in a number of submissions included the relative newness of genetically modified food, the absence of a history of consumption and the perceptions that the current body of scientific knowledge is not sufficiently developed. GE Free New Zealand, for example, questioned whether there was sufficient knowledge to assess the potential risks of genetically modified food, saying:

GE Free New Zealand believes that this indefinite and immediate ban on all genetically engineered food, crops and animals in our food and environment is necessary because we dispute that there will ever be sufficient long term and independent scientific research which will guarantee the safety of genetically engineered food, crops and animals. This is

due to the lack of scientific knowledge about the complexities of DNA and the technology itself, and because it is difficult to conduct research into possible risks of this technology, when the risks themselves are unknown.⁹²

173. Many people expressed particular concern that genetically modified foods were not subject to the same rigorous testing as pharmaceuticals, including long-term testing and human clinical trials. Some submissions suggested that, in the absence of safe testing procedures, a history of safe use or an assurance of no risk, the only safe course was to prohibit genetically modified food.

174. Dr Brent addressed the adequacy of toxicity tests at the hearing before the Commission. He described the approach taken by ANZFA as “holistic” in requiring a comprehensive data set on the molecular characterisation, as well as compositional and nutritional data and data on the toxicity and allergenicity:

We argue that where these demonstrate no significant concerns in comparison to conventional breeding techniques, then the potential for long-term effects is considered no different to that for conventionally produced foods.⁹³

175. He went on to explain the difficulties of applying testing methods used for drugs, chemicals and food additives to the testing of whole foods. He also explained the role of acute studies, required for the newly expressed proteins in genetically modified food, and suggested that the purpose of such studies had been misconstrued.

176. In response to a suggestion from Ms Lees that there was a need for more research before the potential risks of novel organisms could be known, Dr Healy said there was an implicit, but incorrect, assumption that the only information about new genetically modified crops could come from the crops themselves. She pointed out that there had been a long history of research into some of the products of the different genes under discussion, adding:

... there is a lot of research about many of the genes and their gene product and their safety. What is different is their method of delivery and that’s where the intensive analysis needs to take place.⁹⁴

177. It was clear from ANZFA’s presentation that the Authority did not rely solely on the knowledge and experience of its internal staff. The Authority mentioned on several occasions its use of external experts. Dr Healy said:

Quite early on we decided that, given the newness of us all learning how to do these safety assessments, that it would be highly beneficial to have the input of a number of external people. So, we approached a number of people who were experts in the field in, kind of in a range of slightly different areas so we could get some coverage. And, we have used that group, but from time to time we have supplemented it when we have felt that we needed some additional expertise as we’ve gone along.⁹⁵

178. Referring to the Royal Society of Canada report, the Commission asked whether ANZFA saw the need for more research into the methodology used to test food. Dr Healy said that ANZFA had recently revised its guidelines, but saw no alternative ways of testing. She did, however, suggest that there might be need for long-term testing and post-market surveillance in response to community concerns. There would also be a need to alter the Authority's assessment processes in response to changes in technology and information.

Commission's conclusions on the ANZFA process

179. We heard no evidence to suggest that the standards applied by ANZFA were below internationally recognised best practice. Based on the evidence presented to us, the Commission is confident that the Authority's assessment is independent and that by international standards its methodology is sound. Having heard and had an opportunity to question the senior staff at the hearing, we are confident that the Authority carries out its functions appropriately and with due regard to international developments in a rapidly changing area. We were impressed with the conscientious approach that the senior ANZFA staff took to the discharge of their duties.

180. The Commission was also reassured that ANZFA carries out its functions with an appropriate degree of independence not only from political influence but also from the influence of commercial interests. Given the extent of the public mistrust of commercial influence, we believe that a degree of distance from industry is important in maintaining the credibility of the Authority.

181. We understand the concerns that genetically modified foods were allowed to remain on the market pending assessment and approval by the Authority and we suggest that this decision might have served to undermine public confidence in the Authority. Nevertheless, we consider this was a practical transitional response in a situation where withdrawal of the foods may have been difficult and costly to enforce, and might have been in breach of international obligations.

182. It is not correct that, in allowing these foods to remain, ANZFA relied solely on approvals from external agencies. We are pleased, however, that the majority of these foods have now been assessed. We suggest that the results of these tests should be clearly communicated to the general public.

183. The Commission noted that ANZFA is required by statute to consult with the public, and that it carries out this requirement as widely as possible. The development and maintenance of public confidence in the regulator requires, however, not only consultation as directed but also a commitment to transparency of process and clear and appropriate communication of the principles and

outcomes of those processes. Questioning, particularly by other professionals, is important to ensuring maintenance of the highest possible standards.

184. The Commission would encourage ANZFA to make every effort to establish appropriate communication channels with the public. Effective communication will ensure that the public understands the role the Authority plays in setting food standards, is aware of the results of individual assessments, particularly for genetically modified foods, and is able to contribute to the development of standards as is appropriate. The recent appointment of Hiki Pihema to the ANZFA Board shows that steps have already been taken to improve the communication between the Authority and the Maori community. We hope that this is the beginning of better communication between ANZFA and not only Maori but also other groups within the wider community.

185. The Commission is aware of the concerns about the amendments to Australian legislation that will establish Food Standards Australia and New Zealand and effect other changes to the current regulatory system. Some aspects of the proposed changes are the subject of discussion at government level, and we do not, therefore, consider it appropriate to comment on these matters. We see no reason to believe, however, that the standard of the safety assessment currently undertaken by ANZFA will be diminished as a result of the changes.

Labelling

186. The labelling of genetically modified food was one of the key issues raised at many of the forums we attended. Those submitters whose first preference was for all genetically modified food to be removed from the market also addressed the issue of labelling as an alternative in the event this did not happen. Companies such as Monsanto New Zealand [IP6], and umbrella organisations such as the Grocery Marketers Association also supported labelling. Views diverged, however, over the nature and extent of the labelling that should be required. The Dairy Board, for example, suggested that mandatory labelling systems did not necessarily meet consumer needs and were difficult and costly to implement. The Board indicated its preference was for a voluntary labelling system such as that adopted in Canada and the United States.

187. Labelling of genetically modified food was promoted or supported for a number of reasons. The NNFA, for example, said that its members:

... strongly believe that consumers should be able to make informed choices about what they eat. Many consumers choose not to eat GE foods and have a fundamental right to know whether food or food ingredients are derived from GE product.⁹⁶

188. Submitters as diverse as the Ministry of Consumer Affairs and Monsanto supported this view of the consumer’s right to informed choice.

189. We heard that the right of choice could arise out of concerns for the safety of genetically modified food, or because consumption of modified food would be offensive for cultural or spiritual reasons. The New Zealand Jewish Community [IP80] explained in detail the Jewish dietary laws and the importance of informed choice to observance of those laws and we are aware it might be unacceptable to members of other religious groups to consume genetically modified food. We are also aware that there are people who would find it unethical to consume food that has been modified through technology, particularly when modification has involved the use of human genes.

190. Many Maori voices called for the labelling of genetically modified food. The Green Party explained the Maori view of the relationship between the natural world and the human world, and the importance of labelling to ensure Maori are able to exercise rangatiratanga and choose to consume foods “which have not been genetically interfered with”.

191. Dr Carman spoke of the importance of labelling to facilitate monitoring and response to illness or disease resulting from genetically modified food. Several organisations raised this as a reason for labelling, pointing out that, without labelling, genetically modified foods could not be identified and could not, therefore, be associated with any adverse effects.

Proposed labelling regime

192. We heard a number of complaints that, because of the exemptions within the amended Standard A18, the labelling regime to be implemented late in 2001 will not meet consumer needs. The Safe Food Campaign thought:

GM food labelling being introduced by ANZFA will not be adequate to inform consumers, consumers will not have perfect product knowledge and everyone will not have the ability to choose not to consume GM products.⁹⁷

193. There was particular concern about the exemption from labelling allowing 1.0% of unintended and unknown presence of genetically modified matter and one part per thousand of genetically modified colouring. Those who believed that genetically modified food was not safe emphasised that any presence of genetic modification posed a risk to human health. Similarly, submitters suggested that highly refined foods also had the potential for harm, even where novel DNA or protein had been removed, because they were derived from a process of genetic modification.

194. Submitters also questioned the exemption allowed to processing aids and to food additives that did not result in novel DNA and/or protein in the final food. Several, such as Dr Michael Antoniou from Guy's Hospital in London, a witness for the Green Party, pointed out that L-tryptophan would not have triggered labelling under the proposed regime. Dr Antoniou said:

... current New Zealand labelling laws for GM foods should be extended to include genetically modified organism-derived foods, which contain little or no GM protein or DNA. This will assist in the tracing of any future problems that may arise from these products. It is important in this context to bear in mind that the deaths and sickness resulting from Eosinophilia Myalgia Syndrome that has been linked to the consumption of tryptophan derived from GM bacteria, was not only free of protein and DNA, but contaminated by a toxin present at less than 0.1 percent of the final marketed product.⁸

195. In general, the submitters who had concerns about the consumption of food that had any association with genetic modification, even in the production process, emphasised the need for comprehensive labelling. Without such labelling, they said, consumers could not avoid the potentially harmful effects of genetic modification. Dr Joan Mattingly-Cameron, a witness for Pacific Institute of Resource Management, argued it was possible to analyse and detect amounts of DNA in food less than the ANZFA exemption threshold. The Commission considers that, while it may be possible to detect much lower concentrations, the accuracy and reliability of the tests breaks down at very low levels.

196. Dr Geoffrey Annison, Scientific and Technical Director of the Australia Food and Grocery Council, and Michael Rosser a former Director-General of Health in New South Wales and a Director of KPMG Consulting, were witnesses for the New Zealand Grocery Marketers Association. They gave evidence of the difficulties associated with establishing a labelling system that provides meaningful information to the consumer. Dr Annison told us that, during the consultation that preceded the amendment to Standard A18, the Australian Food and Grocery Council had argued for the exclusions contained in the amended Standard because trace-back and audit for refined foods and additives without modified DNA or protein and for processing aids would be difficult and costly. Mr Rosser provided information about the number of ingredients that comprise many manufactured food items, each of which would require tracing, auditing and labelling. He said that a typical processed food could have between five and 15 ingredients, each of which might have their own ingredient streams requiring what Mr Rosser called “due diligence certification” to establish their status. The evidence illustrated the cost and complexity of providing sufficient information to ensure that the presence and level of genetically modified material was

accurately identified. Without the necessary assurances provided by the “due diligence certification”, it was pointed out, any claim that a food contained no genetically modified material was likely to be inaccurate and misleading. The ANZFA thresholds were designed to permit minor accidental contamination but, ANZFA pointed out, were designed to allow for unintended contamination only, and were not a minimum threshold.

197. The Commission does not consider that a wholly voluntary system, as advocated by the Dairy Marketing Board, would provide adequate protection of public health and safety. We therefore support the mandatory labelling system provided under the amended Standard A18 Division 2. We understand that some people are concerned that food not requiring labelling under the new regime may still contain genetically modified material or will have been manufactured through a genetically modified process. From the evidence we heard, however, we accept there are issues of cost, traceability and testing difficulties that mitigate against the imposition of a mandatory labelling requirement covering not only the product but also the manufacturing process.

Point of sale

198. Submitters were also concerned that food prepared at point of sale was exempt from labelling. At the ANZFA hearing, counsel for GE Free New Zealand stated that consumers would not be able to make an informed choice when purchasing food prepared at the point of sale. Mr Lindenmayer responded:

Consumers will have the prerogative of seeking that information from the restaurateur or staff in the restaurant. There will be an obligation on the supplier of the food to the food service outlet to provide the information and an obligation on, as I said, the restaurateur or the staff, to relay that if requested.⁹⁹

199. In response to questions from the Commission, Mr Lindenmayer provided more information about the effect of the United Kingdom requirements for point of sale labels. He said:

... I have found it of some interest that, when I have been in the UK and visited restaurants and other commercial providers of ready to eat foods, I was not able to find on any menu any information in relation to GM, the presence of GM materials. I understand there is an alternative obligation upon the food service sector to make – to place a notice in outlets inviting customers to ask for that information from staff of restaurants. In no case did I find such a notice. I inquired of staff about that information and was told that no-one ever asks for it, and I have also been informed by enforcement authorities that there is little interest in seeking that information.¹⁰⁰

200. The draft Compliance Guide to Standard A18, being developed by ANZFA at the time of our inquiries, states that consumers can request information on the genetic modification status of food prepared for immediate consumption, such as restaurant and take-away food. In New Zealand, the prohibitions against misleading or deceptive conduct in the Fair Trading Act 1986 ensure that, when requested, these businesses must provide accurate information about the status of the food they provide.

Vigilance needed

201. We understand the public health concerns underlying many of the calls for comprehensive labelling of products that use genetically modified ingredients, or are manufactured in processes that involve genetic modification, or are prepared at the point of sale. There are fears that unanticipated toxins or allergens in genetically modified food not requiring labelling will have adverse health effects.

202. We have confidence in the ANZFA safety assessment process. We consider it unlikely that foods that have satisfied the food standard will have harmful effects. It is important, therefore, that the New Zealand regulatory agency responsible for ensuring food safety, either the Ministry of Health or the new Food Administration Authority, is vigilant in ensuring no unauthorised or unsafe genetically modified foods enter the food chain.

Labelling food that is free of genetic modification

203. Many of the people the Commission heard wished to avoid consuming not only genetically modified food but also food produced by a genetically modified manufacturing process. We consider that a standard label should be used, on a voluntary basis, to indicate that a food contains no genetically modified material and has not been manufactured in a genetically modified production process. Such a label would allow those who choose to avoid genetically modified food to do so.

204. We contemplate that the genetic modification-free label will be simple and easily recognised, a symbol similar to the Heart Foundation “Pick The Tick” logo. The Commission suggests a working party of consumer and industry representatives, together with officials from relevant Ministries is convened to develop the symbol that will indicate a product is 100% free of genetic modification. The working party should also consider the standards and accreditation requirements for products wishing to use the symbol, and possibly develop a strategy for promoting its use.

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.

Consumer information

205. The level of public concern about the safety of genetically modified food, and the comments made by submitters on the lack of information, shows there is a need for accurate, independent information about gene technology, and about the foods produced using the technology. Information should also be readily available to consumers about labelling standards and about the consumer's right to ask about the status of food sold in restaurants and takeaways.

206. Responsibility for providing consumer information about genetically modified foods and Standard A18 should rest with the Food Administration Authority. Identifying the appropriate information to be disseminated may be a subject addressed by the working party discussed above.

Recommendation 8.3

that, as a matter of priority, the Food Administration Authority 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.

Recommendation 8.4

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

Enforcement of labelling provision

207. The labelling requirements under Standard A18 will be enforced under the Fair Trading Act, administered by the Ministry of Consumer Affairs, an operating division of the Ministry of Economic Development. The Ministry also has the responsibility of ensuring that consumers obtain accurate information on products. The Commission considers that the high level of public interest in genetically modified food will ensure that any possible breaches of the fair trading provisions will be brought to the attention of the Ministry and the

Commerce Commission. Breaches relating to genetically modified food should be placed high on the Commission's list of priorities for prosecution.

Recommended roles and responsibilities for the Food Administration Authority

208. The Commission welcomes the establishment of the new Food Administration Authority. We consider that amalgamation of regulatory responsibility for food and food safety into one agency will ensure a coordinated approach to matters relating to food safety.

209. In relation to genetically modified food, we would envisage that the Authority assumes the following responsibilities:

- enforcement of food standards
- monitoring health effects of genetically modified food
- management of ANZFA/FSANZ relationship
- public information.

Enforcement of food standards

210. The Food Administration Authority should be responsible for:

- monitoring and enforcing food standards set by ANZFA, including testing for and recalling any product intended for human consumption where there is evidence of possible failure to comply with Standard A18
- managing rapid response food recalls where either there has been accidental contamination of food by unapproved genetically modified substances, or an unapproved genetically modified food has been released into the food chain
- random testing to ensure compliance with standards
- testing regularly for unauthorised genetically modified substances as part of the Total Diet Survey
- prosecuting all significant breaches of food standards relating to genetically modified food.

Monitoring health effects of genetically modified food

211. The Authority should be responsible for developing and implementing public health surveillance systems to monitor unexpected allergic reactions. The Commission noted ANZFA's information on the feasibility study being carried out by the United Kingdom food safety agency.

Management of ANZFA/FSANZ relationship

212. The Authority should be resourced adequately to manage the relationship with ANZFA/FSANZ in a manner that ensures that New Zealand's views are heard in decisions regarding genetically modified food.

Public information

213. The Authority should be responsible for:

- providing and promoting accurate, independent information to the public about genetically modified food
- ensuring that the public is informed of the Authority's activities
- receiving information from the public on public concerns about genetically modified food. The Commission commends the public consultations already arranged by the Ministries of Agriculture and Forestry and Health in relation to Codex.

chapter |

9.

Medicine

9. Medicine

Key issues:

- Genetic modification is widely accepted in the prevention, diagnosis and treatment of disease
- Genetic therapy offers hope of treatment and cure for people with genetic based illnesses
- Confusion exists over differences in the regulation of dietary supplements, food and medicine
- Significant future opportunities for advancement in health are offered by genetic modification.

Introduction

1. Genetic modification is widely used in biomedical research and the study of disease. New Zealand currently makes widespread use of genetic modification in medicine and many genetically modified products and processes have been safely used for more than two decades. Almost all medical applications of gene technology use products derived from live genetically modified organisms, rather than live genetically modified organisms themselves.
2. This chapter discusses existing and potential uses of genetic modification technology and the benefits of using genetic modification in medicine. It looks at uses in the prevention, diagnosis and cure of disease. Particular focus is given to the use of genetic modification technology in vaccines. Other aspects considered include the possible impact of live genetically modified treatments on the environment, products with medicinal properties for human use, animal remedies, the increasing potential of foods as a way to deliver pharmaceuticals or vaccines, and the regulation and control of dietary supplements.
3. New Zealanders appear to be more comfortable with the use of genetic modification technology in medicine than with most other uses. The Commission's survey showed that 71% of the public felt genetic modification

had more advantages than disadvantages in relation to medicines and vaccines. This was a higher proportion of advantages than identified for other uses of genetic modification. Approval for genetic modification was highest in the areas of medical research (65% of respondents) and medicines and vaccines (64%).¹

4. Public submissions also acknowledged potential health benefits from genetic modification. Approximately 10% (1045 submitters) of public submissions mentioned targeted treatments generally, cures for specific diseases, the eradication of inheritable diseases, use of gene therapy or the use and development of nutraceuticals.² Of these submitters 43% (447) said that non-specific medical uses were an acceptable application of genetic modification technology.

5. Most submitters supported current use of genetic modification in medicine. Several advocated the potential benefits of continuing and extending its use. A minority of submitters expressed reservations or outright opposition when it came to using genetic modification in medicine.

Human treatments and issues

Current uses in health

6. Many submitters and witnesses gave detailed information about the type of products used and their availability and use in New Zealand. Associate Professor Ingrid Winship, a clinical geneticist called as a witness by Auckland Healthcare Services [IP91], said that genetic modification technology was used in New Zealand for the investigation and diagnosis of genetic disorders and congenital metabolic diseases in the areas of:

- prenatal diagnosis of a mutation from which the foetus was at risk
- diagnosis confirmation for an individual who manifested a disorder
- carrier detection
- predictive testing prior to the onset of symptoms of individuals who are at risk of developing a late onset genetic disorder where, should the mutation be present, the disorder is inevitable
- predisposition testing of individuals prior to the onset of symptoms, where a mutation may make the individual susceptible to a disorder, but where, should the mutation be present, the disorder is not inevitable (for example, familial colorectal cancer)
- treatment of congenital metabolic diseases in newborn babies
- ongoing monitoring.³

7. Current and future specific uses of genetic modification in medicine are discussed in the following sections.

Existing and potential benefits

8. We received many submissions emphasising the benefits of genetic modification in medicine, from universities, Crown Research Institutes, medical organisations and patient groups. Specific benefits suggested by submitters highlighted New Zealand’s potential in a number of areas.

More treatments and cures

9. The Cystic Fibrosis Association of New Zealand [IP39] contended that “genetic modification offers the only possibility for a cure for a genetic condition such as cystic fibrosis. There is no other option.” The Association considered it was “inconceivable that anyone could decide not to allow research into genetic modification to proceed in New Zealand”.⁴

10. The Researched Medicines Industry Association of New Zealand (RMI) [IP55] noted that, while New Zealand currently had more than 20 protein products of genetic modification that were formulated as medicines, the American FDA had approved 76 genetically engineered biotechnology medicines for human use. It expected there would be applications soon in New Zealand for approval of many of these medicines.

11. In addition, the RMI said that, among pharmaceutical and biotechnology companies in the United States, there were 369 new biotechnology medicines in the development “pipeline”, targeting more than 200 diseases. Nearly half of these new medicines (175) targeted various forms of cancer, some using novel approaches. Infectious diseases, such as hepatitis, genital herpes, urinary tract infections and tuberculosis, were the focus of another 39 biotechnology medicines development projects. Autoimmune diseases, such as rheumatoid arthritis and systemic lupus erythematosus, and digestive disorders, such as Crohn’s disease and acute pancreatitis, were the targets respectively of 39 and 11 new medicines in the research pipeline.

Large scale supply of replacement human proteins

12. The RMI noted that the potential for large scale production of replacement human proteins that would otherwise be in short supply had already been demonstrated with insulin for diabetics and erythropoietin for anaemic cancer patients. Diabetes Youth New Zealand [IP60] told us “the lives of about 32,000 New Zealanders are absolutely reliant on continued access to GE insulin”.⁵

Eliminating contamination risks

13. Genetic modification makes it possible to eliminate the risks of contamination by infectious pathogens through avoiding raw material from human and animal sources. Recombinant Factor VIII is used to treat haemophilia

and human growth hormone to treat growth-deficient children. Deon York, a young haemophiliac presenting for the Haemophilia Foundation of New Zealand [IP48], told us:

Genetically modified products must provide safer and more effective treatment of haemophilia. The world haemophilia population has been one group particularly affected by HIV [the virus causing AIDS] and HCV [the virus causing a type of hepatitis that is difficult to treat]. ... We continue to be reminded of the effects of transmitting viruses or prions [the infectious agents of mad cow diseases, see chapter 8 (Food), page 191] via the public blood donor system. Now we have CJD [Creutzfeldt-Jakob disease] as a concern.⁶

14. The Haemophilia Foundation saw human gene therapy as “a bright light on the horizon after the traumas brought about by haemophilia and the past consequences of its therapy”.⁷ These relate to the so-called “bad blood” problems associated with blood contaminated with hepatitis B and C, and HIV.

15. In its public submission the Ministry of Health noted that, because there are no antibodies produced as a reaction to recombinant human insulins, manufacturers have greater control over the contents and can produce a purer product with less risk of infection. New Zealand Vice Chancellors Committee [IP18] referred to a paper by Dr Sean Devine which said “human health” would be a “winner”⁸ because drugs sourced from genetically modified organisms had a lower risk of HIV infection than those derived from human blood or blood products.

Precise and effective new medicines with fewer side effects

16. Dr Parry Guilford from the Department of Biochemistry at the University of Otago [IP19] explained the use of gene technology in screening synthetic or naturally occurring chemical compounds that may be active against cancer. He argued that “identification of the cellular targets of these compounds meant more rapid development of drugs and greater opportunities to modify drugs to have more effect and fewer side effects”.⁹ Dr Gillian R Woollett, a witness called by RMI, gave the example of Humulog, a more rapidly reacting variant of insulin which could be given at mealtimes, which was more convenient than administration 45 minutes or more before eating. Auckland Healthcare Services noted that “the very specific, accurate and safe treatments that have been established on the basis of genetic modification technology have introduced a marked improvement in the health of people affected”.¹⁰ Auckland Healthcare Services specifically mentioned Pulmozyme in the treatment of cystic fibrosis, insulin in the treatment of diabetes and Ceredase in the treatment of Gaucher disease.

The use of insulin in diabetes¹¹

Today more than 15 million people with diabetes worldwide use insulin derived from genetically modified organisms (recombinant human insulin). In New Zealand about 15,000 type 1 diabetics are completely reliant on this insulin for survival. The number of New Zealanders with type 2 diabetes is estimated at 185,000, and 17,000 or more of these people also use insulin for blood glucose control.

New Zealand was one of the first countries to get recombinant insulin approved, in 1983, very soon after the first worldwide commercial use in the United Kingdom. Before this date, serious diabetics received insulin extracted from pig and cow pancreases. Ageing populations, wider insulin use and obesity meant more and more insulin was being used. Insulin from the equivalent of up to 70 pig pancreases a year is typically used by a diabetic and there were looming supply problems.

Patients can develop resistance to the action of injected insulin. Occasionally this is because of allergenicity to the insulin molecule itself, but more often it is to the chemicals used to modify the speed at which it works, and to contaminants. It was because of this that in 1985 the availability of recombinant insulin was widened, and in 1986 beef insulin use was discontinued in New Zealand. This was before there were concerns about mad cow disease.

Genetic technology makes it possible to produce large quantities of recombinant human insulin at relatively low cost. The first biosynthetic insulin made, and still used, is physically, chemically and biologically identical to the insulin made in healthy human pancreases, except that it is produced by genetically modified organisms in a contained fermentation system.

To avoid the need to attach other chemicals to the insulin molecule to alter the speed and length of time an insulin injection worked, research led to the development of another insulin molecule with a single chemical change known as Humalog™. The first patent in the world for manufacturing this was granted in South Africa on 29 January 1986 [Patent no. 85/4083] and in New Zealand on 3 November 1988 [Patent no. 212243]. Both patents expire on 29 May 2005, and after this time other companies than Novo Nordisk will be able to manufacture insulin in this way.

Better insulin leads to better blood sugar control and a reduction in the nasty complications of diabetes such as blindness, amputations, kidney failure and heart attacks.

Benefits to the health system

17. The Cystic Fibrosis Association gave evidence of potential cost savings in the public health service, noting that there was considerable potential economic gain for the Government and the health sector from having available a cure for, or significant relief from, serious symptoms for a number of genetic conditions. These included savings from fewer routine clinic visits, reduced hospitalisation, smaller volumes of expensive medication taken continuously and fewer services and payments required of the Department of Work and Income. There would

also be more people working reliably in full time employment and contributing to the economy. The Malaghan Institute of Medical Research [IP10] emphasised public health benefits, arguing that the public stood “to benefit enormously in the sphere of health as new knowledge about the human genome and the genomes of pathogenic organisms accumulated and this information is applied to the human condition”.¹²

Only source of hope

18. Representatives from some patient groups consistently reminded us that gene therapy was their only hope for a cure. Margaret Nicholls, the mother of two sons with cystic fibrosis, told us that their family illness is caused by a deletion of genetic material from chromosome 7. After the cause of cystic fibrosis was identified in 1989, “the hope of all the cystic fibrosis community was centred on finding a way for correct gene material to be placed, somehow, in the lung so that it would behave normally”.¹³ Lysosomal Diseases New Zealand [IP99] called Jenny and Paul Noble, parents of two severely disabled children, as witnesses. They told us that “if there had been a cure, we as a family would not be suffering now”.¹⁴ Patient groups argued that any risks of such treatments were borne by the person receiving the treatment and that, with adequate provision for informed consent, the advantages far outweighed any disadvantages.

Maori perspectives

19. Maori were also more inclined to accept genetic modification in medicine than in the environment. Some, however, were not. Some witnesses expressed concern that genetic modification in medicine was misdirected. Representing the New Zealand Maori Council [IP105], Maanu Paul, despite confirming that he himself was a diabetic, said he remained unconvinced of a need for genetic modification in medicines when it was used to treat symptoms rather than address a cause. Similarly, Tim Rochford, lecturer in Maori health and a witness called by Te Runanga o Ngai Tahu [IP41], maintained that the potential medical benefits held out for genetic modification were unproven, misleading and did not address the environmental causes of many illnesses suffered by Maori:

It is important to understand that while there is a genetic influence on type 2 diabetes, the principal determinant is poverty related stress. Type 2 diabetes clusters in the most deprived communities in developed countries. It is an illness that appears to have a particular impact on indigenous people. It is thought that this is a reflection of accelerated aging caused by cultural dislocation, racism and poverty. In clinical terms it is possible to trace the path from chronic stress to the development of type 2 diabetes, hypertension, heart disease, increased risk of cancers and mental health disorders.¹⁵

20. Nga Wahine Tiaki o te Ao [IP64] expressed particularly forceful opposition towards any use of genetic modification.
21. In answer to a question about the use of genetic modification technology for children with growth deficiency syndromes and the impact on such children if these genetically modified products were taken away, Dr Fiona Cram, for Nga Wahine Tiaki o te Ao, stated that a clear distinction should be made between “what is a medicine and what is sheer experimentation”.¹⁶ Nga Wahine Tiaki o te Ao considered that “this is experimentation”, and did not support its use in New Zealand. Alternative therapies needed to be explored as treatments for growth hormone deficiency before genetic modification therapies were used.
22. On the other hand, Des Ratima (Ngati Porou, Ngati Kahungunu) said at the Wellington regional hui at Waiwhetu Marae that:
- In parts of genetic engineering I think there are things we should embrace. If we can get rid of the diabetes ... and cancer that affects our people so drastically, then lets pursue that ... and the reason I say that is that we can control those measures.¹⁷
23. Other possible benefits from medical research were detailed by a number of witnesses and are discussed in chapter 6 (Research).

Actual and perceived risks

24. A witness for the Human Genetics Society of Australasia [IP59], Dr Joanne Dixon, a clinical geneticist, said that risks would arise from genetic modification techniques unless there was adequate regulation, monitoring, auditing and reporting, and if New Zealanders did not understand the process. She added that some already-identified risks included allergic reactions and other failures of experimental therapies. The purpose of such experiments was, in part, to identify safety as well as efficacy issues. If all new therapies were adequately trialled and monitored after general introduction, harm should be minimised. With regard to therapeutic risk, Dr Dixon noted that New Zealanders already evaluated and then accepted the risks associated with untested, unproven and possibly unsafe “alternative” therapies.
25. Groups such as Physicians and Scientists for Responsible Genetics New Zealand (PSRG) [IP107] and the Green Party of Aotearoa/New Zealand [IP83] expressed general concern but recognised the potential for medical applications. PSRG saw the benefits in medicine as being “enormous” but said that the potential could only be realised if all associated risks were adequately mitigated. They saw these risks as the possible creation of previously unknown diseases and disease vectors such as bacterial pathogens or viruses, possible side effects from experimental genetic therapies, and novel selective pressures producing possible

new strains of existing pathogens. Jeanette Fitzsimons, MP and Co-leader of the Green Party, said she had listened to the extensive testing process for new pharmaceuticals described by Professor Garth Cooper, a witness appearing for the University of Auckland [IP16]. Ms Fitzsimons said the testing “does lower the risk from genetically modified medicines to the point where they are probably not dissimilar to the risks from other synthetic medicines, and that is why we are not opposed to the development of genetically engineered medicines in the laboratory”.¹⁸

26. The Commission is confident that the international research process, and the regulatory systems in place, or recommended by this Report, will ensure risks will be assessed as the technology progresses. As discussed in chapter 4 (Environmental and health issues), the degree of risk will be related to the gene construct used. Further, as recommended in chapter 6 (Research), we call for additional research in the form of environmental impact studies on the effects of genetically modified organisms and their products.

Current and future specific uses

Therapeutic treatments

27. In a background paper prepared for the Commission, Dr Michael Berridge¹⁹ identified many genetically modified medicines in use in New Zealand. Dr Winship noted that genetic modification therapy is currently used in many medical specialties of clinical medicine, including cardiology, endocrinology, renal medicine, respiratory medicine, gastro-enterology, neurology, haematology and oncology. The therapeutic agents used are nearly all protein products derived using DNA technology and include products such as insulin, growth hormone and interferon.

28. The following table details the current commercially available therapeutic uses of genetic modification in New Zealand. It is based on information as at 1 October 2000 supplied by Dr Winship and Dr Berridge. Only two of the products in the table, insulin and hepatitis B vaccine, are used outside a hospital setting. Most are used in highly specialised, uncommon situations. Other therapeutic treatments are available free of charge from pharmaceutical companies as part of research trials and are therefore not on this list.

Vaccines

29. Genetic modification enables a substantial expansion in the range of diseases for which vaccines can be developed. For example in the future vaccines may be available for diseases such as melanoma, asthma and psoriasis. The three

Therapeutic uses of genetic modification commercially available in New Zealand

Products available	Medical use in New Zealand
Insulin	Diabetes
Growth hormone	Childhood growth retardation
Interferon- α	Hairy cell and chronic myeloid leukaemias, Kaposi sarcoma, hepatitis B and C
Interferon- β	Multiple sclerosis
Interferon- γ	Chronic granulomatous disease
Erythropoietin	Anaemia associated with kidney failure
G-CSF	Neutropenias, stem cell collection
GM-CSF	Marrow transplantation
Factor VIII	Haemophilia
Factor VIII antibody inhibitor	Haemophilia
Factor IX	von Willibrand disease
Tissue plasminogen activator (TPA)	Heart disease and stroke (dissolves blood clots)
Interleukin-2	Cancer and cancer immunotherapy
Adenosine deaminase	Severe combined immunodeficiency (SCID)
DNAase (Pulmozyme®)	Cystic fibrosis
α -1 antitrypsin	Cystic fibrosis and emphysema
Follicle stimulating hormone (FSH)	Infertility
Alglucerase (Ceredase®)	Gaucher disease
TNF- α receptor Ig	Arthritis
IL-1 receptor-Ig	Arthritis
IL-1 receptor antagonist	Osteoporosis
Hepatitis B vaccine	Prevention of hepatitis and liver cancer
Cholera vaccine (live)	Prevention of cholera approved but withdrawn
Herudin	Anticoagulant
PDGF-A	Diabetic ulcers
Stem cell factor	Stem cell peripheralisation and transplantation
Monoclonal antibody treatments	Organ rejection Non-Hodgkins lymphoma (B-cell) Acute organ rejection Childhood RSV infection

genetically modified human vaccines currently used in New Zealand are produced from a genetically modified organism, but are not themselves genetically modified organisms. These are the vaccines for hepatitis A, hepatitis B and pertussis (acellular).

30. Most of the detailed evidence we received on vaccines related to use in animal welfare. These are discussed below in a section on animal remedies. Similar issues apply to human and animal vaccines.

31. Dr Glenn Buchan, a senior lecturer in immunology and a witness for the University of Otago, said:

The development of new and improved vaccines cannot be left to chance . . . The search for a vaccine against HIV, the causative agent of AIDS, has continued for over two decades now.²⁰

32. He said this was due to the slow, haphazard and unreliable nature of existing technologies, which had failed to safely attenuate the virus and had failed to produce an effective vaccine from the killed virus. Dr Buchan considered that:

GE supplies a powerful tool which allows us to understand how the body responds to infection, how microbes become disease causing and how vaccines can be designed to protect against existing and new diseases that may appear.²¹

33. Not all submitters were as optimistic about the effectiveness of the new technology in vaccines. Dr Michael Godfrey, Medical Director of the Bay of Plenty Environmental Health Clinic and a witness appearing for PSRG, told us that the hepatitis B vaccine, which was genetically modified, “could cause a variety of immune and neurological health problems”²² However, Dr Garth Cooper, Professor of Biochemistry and Clinical Biochemistry at the University of Auckland, for which he appeared as a witness, argued the importance of the genetically modified hepatitis B vaccine to the health of New Zealanders. He said he was responsible for oversight of a programme that was currently using recombinant [genetically modified] hepatitis B vaccine to eradicate hepatitis B virus from Maori, Pacific Island and Asian populations in New Zealand where it was:

currently estimated that probably around . . . 40,000 to 50,000, primarily Maori, are infected with the virus, and . . . all their contacts are at risk. [This vaccine has] probably be[en] administered to around three quarters of a million New Zealanders over the last 20 years in an attempt by the health system to protect New Zealanders from the ravages of the hepatitis B virus.²³

34. The Commission was told that the genetically modified organisms in these vaccines are highly attenuated (their ability to reproduce is severely curtailed).

35. We consider that, in terms of safety, genetically modified vaccines are comparable to or better than their non-genetically modified counterparts.

36. When live genetically modified organisms are used in medicine, it is generally in vaccines. In New Zealand only one vaccine, the cholera vaccine, has contained live bacteria. These were genetically modified to remove the gene coding for the active cholera toxin. This vaccine was introduced into New Zealand in 1998. The Ministry of Health advised us in its public submission that in May 2000 it realised, in discussions with the Ministry for the Environment while preparing for this Royal Commission, that the vaccine fell within the regulatory frameworks of both the Medicines Act 1981, as a medical product, and the Hazardous Substance and New Organisms Act 1996 (HSNO), as a “new organism”, and that because of an oversight, approval from the Environmental Risk Management Authority (ERMA) had not been sought. ERMA then requested that the distributor recall the product. The Ministry of Health is negotiating with suppliers of alternative vaccines that would not require approval under HSNO. However, the Ministry considers that the medicine is more effective than other cholera vaccines and does not pose a significant risk to human safety. Another genetically modified vaccine, for rotavirus, was in the approval process at the time the cholera vaccine oversight was found, and was then withdrawn from the process. It is likely that, because of the increasing international trend toward developing live genetically modified vaccines, more medicines in future will require double approval unless legislation is modified.

Diagnostics

37. Genetic modification technology is routinely used in diagnostics in New Zealand. We were told of many applications, typically in medical research and, in particular, the management of genetically-determined human health conditions. Most submitters supported the continued use of genetic modification technology in diagnostics.

38. In diagnostics, products of genetic modification and genetic modification techniques are used in two main areas: the identification of genetic differences, and the use of this information in the subsequent treatment of illness and disease. Use of genetic modification in diagnosis enables more accurate diagnosis, prevention and treatment of disease, and more accurate prescribing and patient management. Literally thousands of genetically modified products are used in clinical and diagnostic medical laboratories throughout the country. The Council of Medical Colleges in New Zealand [IP37] said in its submission that without continued access to genetic modification in diagnosis “many diagnostic tools would have to be removed”.²⁴

39. Genesis Research and Development Corporation [IP11] noted that genetic modification technology is used in screening for HIV and hepatitis B viruses in infected blood products and donated organs. The New Zealand Biotechnology Association [IP47] told us of benefits, including: increased understanding of the genetic contributors to diabetes, the development of new opportunities for cancer treatment, better understanding of the genetic basis for differences in response to drug treatment, and in particular the possibility for better tailored treatment in psychiatric illness.

40. The University of Auckland drew attention to the importance of genetic modification technology in underpinning programmes for early detection of prostatic carcinoma. It maintained that a “removal of this test is likely to place all older males at increased risk of prostatic cancer”.²⁵

41. Dr Dianne Webster, Clinical and Technical Head of the National Testing Centre [IP44], noted that New Zealand currently used genetic modification technology to test for seven metabolic disorders, but that overseas, technologies were available that would allow “screening for maybe up to 20 more”.²⁶ Dr Webster spoke of more than 500 inherited metabolic disorders or inborn errors of metabolism that affected various kinds of body chemistry. Dr Webster estimated that in New Zealand metabolic disorders were associated with about one birth in 1000, that is about 60 births each year.

42. Dr Christine Morris, Senior Researcher in Cancer Genetics, Christchurch School of Medicine, who was called as a witness by the Human Genetics Society, spoke about the widespread application of FISH (protocols using fluorescent *in situ* hybridisation) in human genetics research, and in clinical testing in laboratories. Dr Morris said FISH-related techniques were routinely used in laboratories in Auckland, Hamilton, Wellington, Christchurch and Dunedin. Dr Morris added that the use of these techniques in the diagnostic setting was:

... expected to grow exponentially over the next few years as the molecular basis of each of the approximately 4000 or so human genetic conditions unfolds. Their use in research is inevitable for as long as human genome mapping and the investigation of natural and disease-related genetic-related variations continues.²⁷

43. We also received evidence of the beneficial use of genetic modification technology in relation to members of a particular family who because of genetic predisposition had a high risk of contracting stomach cancer. The affliction was regarded as a curse on the family. It meant that many members of a particular whanau and hapu developed cancer, necessitating major surgery. The E-cadherin gene predisposed one quarter of the family towards cancer. Maria Tini (Te Arawa, Ngai Tahu) said at the hui at Tamatekapua, Rotorua, use of diagnostic

techniques involving genetic modification enabled the family to identify those members who were predisposed to this cancer:

... in November 1996, an agreement was entered into with the Cancer Genetics Laboratory, Biochemistry Department, University of Otago, for a cancer genetic research project to study the basis for familial gastric cancer prevalent within members and descendants of our whanau. The research project was a joint venture between the parties. The project involved analysing genes from blood samples, histology material, archived biopsy samples and tumor material or tissue, in the hope of identifying a cancer predisposition gene. The research project and information obtained would be used for diagnostic purposes only, in the hope that it may lead to a better understanding of the genetic factors that may lead to the early onset of familial gastric cancer within the whanau and its descendants. Stomach cancer, like all cancers, can be treated more effectively if detected early. The aim of the project was to develop a genetic test to enable people at very high risk of getting stomach cancer to be identified before the person becomes sick. That way treatment protocols and clinical surveillance can start before the cancer has spread.²⁸

44. Maria Tini told us that “dispelling the notion of the curse through knowledge, information and ongoing education has been fundamental to the whanau growth, development and survival”.²⁹

45. We also heard at the Auckland regional hui at Orakei Marae from Dr Jan Bryant (Nga Puhi, Ngati Porou) who was involved as a doctor with the whanau who have adrenoleucodystrophy:

[It's] a very sad issue to see the offspring with adrenoleucodystrophy, and the fact that some of their mokopuna make it, others don't. So ... along with what [Dr David Jansen] said, if what we can do is bring these tools and this genetic research [to these people], then it is a tool for us to help our whanau.³⁰

46. We accept the evidence we heard about the value of genetic modification technology in diagnostic medicine.

Gene therapy

47. There are two types of gene therapy. Germ line therapy changes the genetic make-up of an individual in a way that can be transmitted to future generations, for example to correct an inheritable genetic disease such as Huntingtons disease or cystic fibrosis. Somatic therapy on the other hand involves changes to the genetic make-up of an embryo or a person in such a way that the changes are not passed on to future generations. The Ministry of Health told us that somatic gene therapy had been used in New Zealand in recent years to treat a few children with a rare fatal disease, but with limited success. We are also aware of a small number of instances where New Zealanders have been treated with somatic therapy

overseas as part of research trials. Apparently these treatments have been at least partially successful.

48. Gene therapy also includes some treatments for cancer, as detailed by Dr Woollett of RMI, which operate by manipulating genes and their properties so that they induce the body's own cells to replace defective tissue or grow new tissue.

49. The techniques used for some forms of somatic gene therapy are similar to those used with vectored vaccines, in that a vector, such as a harmless virus, is used to carry the new DNA into the cells where it is needed. With a vectored vaccine, the new gene produces a protein, which triggers an immune response. In contrast, gene therapy aims to replace a defective gene with a normal copy, to correct the problem caused by the mutation. The concerns associated with gene therapy are therefore similar to those for vectored vaccines and revolve around the high level of uncertainty about the safety of using viruses for these therapies.

50. As identified above, these therapies have provided considerable hope to families affected by genetic diseases. The Royal Society of New Zealand [IP77a] among others said that it was essential that this therapy be available in New Zealand for the benefit of patients. In reality, however, any practical use of these therapies lies well into the future. Dr Winship, when a witness for Auckland Healthcare Services, told us that in her opinion this would not happen in the next two decades. She also said that if continued research and clinical uses of genetic modification technology were prevented, there may be serious adverse consequences for people with acquired and genetic diseases who would be disadvantaged in the investigation and management of their health problems.³¹

51. Recent genome research has identified many unexpected similarities between mammalian genomes. This means that New Zealand agri-scientists who have been researching animal genetics are now at the forefront of research relevant to human health. Lysosomal Diseases stated research into a cattle disease at Massey University in the 1970s and 1980s led to the finding that it was the same genetic variation as a type of lysosomal disease in humans, and also as a certain sheep disease:

Significant research into Alpha-Mannosidosis in Aberdeen Angus cattle, carried out at Massey in the '70s and '80s, greatly assisted overseas researchers in the development of bone marrow transplant as a treatment option for a number of lysosomal storage diseases [LSD]. This work also provided significant baseline information for use in other related research which in turn has led to GM products for these diseases.

Similar work on another LSD – Batten disease – at Massey and Lincoln, using a naturally occurring sheep model, has provided the world with significant knowledge about this

disease. Although Batten is a very rare disease, it is also probably closer than any other disease to the biochemical pathway of other major diseases such as CJD [Creutzfeldt-Jakob disease] and Alzheimers. The animal model of Batten is therefore one of the likely pathways to understanding and hopefully treating or controlling these major health problems.³²

52. Lysosomal Diseases described the various therapies currently available for sufferers of these severe diseases, and the limitations of those therapies. Its conclusion was gene therapy is well suited to treatment of lysosomal diseases as these are caused by mutations in a single gene. Further, it told us that gene therapy would be useful where the disease affects the brain as conventional treatments often cannot reach the brain.

53. While families burdened by inherited disease have great hope for gene therapies, others are concerned about the wider implications of this new technology. The New Zealand Catholic Bishops' Conference [IP38] called for a prohibition on germ line therapy for a defined period while New Zealand grappled with the uses of genetic modification that have less serious consequences. It also argued that while “in principle we would also see germ line therapy to be an ethically acceptable therapeutic intervention, providing safety issues are resolved and the welfare of future generations can be assured”,³³ it also argued that “we all share the human gene pool and it is not the property of any one of us, so our decisions in this respect need to be agreed upon collectively, rather than being individual decisions”.³⁴

54. No submitters disputed that gene therapy could have positive therapeutic effects for sufferers of genetic diseases. However, many drew a line between therapeutic effects and genetic enhancement, also called eugenics. Hana Jensen (Tainui), Trustee of Raupatu Maori Lands Trust and Huakina Trust, said at the Ngaruawahia national hui:

To Maori, it would raise an ... ethical question as to what would be done with the failures. Selective beings and breeding may give a wonderful looking shell but no wairua within the shell.³⁵

55. The New Zealand Organisation for Rare Diseases [IP98] said our beliefs would lead to personal choices about the use of this therapy; but our choice should not deny others opportunities, choices or benefits.

56. The Catholic Bishops' Conference, among others, opposed any use of gene therapy for enhancement purposes.

57. Toi te Taiao : the Bioethics Council should consult widely and develop guidelines for the uses of gene therapy, including therapeutic uses.

58. The coding of the human genome and the prospect of individuals having access to more complete information about their own precise genetic make-up has intensified the debate over individual privacy. Many submitters expressed concern about the prospect of having to relinquish ownership of knowledge relating to their genes, about being under pressure to produce information about an existing or expected medical condition and also about prejudice towards those with an existing or expected medical condition. The Youth Forum participants made the following comments on a mural they constructed: “All Beethoven’s family had some irreversible physical problem. If we had used genetic modification technology on him, would there have been a Beethoven?” and, “Should parents be able to choose traits in their children? My daughter will have blonde hair, blue eyes, be the prettiest, the most intelligent ...”.³⁶

59. In gene therapy applications in New Zealand there may be an area not covered by legislation, even if the Assisted Human Reproduction Bill before Parliament becomes law. This bill will require all assisted reproduction procedures up to the stage of fertilised eggs to be approved by medical ethics committees, whether undertaken in public or private medical facilities.

60. Biotechnology is evolving so rapidly that the bill does not cover the newest technologies, for instance use of stem cells, which may open the possibility of gene therapy and “genetic enhancement” clinics. Genetic Technology Advisory Committee (GTAC) and Standing Committee on Therapeutic Trials (SCOTT) approvals are required for any gene therapy trial where the primary aim of the project is research. GTAC approval is required for any gene therapy carried out in public hospitals or medical facilities. Both bodies require formal ethics committee approval. However if a gene therapy were to complete phase 3 trials overseas and become available commercially, then use in New Zealand might not trigger any compulsory ethical committee oversight. The only ethical oversight of a private medical facility then would be with the professional colleges of the doctors and nurses offering the service. To avoid the need for prescriptive and possibly incomplete legislation in such contentious areas as gene therapy and cloning, general approval from the Bioethics Council and case-by-case local medical ethics committee approval should be legally required wherever the procedure is carried out, and regardless of who is paying for it.

Recommendation 9.1

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

Xenotransplantation

61. Xenotransplantation involves the transference of a body organ from one species to another, although use of the term is usually restricted to a transfer from an animal to a human. The need for xenotransplantation arises because of the widespread worldwide shortage of human organs for transplantation, worsened by a low donation rate, increased demand with medical advances and decreases in the number of road deaths.

62. This technology is at a very early developmental stage. There are no examples in New Zealand of xenotransplantation in humans, even as part of research trials. However, pigskin is used as a temporary cover for badly burned patients, and pig heart valves have been used for many years to replace human valves damaged as a result of rheumatic fever. We are aware that xenotransplantation technology could be used in animal medicine to preserve the breeding potential of very valuable livestock and, while this may not raise the same ethical objections as in human use, the scientific risks are similar.

63. The evidence presented about xenotransplantation largely focused on the medical risks involved, specifically the risks of importing viruses from one species to another. The issues of porcine (pig) endogenous retroviruses (PERV) and human endogenous retroviruses (HERV) were raised. Endogenous retroviral DNA sequences are found in the chromosomes of all mammals, but currently their significance is unclear. Submitters varied in how they regarded these retroviral sequences. Some believed that they were harmless, and would not be affected by xenotransplantation. Others were very concerned about possible potential reactivation of the retroviral sequences.

64. Concern was expressed that xenotransplantation could cause a situation where either a HERV or PERV was reactivated and caused disease. Alternatively the strong promoters, often part of the modified gene, could accidentally turn on a PERV or HERV. We heard evidence that many scientists working in the field shared these concerns and were actively researching these potential problems. We agree clarification is needed before human trials can take place.

65. Associate Professor Richard Squires, a witness called by the New Zealand Veterinary Association [IP28], said “some virologists [were] deeply concerned that the transplantation of PERV-containing porcine organs into immunocompromised HERV-containing humans may eventually lead to emergence of new variant viruses, similar to one of the HERVs, but pathogenic”.³⁷ He noted that “deep concern, about what is, at this stage, a theoretical threat, has delayed progression of clinical trials with xenotransplantation”.³⁸

66. One problem with PERVs relates to genetically modifying a pig to reduce the glycosylation in the membrane, a major cause of organ rejection in humans.

This would mean humans with pig organs would not need to take the toxic drugs that are needed to prevent rejection in the absence of genetic modification technology. However, if membrane glycosylation is reduced or removed, the pig's immune-recognition system could be damaged and a currently subdued PERV might reactivate and cause diseases that are transferred with the organ. Dr Squires said virologists claimed there was potential for one or more of these new viruses to pose a threat to the health, not only of the unfortunate organ recipients from whose bodies they might emerge, but also to society at large as contagion spread.³⁹

67. The Ministry of Health advised that the Health Research Council referred clinical trials involving xenotransplantation to its SCOTT committee, whether or not genetic modification was involved. We have confidence in the professional judgment exercised by members of this committee. However wider consultation on these difficult issues is now appropriate.

68. The use of animal organs to prolong human life has both ethical and cultural implications. Organisations concerned with animal welfare, such as SAFE (Save Animals from Exploitation) [IP85], considered the use of transgenic animals to provide replacement parts for humans as exploitation. SAFE also described specific animal welfare concerns, for example that “donor cattle are frequently subjected to hormonal injection, artificial insemination and surgical removal of embryos or slaughter; sometimes the oviducts are removed by castration, or embryos are collected by flushing of the oviducts”.⁴⁰ Other submitters were concerned with the use of specific animals. We heard from the New Zealand Jewish Community [IP80] that Jewish dietary laws do not allow the consumption of pigs or the use of any product derived from pigs.

69. Joanna Paul, a witness for the Quaker Spiritual Ecology Group, Religious Society of Friends [IP50], objected to the mixing of animal and human parts in an unnatural way:

... trying something out on an animal ... seems a very crude way of finding whether that's going to work for a human being. ... There's a qualitative difference between that kind of thing and actually unhousing a mouse. ... I think that to make something what it is not is a sin and a crime. ... I think we have to regard the specificity of things as a sacred trust ... this is a new language we have to talk because it's a new problem.⁴¹

70. At the Wanganui hui, Pare Bennett spoke against the mixing of mauri, saying that:

No Rangi-tu-ha-ha nga mea katoa, tona whakairatanga ka hono te wairua me te tinana o nga tipu, o nga kararehe, o nga tangata katoa. He tino motuhake enei ahuatanga ki a matou. Ko tenei hoki te kakano i ruia mai i Rangiatea; te kakano o te maramatanga, te

tapu o nga mea katoa. Ka waihotia e nga tipuna enei ahuatanga motuhake mo matou nga uri hei tiaki mo ake tonu ake.

(All things emanate from the heavens, where the spirit and the body are joined, of plants, of animals, of all peoples. These are basic tenets to us, for this is the seed that was sown in Rangiatea, the seed of clarity, the most sacred of sacreds. These things were left by our ancestors as legacies for us to perpetuate forever. However, we maintain that by tampering with the genetic make-up of things, we make this thing not sacred, this is our grave concern.)⁴²

71. We consider that more research is required before xenotransplantation could be considered seriously as an option. However, when eventually the issue arises as a practical question, either in the context of growing organs in New Zealand or the importation of an organ, the issue will first need to be referred to the Bioethics Council. Should the Council recommend in principle in favour of proceeding, the question of approval in the specific instance can be decided under the existing regulatory mechanisms.

72. It is noted that, if the Council decided to reject the use or importation of genetically modified organs for transplantation, ethical issues would remain since New Zealanders are likely to travel overseas to take advantage of the technology wherever it may be permitted.

Recommendation 9.2

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

The convergence of food and medicine

73. When is medicine a food and food a medicine? We heard evidence on a wide range of products ingested by humans that supplemented or enhanced normal dietary intake. Genetic modification makes it more possible for a substance to be both a food and a medicine. Several issues were raised (see below):

Problems of definition

74. Because of the speed of change, the current terminology is confusing. There are no internationally recognised definitions. Submitters used a plethora of terms, including “dietary supplements”, “functional foods”, “nutriceuticals” and “nutraceuticals”, that lacked clear and concise definition. Several categories of products were new and appeared to be evolving. The distinction between others appeared to be blurred. It was evident to us that it was unclear, both in legislation and in the wider public mind, what was essentially a food and what was

essentially a medicine. Confusion appears to be exacerbated by the use of the term “natriceutical” by the alternative health product industry.

Inconsistent regulation

75. The confusing terminology is reflected in inconsistent regulation. Different regulatory arrangements apply to various products intended for human consumption. The Ministry of Health gave us information on the regulatory arrangements applying to medicines and foods. Since 1981 medicines and foods have been regulated separately under different statutes. Previously, medicines, foods and dietary supplements were all regulated under the Food and Drug Act 1969, but in 1981 regulation was divided between the Medicines Act 1981 for restricted medicines and the Food Act 1981 for food or dietary supplements. The Ministry explained that the Medicines Act and associated medicines regulations gave a framework for the approval of medicinal products. Medsafe, a unit of the Ministry of Health, approves medical products for distribution.

76. Under the Medicines Act, the Medicines Regulations 1984, the Misuse of Drugs Act 1975 and the Misuse of Drugs Regulations 1977, Medsafe regulates products used for a therapeutic purpose. The objective of the medicines legislation is to manage the risk of avoidable harm associated with the use of medicines. The legislation is designed to ensure that medicines meet acceptable standards of safety, quality and efficacy, that the manufacture, storage and distribution of medicines complies with standards applying right up to delivery to the end-user, and that information about the selection and safe use of medicines is provided to health professionals and consumers. Medsafe achieves this through pre-marketing approval of products and post-marketing surveillance.⁴³

77. We heard evidence that submitters had confidence in Medsafe’s regulation. Sue Kedgley, Member of Parliament and a witness for the Safe Food Campaign [IP86], told us under cross-examination that genetically modified food should undergo “the same safety testing regime as genetically engineered pharmaceuticals”.⁴⁴

78. We understand that dietary supplements are defined and regulated under statute but that other products are not. The Ministry of Health pointed out that dietary supplements are defined in the Dietary Supplements Regulations 1985 as “any amino acids, edible substances, foodstuffs, herbs, minerals, synthetic nutrients and vitamins sold singly or in mixtures in controlled dosage forms as cachets, capsules, liquids, lozenges, pastilles, powders, or tablets which are intended to supplement the intake of those substances normally derived from food”. These products come under legislative arrangements for food rather than medicine.

Other products alluded to by submitters, such as nutraceuticals and functional foods, appeared to lack consistent definition or legislative provision.

Joint trans-Tasman arrangements

79. We were advised of discussions between the Australian and New Zealand Ministers of Health to establish a single joint trans-Tasman agency to replace Medsafe. The new agency would be responsible for evaluating medicines and medical devices, setting standards, compliance monitoring and enforcement activities.

80. Ian Lindenmayer, Managing Director of the Australia and New Zealand Food Authority (ANZFA), noted nutraceuticals and functional foods were “a very topical issue to the extent that the regulatory environment in New Zealand and the regulatory environment in Australia ... are different”.⁴⁵ He commented further that when the newly adopted joint Food Standards Code of Australia and New Zealand (Joint Food Treaty) became the source of the standards for the two countries it would be awkward to have “a group of products such as dietary supplements, which are regulated as dietary supplements still in New Zealand but regulated as foods in Australia”.⁴⁶

Functional foods and nutraceuticals: foods or medicines?

81. Functional foods and nutraceuticals are not specifically defined in legislation or regulations, but these terms are being increasingly used by industry. The meanings appear similar. Nutraceuticals are generally taken to be products that are extended to provide enhanced nutrition, for example vitamin A-enriched rice. Functional foods, on the other hand, were described by one source as being similar in appearance to conventional foods, and intended for consumption as part of a normal diet, but with modifications to take on physiological roles beyond simple nutrition.⁴⁷ The addition of plant sterols to margarine was given as an example. However, there is little published data or any consensus on just what comprises a functional food.

82. It is also becoming increasingly unclear whether functional foods and nutraceuticals are essentially foods or medicines. Dr Ross Clark, molecular geneticist and witness called by Auckland UniServices [IP23] confirmed “there is no clear distinction between what is considered a drug and what is considered to be a food”. He added that “the ‘health food’ industry highlights this blurred distinction. In the future this distinction will become even further blurred”.⁴⁸

Foods with medicinal properties

83. The increasing potential for developing and producing nutraceuticals and functional foods with medicinal properties and uses was constantly stressed. Dr Clark spoke of New Zealand’s ability to “leverage off its agricultural

sector and become a world leader in novel, high value nutraceutical products”.⁴⁹ Submitters, including the New Zealand Wool Board [IP30], the New Zealand Dairy Board [IP67] and the Foundation for Research, Science and Technology [IP21] stressed opportunities for the development of nutraceuticals. The New Zealand Arable-Food Industry Council [IP56], the New Zealand Feed Manufacturers Association/Poultry Industry Association of New Zealand/Egg Producers Federation of New Zealand [IP35], the New Zealand Grocery Marketers Association [IP54] and Comvita New Zealand [IP74] outlined the potential for New Zealand to develop functional foods.

84. Dr Brian Jordan, a witness called by Arable-Food Industry Council, told us that “New Zealand has real potential to use its biological base as the ‘science platform’ of a molecular revolution in health ... and functional foods”.⁵⁰ The Grocery Marketers Association predicted “the range of these specialised functional foods will significantly increase over the next few years as technological advances occur in the food industry”.⁵¹ The Association presented a chart of the potential health benefits from genetically modifying plants. This indicated that potatoes could have increased levels and better distribution of starches that would make them easier to process and less prone to absorb fat when fried. Tomatoes could have higher lycopene levels to increase their antioxidant effects. Garlic could have higher allicin levels to lower cholesterol.

85. Given the likely expanded market for foods with enhanced medicinal properties, we have decided that clarity in terminology and a clear and robust regulatory system are priorities. Putting aside for the moment the issue of genetic modification, there appear to be three broad categories of product involved in this market: dietary supplements, functional foods and “pharmaco foods”.

86. Dietary supplements are products containing extracts, concentrates or synthetic versions of food substances. They are defined and regulated under the Dietary Supplements Regulations (discussed above). Functional foods are foods with enhanced nutritional value and include foods that have been genetically modified to enhance their nutritional value, including products generally referred to as nutraceuticals.

87. “Pharmaco food” is a new term we are using to encompass a new and evolving product. A pharmaco food is essentially a vehicle to convey a specific medicine or vaccine. We envisage applying this term to all foods that are genetically modified to deliver a particular therapeutic agent, such as a vaccine or a pharmaceutical. Historically medicines and vaccines have been delivered by a variety of means, including pills, capsules, drinks and injections. A pharmaco food would simply be another delivery mechanism for such medicinal purposes. The term would be used for products such as a proposed banana incorporating a

hepatitis B vaccine. In our view the regulation of these pharmaco foods should be the responsibility of Medsafe, as discussed below.

Regulatory regimes

88. The regulatory issues for dietary supplements, functional foods and pharmaco foods were similar to those for medicines, food and crops. Because the risks involved in consuming medicinal products, foods and nutritional supplements are similar and vary only with the degree of concentration, volume consumed and frequency of consumption, the same standards of testing, monitoring and ongoing surveillance should apply to all.

89. The critical issues raised with us involved regulatory costs to industry, the safety of products consumed by humans and the requirements for labelling. We consider these issues can all be addressed under a clear, concise and robust regulatory arrangement.

Labelling

90. The evidence concerning labelling is discussed extensively in chapter 8 (Food). We consider the issues are the same for dietary supplements, functional foods and pharmaco foods, which are all intended for human ingestion. It seems to us unnecessary to make distinctions among them.

91. The Ministry of Health believed some dietary supplements fell outside the scope of the Joint Food Treaty. If this were the case, “the labelling provisions of Standard A18 would not apply to all dietary supplements produced using gene technology”.⁵² (Standard A18 requires all ingredients to be labelled if of genetically modified origin.) They noted however that dietary supplements were still covered by the provisions of section 9(4) of the Food Act 1981, “which prohibit the sale of food unfit for human consumption, and section 10 which prohibits misleading labelling”.⁵³

Regulatory oversight

92. As mentioned above under “Inconsistent regulation”, the approval regimes for nutritional products and medicines are covered by separate legislation with foods generally covered by the Food Act and medicines by the Medicines Act. The approval bodies established under this legislation also vary. Food approval, as discussed in chapter 8 (Food), is the responsibility of ANZFA in administering the Joint Food Treaty. Medicines approval is within the ambit of Medsafe, as discussed above.

93. These regimes apply to all products, irrespective of whether genetic modification technology is involved. The approval regime is further complicated if a product involves genetic modification. It then requires approval by ERMA

under HSNO. This means that some products require two approvals, others three. For example, a live genetically modified organism that is a vaccine requires approval from ERMA and Medsafe. If the compound is ingested as “food”, further approval is required from ANZFA. Milk from a cow genetically modified to incorporate a vaccine (in a product such as butter or ice cream), would need three approvals: from ERMA, because a genetically modified organism is involved, from Medsafe because it is a medicine, and from ANZFA because it is a food.

94. These regulatory requirements cause confusion and compliance is expensive. Many submitters gave evidence on the extent and impact of these expenses and this discussion is covered in chapter 6 (Research).

95. Medicines and medicinal products involving genetic modification fall within four product categories: medicines, pharmaco foods, functional foods and dietary supplements. Attention should be given to streamlining the approval processes so as to reduce costs and confusion. This process could be achieved by extending the role of Medsafe to encompass approval of such products.

96. In the situation where multiple approvals are currently required for genetically modified medical products grown in New Zealand (such as the earlier example of a vaccine incorporated into butter or ice cream), we recommend that the existing ERMA approval regime should continue if the original transgenic organism is developed and grown in New Zealand. This would allow ERMA to fully assess the environmental impacts of the product. For medical products not developed or grown in New Zealand, we recommend that an extended Medsafe be the only approval authority required. These suggestions are summarised in the table opposite.

Recommendation 9.3

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

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 the Environmental Risk Management Authority.

Recommended approval process for genetically modified products

Type of product	Regulatory oversight*	Label
Food	<ul style="list-style-type: none"> • ANZFA for approval • Food Authority for surveillance of compliance with standards 	ANZFA
Dietary Supplement	<ul style="list-style-type: none"> • ANZFA for approval • Food Authority for surveillance of compliance with standards 	ANZFA plus Medsafe requirements
Functional Food	<ul style="list-style-type: none"> • ANZFA for approval • Food Authority for surveillance of compliance with standards 	ANZFA
Pharmaco Food	<ul style="list-style-type: none"> • Medsafe for approval • Ministry of Health for surveillance • Food Authority for surveillance of compliance with standards 	ANZFA plus Medsafe requirements
Medicines	<ul style="list-style-type: none"> • Medsafe/Ministry of Health 	Medsafe

*For products grown or produced in New Zealand, ERMA approval required in addition.

Animal remedies

Veterinarian medicines and nutritional supplements

97. Evidence we received on the genetic modification of animal feed focused mostly on lysine, the amino acid that is added to corn and fed to livestock. Adding lysine means a far greater proportion of corn can be used in chicken diets, and used more efficiently. Bob Diprose, Executive Director of the Poultry Industry Association of New Zealand, presenting for the Feed Manufacturers Association/Poultry Industry Association/Egg Producers Federation, told us that for the year ended 1999 it was estimated that 1200 tonnes of the amino acid lysine was used in the livestock industry in New Zealand. Lysine is a product of genetically modified bacteria, similar to tryptophan, produced in fermenter vats. (See box in chapter 4: Environmental and health issues.)

Vaccines for animals

98. The Veterinary Association cited several benefits to be obtained from the continued use of genetic modification technology in animal treatment. Most of this evidence centred on the use of so-called “new generation” of genetically modified vaccines. The Association said that such vaccines would reduce animal suffering, make New Zealand’s animal industries more efficient and reduce the use of antibiotics in animals. It also emphasised that genetically modified vaccines with “markers” would allow tests that could distinguish between vaccinated animals and those which had been exposed to disease. It regarded such vaccines as “an unique and efficient tool for the eradication and control of diseases which are [not] endemic or normally exotic to New Zealand”.⁵⁴ Such diseases would include foot and mouth disease.

99. Professor Emeritus Bill Manktelow of Massey University’s Veterinary School, called by the Veterinary Association, spoke of the “considerable advantages” of genetically modified vaccines over conventional products, saying they were “often more effective, often safer”⁵⁵ and that they provided opportunities to vaccinate against more diseases than was previously possible. He stressed New Zealand’s “enviable high standard of health in its livestock” and said that maintaining this high standard was “a vital and continuing task for our biosecurity defences”.⁵⁶

100. The benefits of further research and development of such new vaccines were stressed by Dr Kenneth McNatty, a scientist at Wallaceville Animal Research Centre, presenting evidence on behalf of AgResearch [IP13]. He identified the need for improved vaccines to prevent major farm animal diseases such as tuberculosis, Johne’s disease, helminthosis and campylobacteriosis.⁵⁷

Dr McNatty stressed the views of the Veterinary Association with his comments that “vaccines should substantially reduce the amounts of drugs and chemicals required for farming, and substantially reduce the billion dollar impact of farm animal diseases on the New Zealand economy”.⁵⁸ As an example, he cited the case of a bovine tuberculosis vaccine that had the potential to eliminate the disease from wildlife, and thus reduce control costs of more than \$40 million per year. Meat New Zealand [IP31] also identified potential vaccine uses as alternatives to chemical drenches in animals such as cattle and sheep. It said “chemical drench resistance in ruminant animals continues to develop on New Zealand farms and we need new techniques to control this problem”.⁵⁹

101. Vaccines were discussed under four classes:

- **Live attenuated vaccines** These are currently used in New Zealand for immunisation of cats. The Veterinary Association gave the example of Leucogen, a vaccine against feline leukaemia virus, also known as feline AIDS. These vaccines consist of disease microorganisms that have been genetically modified so that they no longer have their virulence, but can still induce immunity. Such vaccines could also be made by introducing into harmless microorganisms sequences of DNA containing code for the production of proteins that induce immunity.
- **Subunit vaccines** These vaccines typically contain parts of the disease-causing microbe that will induce immunity. Parts of the organism required for it to cause disease are absent. Although these vaccines could be produced using non-genetic modification technology, the new technology has greatly advanced opportunities for their production. Subunit vaccines have widespread acceptance and use in New Zealand and overseas. In the past many conventional animal vaccines have been made from whole live weakened (attenuated) microorganisms, a method with several risks. These include mild disease, severe side effects, reversion to full virulence in the field and infection of other non-target animal species. Subunit vaccines reduce these risks.
- **(Naked) DNA based vaccines** These vaccines are not currently used in New Zealand. The Veterinary Association told us these vaccines are similar to other vaccines derived from genetic modification, but that they “rely entirely on the animal’s own cells to take up the injected DNA and cause the host animal cell to make the foreign antigenic (immunity inducing) protein”.⁶⁰ Several submitters gave evidence of their concerns about the impact of naked DNA in the environment at large, among them Professor Terje Traavik, Head of the Department of Virology at the University of Tromsø School of Medicine in Norway, who appeared as a witness for Greenpeace New Zealand [IP82], Friends of the Earth (New Zealand) [IP78], and

Environment and Conservation Organisations of New Zealand [IP102]. He described a series of virus infection trials carried out at his university in which naked genomic DNA was injected into rabbits and mice and, contrary to “what was known from the literature, ... so-called conventional wisdom”⁶¹ and the researchers’ expectations, the DNA was not broken down but instead produced illness. Professor Traavik also noted that:

... the problem is ... we know in the case of a few, perhaps rare, combinations of nucleic acids and circumstances, nucleic acids will be able to be taken up from the mucous membranes. However, we have no knowledge of the sequences, structures or environmental factors that can contribute to such stability [ie, failure to break down]. Nor can we therefore, at the present time, predict what type of DNA will avoid rapid breakdown in the organism and which environmental factors may contribute to this.⁶²

We are aware that Professor Traavik’s research was carried out from 1989 to 1993, and that since that time his findings and those of others have been used to develop vaccines.

- **Vectored DNA vaccines** These are not available in New Zealand. However, the Veterinary Association said it understood the United States Department of Agriculture had approved a vaccine for immunising chickens against Newcastle and fowl pox diseases. Although fowl pox was present in New Zealand, it was not significant, and there was no problem here with Newcastle disease. The Association also said that, in the event that Newcastle disease became established here, availability of the vaccine from an overseas source provided “another strategic option”.⁶³

102. We regarded the evidence on the potential use of vaccines for animals as significant for two reasons. First, the technology has the potential to impact on New Zealand’s primary sector. Second, the technology used for animal vaccines, including the research and development of such vaccines, has implications for humans.

103. We consider moves to have these “new generation” vaccines more widely available in New Zealand are likely to be made first for animal remedies. We cannot ignore the possibility that a threat to New Zealand’s biosecurity in the form of a major livestock disease may be the impetus for such increased use.

104. As noted earlier in this chapter, we have concerns about the potential environmental impact of live genetically modified organisms. Such effects do not at the moment appear to be a major problem in New Zealand, and we cannot say what effect, if any, they would have on the environment. However, New Zealand should anticipate the likely increased availability and use of such products in relation to both humans and animals.

105. The Veterinary Association recommended that:

... for any GM-based product proposed as an animal remedy, provision of adequate information on efficacy and the genetic modification involved in its manufacture must become a statutory requirement for any application for its registration.⁶⁴

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 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.

Emergency use of genetically modified organisms

106. Submitters questioned the adequacy of the statutory powers for emergency use of genetically modified organisms. We are also aware that it is not possible to hold as a stockpile enough animal vaccine to respond to a major outbreak of all diseases.

107. The Veterinary Association told us that stockpiling of vaccines for control of possible outbreaks was becoming a common phenomenon overseas. For example, the United States Department of Agriculture currently held a stockpile of a vaccine against avian influenza.

108. New Zealand's ability to respond quickly to any outbreak of disease in animals and humans was raised with the Commission. We made enquiries of relevant government agencies, including the Ministry of Health, the Ministry for the Environment, the Ministry of Agriculture and Forestry, and ERMA, to ascertain what legislative powers they had to authorise emergency imports of a genetically modified organism.

109. Currently three statutes cover the possible use of organisms in emergencies, or in relation to them. These are HSNO, the Biosecurity Act 1993 and the Health Act 1956.

110. In terms of HSNO, section 46(1) lists the types of emergency situations in which the Act applies. If the emergency is not within these categories, an application for the importation or release of a new organism must be made to ERMA under normal application procedures. Any other import or release is illegal.

111. If the situation meets the conditions in section 46(1), an emergency can be declared and sections 47 and 48 apply. These sections allow for emergency applications for importation or release of organisms, in foreseeable emergencies only. If the emergency or the use of the organism in relation to it was unforeseeable, HSNO does not apply to the importation or use of that genetically modified organism, provided it is not one of the prohibited organisms in the second schedule of the Act.

112. ERMA advised that it expected most emergencies were likely to be declared, in which case HSNO would apply.

113. The Ministry for the Environment told us that “section 49 of the HSNO Act, in order to provide a workable solution to the minimisation and remediation of emergencies, must be interpreted narrowly. Foreseeable therefore must mean ‘foresight of the use of the exact organism’ or ‘foresight of the exact emergency’”.⁶⁵

114. There are powers under sections 144–145 of the Biosecurity Act to declare an emergency. Provisions under this section allow for action to be taken to manage or eradicate the organism in respect of which the emergency has been declared.

115. The Health Act also has provision for the control of infectious diseases in emergencies, and these are in addition to the powers conferred under the Biosecurity Act. The Ministry for the Environment also advised that expanded public health emergency provisions are being considered for inclusion in a proposed Public Health Bill, which is intended to replace the Health Act.

116. In anticipated disease outbreaks rapid importation of vaccines may be required. Where the emergency provisions under HSNO, the Biosecurity Act and the Health Act are invoked to control the outbreak of disease in humans or animals, but it could reasonably be argued that such an outbreak was foreseeable, rapid importation of vaccines or medicines containing live genetically modified organisms may not be possible.

Recommendation 9.6

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

chapter |

10.

Intellectual property

10. Intellectual property

Key issues:

- The scope of intellectual property rights
- Balancing community interests and individual rights
- Intellectual property rights and life forms
- Protection of traditional knowledge
- Changes required to present system.

Introduction

1. The Commission’s Warrant asked that we investigate and hear views on the intellectual property issues involved, now and in the future, in relation to the use in New Zealand of genetic modification, genetically modified organisms, and products.

2. In the course of its consultation, the Commission heard a variety of views about intellectual property rights (IPRs). Some suggested IPRs were “inherently evil”. According to a number of value systems, it was unethical or immoral to allow an individual (corporate or otherwise) to own or control the “stuff of life”.¹ Also, IPRs were seen as increasing costs and denying access to new and improved products and processes. But other submitters pointed out that, consistently, innovation and economic benefits were higher in countries having well-developed systems for recognising and rewarding inventions through intellectual property rights.² These submitters emphasised the nature of the social contract that IPRs represent, between individuals rewarded for their innovation or foresight, and society as a whole, which accrues benefits from the development of new products and processes and the enhancement of the sum of human knowledge.

3. Many submitters argued that the protection provided by an intellectual property (IP) system is a basic necessity for the development of genetic modification technology. A strong IP system means that New Zealand inventors can protect their ideas and investment and receive the benefits from their commercial

applications.³ Indeed, the New Zealand Institute of Patent Attorneys (NZIPA) [IP71] submitted that New Zealand must expand and update its patent and plant breeders' rights legislation to provide adequate protection and comply with international obligations.⁴ The Commission is indebted to the NZIPA and its principal witness Doug Calhoun for their comprehensive presentation. We have drawn on the evidence of Mr Calhoun, a past president of the NZIPA, for material included in this chapter.

4. The Commission notes there is a worldwide movement for development and harmonisation of IPR regimes, as there seems to be acceptance that the social and economic benefits of such systems are of universal application.⁵

Nature of intellectual property rights

5. This section discusses the various IPRs, how they are created and their application to biotechnology and genetically modified organisms and products. This is to address the confusion in general perceptions about the scope of IPRs. We need to explain what intellectual property rights do and, as importantly, what they do not.

What are intellectual property rights?

6. Intellectual property rights are rights in creations of the mind, such as inventions, industrial designs, literary and artistic works, symbols, and names and images. "Intellectual property" is defined in Article 2(viii) of the 1967 Convention Establishing the World Intellectual Property Organization (WIPO) to include rights relating to:

- literary, artistic and scientific works
- performances of performing artists, sound recordings, and broadcasts
- inventions in all fields of human endeavour
- scientific discoveries
- industrial designs
- trademarks, service marks, and commercial names and designations
- protection against unfair competition
- all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields.

New Zealand is a member of WIPO.

7. IPRs can be divided into two main categories:

- The protection of **industrial property** covers patents, utility models, industrial designs, trademarks, service marks, trade names, geographical

indications (indications of source or appellations of origin), and the repression of unfair competition.

- **Copyright** includes literary and artistic works, such as novels, poems and plays, films, musical works, and drawings, paintings, photographs and sculptures, computer software, databases, and architectural designs. **Related rights** include the rights of performing artists in their performances, producers of sound recordings in their sound recordings, and those of broadcasters in their radio and television broadcasts.
8. Additionally, **plant varieties** can be protected in many countries under IP-related systems of plant breeders' rights.
9. Under the WIPO Convention,⁶ “intellectual property” is not confined to the examples given above. The definition in the Convention concludes with the phrase “all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields”. It is clear that “intellectual property” is a broad concept and can include productions and things outside the existing categories of intellectual property, provided they result from “intellectual activity in the industrial, scientific, literary or artistic fields.” Other means of protecting intellectual property are available, such as trade secrets and private agreements for access to “know how”.

Patents

10. Patents are a form of social contract, where inventors receive an exclusive right for a specific period (20 years) to exploit their invention commercially in return for public disclosure of information about it. During the term of the patent, only the patentee may make, use or sell the invention.

11. A patent is granted for an invention, being a product or process offering a new technology, device or material. To be protected by a patent, an invention must:

- be novel, that is, the invention must have some new characteristic which is not known in the body of existing knowledge
- show an inventive step or be non-obvious
- be useful or a manner of new manufacture, and
- be sufficiently and fairly described.

12. Under the Patents Act 1953, all inventions may be patented as long as they meet the above criteria, with the exception of any the use of which would be contrary to morality.⁷ Other relevant features of patents include:

- patenting is an expensive process
- enforceability is geographically limited

- universality is expensive
- only reasonable exploitation is allowed
- statistically only a small number of patent applications are successful.

Plant variety rights

13. The intellectual property rights known as plant breeders' rights or plant variety rights (PVRs) are supplementary to the patent system. New Zealand is a signatory to the 1991 international convention known as the Union for the Protection of New Varieties of Plants (UPOV)⁸ but has yet to update the Plant Variety Rights Act 1987 to comply with this version of the convention. In order to gain protection, a plant variety must be:

- new
- distinct
- uniform, and
- stable.

14. A “distinct” plant variety is sufficiently different from existing plant varieties such that there is no confusion in identifying members of the new variety as separate from members of the old variety. A plant variety is “uniform” when the plants that make it up are sufficiently similar. A variety is “stable” if it remains unchanged through successive generations of reproduction or propagation. The “stability” of genetically modified plants is discussed in chapter 4 (Environmental and health issues).

15. PVRs are subject to two exceptions, differentiating them from the exclusivity provided by a patent. Other breeders may use a variety to develop new varieties and farmers may save seed for their own sole use in crop production, but not for sale.

16. However, because of the breeders' exemption, a person who patented a genetically modified variety of an existing variety would have exclusive rights. They would not require the permission of the New Zealand breeder of the variety they had genetically modified. Genetic modifiers could potentially free ride on years of research in breeding the unmodified varieties. For example, we were told of research overseas to develop a genetically modified Royal Gala apple. Commercial production of this variety has the potential to damage our market if consumers stop buying all Royal Gala apples because they cannot tell the difference between genetically modified and non-genetically modified apples.

17. This gap in protection was recognised internationally by provision of the concept of “essential derivation” in the 1991 version of the UPOV Convention. An essentially derived variety is one that is distinct from the initial variety in one

characteristic but otherwise has all of the characteristics of the initial variety. The essentially derived variety can be protected. However, it cannot be exploited without permission of the owner of the PVR for the initial variety. We agree with the NZIPA submission that, to protect New Zealand’s classically bred varieties, the New Zealand Plant Varieties Act ought to be amended to introduce the concept of essential derivation.

Recommendation 10.1

that the New Zealand Plant Variety Rights Act 1987 be amended to introduce the concept of essential derivation.

What IPRs are not

18. An inventor can register an IPR only over a new, non-obvious, inventive and useful idea. Anything that is in nature is part of the public domain. Traditionally a basic test of patentability has been whether the product or process has arisen from “a product of human ingenuity”?

19. A further point is that “invention” is not the same thing as “discovery”. For example the identification of a cell line or other genetic material is a discovery. To be granted a patent or other intellectual property over that discovery requires the application of that discovery to create a new product or process.

20. This means there is a distinction between a life form or its DNA and an industrial, agricultural or technological use of that life form or DNA. This leads to the distinction between the ownership of genes, as they exist in nature and a patent or other IPR over a gene or gene sequence. It has long been a feature of the patent system that naturally occurring products or “laws of nature” cannot be patented because they are not new or inventive and patentees could not describe how to make them.

21. Furthermore the grant of a patent does not confer immunity from challenge. If any part of a patent is shown to be invalid, the whole patent is invalid. Patents are also contestable. If a patent application is too wide, it can be challenged for “covetous claiming”.

22. On the other hand, the issue of a patent does give force to the patented product or process. This means people may choose to pay for licences to use potentially invalid patents rather than challenge the patent itself. This is often a commercial decision based on the cost and benefits of challenge against negotiating a licence and using the possibility of challenge as a bargaining tool.

23. Further, the grant of a patent is not an automatic right to use the invention. Any use by a patent holder is controlled under other applicable legislation, such

as the Hazardous Substances and New Organisms Act 1996 (HSNO), the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM), the Medicines Act 1981 and so on.

24. A patent granted under the Patents Act is effective only in New Zealand and Tokelau. New Zealand patents are also effective in Niue and the Cook Islands under the domestic laws of each country.¹⁰ Patents granted in other countries cannot be enforced in New Zealand. While there is no such thing as a worldwide patent, an international patent application may be filed under the Patent Cooperation Treaty¹¹ to protect an invention between the time of filing an application at home and the filing of applications in other countries where IP protection is sought. (Also see the box “The use of insulin in diabetes” in chapter 9: Medicine.)

25. The exercise of a patent is also limited to commercial activities.¹² Generally, information disclosed in a patent can be the basis of further experimentation or research without the authorisation of the patentee. This is subject to some limitations: if the patent is for a research application or tool then research is also the commercial use and must be licensed, and if the research user of information disclosed in a patent later wishes to market their invention which uses the first invention, they would need a licence from and pay royalties to the patent-holder.

International obligations applicable to intellectual property rights

26. New Zealand is a member of the World Trade Organization (WTO) and a party to the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement, which came into effect on 1 January 1995, is a comprehensive multilateral agreement on intellectual property rights.

27. The areas of intellectual property that it covers are: copyright and related rights (ie, the rights of performers, producers of sound recordings and broadcasting organisations); trademarks, including service marks; geographical indications, including appellations of origin; industrial designs; patents, including the protection of new varieties of plants; the layout-designs of integrated circuits; and undisclosed information, including trade secrets and test data.

28. The Agreement sets out the minimum standards of protection to be provided by each Member:

- The substantive obligations of the main conventions of the WIPO (the Paris and Berne Conventions) must be complied with. Secondly, the TRIPS Agreement adds a substantial number of additional obligations on matters where the pre-existing conventions were silent or seen as inadequate.

- Certain general principles are applicable to all IPR enforcement procedures. In addition, provisions specify procedures and remedies that must be available so that right holders can enforce their rights.
- Disputes between WTO members about the TRIPS obligations [are] to be subject to the WTO's dispute settlement procedures.¹³

29. In addition the Agreement provides for certain basic principles that prohibit discrimination. These require equality of treatment between nationals of member countries, and between a member's nationals and nationals of other members (articles 4 and 13). "Nationals" include companies as well as persons. Additionally, there are some general rules to ensure that procedural difficulties in acquiring or maintaining IPRs do not nullify the benefits that should flow from the Agreement.

30. Article 27(3) of TRIPS provides that members may exclude from patentability:

- (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
- (b) plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

The provisions of that subparagraph are to be reviewed four years after the date of entry into force of the Agreement. That review was initiated last year.

31. WIPO is an international organisation promoting the use and protection of intellectual property. It is one of the 16 specialised agencies of the United Nations system of organisations, administering 21 international treaties dealing with different aspects of intellectual property protection. WIPO counts 175 nations as member states, of which New Zealand is one.

32. UPOV is an intergovernmental organisation, based on the International Convention for the Protection of New Varieties of Plants, as revised since its signature in Paris on 2 December 1961. The objective of the Convention is the protection of new varieties of plants by an intellectual property right. The main activities of UPOV are concerned with promoting international harmonisation and cooperation, mainly between its member states, and with assisting countries, in the introduction of plant variety protection legislation. New Zealand has been a member of UPOV since 1981.

Community and individual rights

33. This section looks at the balancing of community interests against the economic and property rights of individuals, and the impact of international obligations. This section also considers questions of access and costs in relation to IPRs over genetic modification techniques and products.

Objectives of IP systems

34. The primary purpose of IP systems is to promote and protect human intellectual creativity and innovation. IP law and policy does so by striking a balance between the rights and interests of innovators and creators to benefit from their work, on the one hand, and of the public at large to have access to new ideas and technology on the other.

35. The argument in favour of IP systems is that, by granting exclusive rights in an invention, they encourage further innovation, reward creative effort, and protect the (often substantial) investment necessary to make and commercialise the invention. Public dissemination is an important IP objective. The patent system encourages people to disclose inventions, rather than retain them as trade secrets, increasing publicly available knowledge and promoting further innovation by other inventors. These submitters believe the progress and well-being of humanity rests on its capacity for new creations in areas of technology and culture.

36. Likewise, such submitters argue that the promotion and protection of IP can also spur economic growth, create new jobs and industries, and improve the quality and enjoyment of life. However, the IP system also responds to the needs of the public at large. Generally IPRs are of limited duration, after which they fall into the public domain (only trademarks and geographical indications can subsist indefinitely).

The demerits of IP systems

37. Dr Ulrich Loening, a molecular biologist who founded the Centre for Human Ecology, Scotland, gave written evidence on behalf of the Koanga Gardens Trust [IP72]. He referred to the economic and social implications raised by the introduction of gene biotechnology into regular agricultural usage, pointing out that without patenting and corporate ownership the present generation of genetically engineered crop plants would not exist. His view was that this results in the central control of products, reducing social and biological diversities with “monolithic consequences” for agriculture.¹⁴ Dr Vandana Shiva (Director of the Research Foundation for Science, Technology and Ecology, India) who wrote a witness brief for the Pacific Institute of Resource Management [IP84] made similar statements about the monopoly control on seeds through IPRs and the growing concentration of ownership control over agricultural inputs, which will increase food insecurity for millions of poor farmers.¹⁵ Dr Shiva also maintained that the monopolisation of life forms through IPRs makes for

“absolute rights and absolute irresponsibility” which she described as a recipe for disaster.¹⁶

38. Friends of the Earth New Zealand [IP78] made similar submissions about access to and use of seeds of genetically modified plants subject to patents.¹⁷

39. Professor Jonathan King, chair in molecular biology at the Massachusetts Institute of Technology, USA, was a witness by videolink on behalf of Greenpeace New Zealand [IP82]. On the issue of access to information, and who should control and benefit from it, he argued that the biotechnology revolution was the product of a broad-based biomedical research and training enterprise based in colleges, universities and medical schools.¹⁸ Essential to these efforts were the free communication and exchange of materials and ideas, and the organisation of research in the public interest. Major scientific advances, such as the determination of the amino acid sequences that made up protein chains, were openly communicated and entered the public domain.

40. Professor King’s opinion was that, because oral reports, abstracts, grant proposals and published papers all constitute prior art, individuals or groups planning to file for a patent have to avoid public disclosure of the work before the filing of the claim.¹⁹ Patent attorneys regularly advise researchers to restrict presentations to colleagues, so as not to jeopardise planned patent submissions. Professor King said that the resulting undermining and reversal of the scientific culture of open communication and exchange was one of the most destructive impacts of gene patents.²⁰ Whatever validity these arguments may have, the Commission considers they are not specific to gene patents.

41. NZIPA presented a different point of view. In the patent social contract the patentee’s consideration includes a full disclosure of the patented invention and the best way of practising that invention.²¹ Patent Cooperation Treaty international applications are published before a patent is granted in any country giving the public at large a description of what is intended to be protected. The discovery that led to the invention may be used in further academic research. For instance, although the sequences to the breast cancer genes BRCA have been patented, a recent Medline search shows several hundred papers have been published discussing these genes.

42. NZIPA submitted that another issue arising with patents generally, and no less so with those for genetic modification, was the relationship between the pioneer patent and improvement inventions.²² A simplistic example is a patent for a mousetrap (the pioneer patent) and a subsequent patent for a better mousetrap (the improvement patent). The exploitation of any patented invention must comply with all other laws, and that includes avoiding infringement of other

patents. It is likely that exploitation of the better mousetrap invention will, in the absence of permission from the pioneer, be an infringement of the pioneer patent. On the other hand the owner of the pioneer mousetrap patent may not exploit the better mousetrap invention without the permission of the owner of the improvement patent. Both owners have a negotiating chip and the commercial outcome of bargaining between them depends upon the relative commercial values of their respective inventions.

43. Further, NZIPA pointed out that the recognised pioneer US patents for genetic modification (US 4468464 and 4740470, biologically functional molecular chimeras) were licensed on a non-exclusive basis to anyone who applied.²³ The royalty rules were based on the level of commercialisation for which the licence was granted.

44. It was almost inevitable, in NZIPA's submission, that different owners will hold patents for different genes and different modification techniques.²⁴ Just as the mousetrap and better mousetrap patent owners need to strike a bargain, likewise the owners of patents for the different aspects of genetic modification to be used together in commercialisation must reach some accommodation. This is discussed further in chapter 8 in the boxed section on Golden Rice at page 180.

45. To a degree, the New Zealand Patents Act also guards against a patentee not making an invention available in New Zealand. Section 46 provides for an application to the High Court for issue of a compulsory licence to a third party if a market for the invention covered by a New Zealand patent is not being supplied on reasonable terms. This helps ensure that the patentee is not draconian about issuing licences or locking up the invention.

46. The New Zealand Dairy Board [IP67] told the Commission that:

... in many areas of genetic modification, the intellectual property is already closed off. Accessing this intellectual property for the purposes of research and development involves payment of royalties. For example, in the case of isogenic or transgenic cloning, currently the Roslin Institute in Edinburgh owns most of the intellectual property involved in the production of cloned or transgenic animals. It licenses this intellectual property to other organisations, such as Geron and PPL. Even the intellectual property represented by the tools used for phenotypic research or to produce genetic markers for use in breeding programmes is licensed.²⁵

47. The Board said it is therefore essential for the New Zealand dairy industry to obtain intellectual property so that it can have a base of IPRs to bargain with when seeking access to the intellectual property owned by others.²⁶

48. NZIPA provided the following estimate of genetic modification patent applications filed and/or granted in New Zealand to 24 October 2000:²⁷

Class description	Class number	Number of patents and applications
Cells modified by introduction of foreign genetic material, eg virus transformed cells	C12N5/10	538
Mutation or genetic engineering; DNA or RNA concerning genetic engineering vectors, eg plasmids, or their isolation, preparation or purification; use of hosts therefor	C12N15/00	580
Genes encoding animal proteins	C12N15/12	405
Genes encoding plant proteins	C12N15/29	137
Medicinal preparation containing genetic material which is inserted into cells of the living body to treat genetic diseases; gene therapy	A61K48/00	228

49. To put this in context, NZIPA advised that over the period July 1999 to June 2000 the Intellectual Property Office of New Zealand (IPONZ) recorded a total of 4187 patent applications (including International Patent Cooperation Treaty filings within New Zealand).²⁸ NZIPA commented that, while genetic modification patents represent a relatively small proportion of total patents filed, in the last decade there has been a significant increase in the number of biotechnology patent applications internationally.²⁹

50. In NZIPA's submission, if biotechnology is to be an important part of New Zealand's economic future, maintenance and improvement of intellectual property protection for genetic modification and genetically modified organisms is essential.³⁰ If patents for the product of research on genetic modification and genetically modified organisms could not be obtained in New Zealand, a number of negative economic outcomes would follow, including:

- increased cost for New Zealand to access international intellectual property, with less bargaining power from reciprocal information exchange
- the cost and difficulty in maintaining information as a trade secret

- exploitation of unprotected New Zealand information and products by others
- loss of revenue from licensing and royalties
- loss of revenue consequent on loss of competitive advantage.³¹

Moral and ethical issues

51. Submitters drew attention to the problem of accommodating moral and ethical considerations in the grant of IPRs. Section 17 of the Patents Act provides that:

- (1) If it appears to the Commissioner in the case of any applicant for a patent ...
- (b) That the use of the invention in respect of which the application is made would be contrary to law or morality ... he may refuse the application.

52. Article 27(2) of the TRIPS Agreement (see paragraphs 86 to 89) allows Members to exclude from patentability inventions:

... the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.³²

53. The relevance of the moral concerns is also recognised in Article 7 of TRIPS:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare and to a balance of rights and obligations.

54. Moral concerns and public policy issues, therefore, are not excluded from the ambit of intellectual property law. However, we were not made aware of any instance where a New Zealand patent application had been refused on the basis of section 17.

55. NZIPA submitted that issues of “morality” or ethical considerations, particularly those arising in connection with the patenting or granting of IP rights over genetic material or genetic modification processes, should not be dealt with under the IP framework or legislation.³³

56. The Commission recognises that biotechnology and genetic modification have ethical components not generally present in other IP applications. This is part of our reasoning for the establishment of Toi te Taiao : the Bioethics Council. In the case of an application for a patent that raises issues of public morality or ethics, IPONZ should have the ability or option to seek the views of the Council,

which will have the membership and expertise to consider issues sitting over and above the usual considerations for the grant of IPRs or PVRs.

Patenting living organisms

57. This section addresses the question “should we allow intellectual property rights over life forms?” There is public concern about the ownership of property rights in genetic material, and issues associated with such rights.

58. Current criteria of patent systems date from the eighteenth century, long before development of the technology that allowed the genetic modification of living organisms. Initially patents were mainly concerned with chemical compounds and industrial processes and devices. The commercial possibilities of the novel products and processes that could be developed through genetic engineering quickly led to applications for protection under intellectual property regimes.

59. Professor King argued on behalf of Greenpeace that an aspect of the rapid commercialisation of biotechnology troubling people was the transformation of biological entities into private property through the use of IPRs.³⁴ They were the products of hundreds of millions of years of evolution and this transformation represented a radical change in the relations between human societies and biological species and resources. Professor King went on to say that the mutation of the common biological heritage into corporate property through patent monopolies was proceeding without social oversight or democratic input.³⁵

60. Te Runanga o Ngai Tahu [IP41] said that it is as if:

every living species has suddenly become a reservoir of potentially useful genes or the possible hosts for the cultivation of interesting genes or substances that can later be extracted.³⁶

61. While the “product of nature” doctrine protected biological entities from patentability, genetic modification of microorganisms and other products has challenged this. In 1980 the United States Supreme Court allowed a patent on a new genetically engineered bacterium³⁷ and eight years later the Harvard “oncomouse” was patented.³⁸ In Europe, the patentability of living organisms did not proceed as quickly as in the United States. An EU Directive on the Protection of Biological Inventions allows patents on plants and animals if the invention is applicable to more than one variety, so genetic modification of plants with the Bt gene is patentable.

62. The debate on patenting living organisms also covers the identifying and characterising of particular biological molecules or genes.

63. From the time of development of the first agrarian society, humans have held and traded property in life forms. New Zealand’s predominantly agricultural economy is founded on the principle that plants and animals can be owned, bred and sold. Despite this, a common public concern about gene modification relates to the legitimacy of “owning life”. Various groups objected to the concept of private ownership of genetic material or activities associated with it.³⁹ NZIPA submitted that these concerns were based on a misunderstanding of the patent system and the extent of the property rights granted.⁴⁰

64. Natural products and naturally occurring DNA sequences cannot be patented in their natural source or environment because they are not new or inventive. This means that genes, whether human or not, must have been isolated, purified or recombined to a degree that does not exist in nature before patent protection can be obtained. To ensure a valid patent the applicant for a patent must also establish the function of a gene sequence. Furthermore, a gene sequence is not “life”. It is the chemical code for a sequence of DNA. Genes used in genetic modification are synthesised constructs based on this code. However, once genes are inserted into an organism such as a plant or animal, this new life form may also be patented and the patentee has the right to defend the invention from unauthorised commercial exploitation by others.

Ethical, social and cultural objections to patenting genetic material

65. A strong theme in a number of submissions to the Commission was that the obtaining of patents on genetically modified cells and organisms represented a sharp departure from the traditions of human societies. Farmers have always owned the crops they grew, but they had no legal rights to restrict others from growing those crops. Professor King submitted:

The Monsanto patent on transgenic cotton extends to all the progeny of such plants and allows Monsanto to prevent farmers from saving the seed of crops they have grown and planting them the next season. The cloning of Dolly was not announced until the Roslin Institute had filed patents not just for cloned sheep, but for all animals produced anywhere in the world by a similar process. The patent claims being filed within the US on the genes of humans, sheep or corn are being enforced on a worldwide scale. They expropriate the common heritage of New Zealanders and humans everywhere. Such private expropriation of fundamental biological resources reflects a qualitative change in access to basic biological knowledge and to the relations between human society and the natural world.⁴¹

66. SAFE (Save Animals From Exploitation) [IP85] submitted that the patenting of sentient beings was morally wrong and that the notion of intellectual property

should not extend to the legal ownership of a genetically modified species of a sentient being. It argued that “it is a significant and dangerous jump to move from ownership of individual animals to ownership of an entire species of animal that has been genetically engineered”.⁴²

67. By way of comment on the SAFE submission, the Commission has already noted that an essential feature of patentability is the product has arisen as “a product of human ingenuity”. On this ground, patenting has been unavailable in respect of the establishment of new lines of progeny by conventional breeding, whereas when similar results are now produced by genetic modification, patents may be available to protect the process.

68. Greenpeace also called for a halt to the granting of any patents on life, its parts, products and processes.⁴³

“Patenting of humans”

69. The morality question also arises when considering whether patents should be granted for humans and human related matter. The morality section (section 17) of the Patents Act is the basis for IPONZ policy to refuse patents for humans. Also, sections 2 and 10(7) prevent the patenting of a substance found in nature. Further, as already noted, the novelty requirement means that the invention to be patented cannot constitute something already known or disclosed to the public, which therefore excludes body parts and organs.

70. Taken together, these patent criteria ought to mean that a patent cannot be obtained over a human, a human body part, or a human gene in its natural host, a human. At best a patent could be granted for a synthetic DNA molecule carrying the same information as found in the human body, or a method for producing a novel human organ or body part suitable for transplantation. It should be noted that the discovery of a method of producing a liver “in vitro”, for example, would only give the patentee a right to exclude others from producing livers using this method. It gives no ownership rights to any person’s liver. Consequently any public perception that “people are being patented” is a misconception of patent law.

71. Under existing New Zealand legislation and practice it is unlikely that a patent covering human beings would be granted. However, to put the issue beyond doubt it would be desirable to cover the point specifically by statute.

Recommendation 10.2

that the Patents Act 1953 be amended by adding a specific exclusion of the patentability of human beings and the biological processes for their generation, in line with section 18 of the Patents Act 1990 (Commonwealth).

Protection of traditional knowledge

72. This section discusses particular concerns raised by Maori submitters about the IPR system.

73. A fundamental issue was the incompatibility of the Western IPR system with the principles of the IPR systems of indigenous people. This has two aspects: at the national level, Maori submissions pointed out how the IPR system within New Zealand is in conflict with Maori values such as kaitiakitanga, tapu, mana o te iwi, and communal ownership. At the international level, states that are signatories to international agreements, such as TRIPS, are restricted in how far they can change their IPR systems unilaterally to meet the concerns of indigenous peoples.

74. A second major issue was that of sovereignty over genetic resources, in particular native flora and fauna. This is the subject of claims to the Waitangi Tribunal, the WAI 262 and WAI 740 claims.

Intellectual property rights and traditional knowledge

75. Native flora and fauna, and traditional knowledge of their properties and uses, can be used as a resource for furthering Western scientific knowledge, or for commercial exploitation, for example through processes which may use genetic modification techniques.⁴⁴ This in turn gives rise to issues of ownership, veto, access, and benefit sharing with indigenous peoples who have developed the knowledge, and have guardianship responsibilities for the plants and animals. There are values held in common amongst indigenous peoples worldwide which are relevant to such issues. The WAI 262 claimants, Ngati Wai, Ngati Kuri, Te Rarawa [IP89] submission,⁴⁵ for instance, referred to a draft code of ethics prepared by the International Society of Ethnobiologists which records such principles as traditional guardianship, confidentiality, and the communal nature of “rights” to natural resources.⁴⁶

Te Ao Maori and IPRs

76. Submissions to the Commission set out how IPRs and the traditional values of Maori society are at odds.

77. Te Runanga o Ngai Tahu said:

There is inadequate legal protection of biodiversity-related knowledge. The conventional intellectual property rights systems that are based on the concepts of individual ownership and private property rights are designed essentially to act as an incentive for inventions and to facilitate technology transfer and access. Current processes are inadequate to protect indigenous knowledge essentially because it is based on the protection of individual rights while the ownership of traditional knowledge is by and large collective in nature.⁴⁷

78. Sister Makareta RMJ (Atihaunui-a-Paparangi) at the Wanganui hui reminded people that the celebrated composer Ngoingoi Pewhairangi of Ngati Porou refused to copyright her songs:

as the gift belonged to her hapu and not only to her. And so, to copyright her songs in her name as an individual would be to deny her whakapapa.⁴⁸

79. The WAI 262 submission summarised the problems in this way:

The IPR system is concerned with private economic rights whilst those of indigenous people are collectively based and consider obligations to and respect for natural resources as important as the right to use those resources.⁴⁹

80. To look at the issues in more detail, it seems that the basic criteria for obtaining, say a patent, are opposed to the relevant principles in te ao Maori. For example, a patent is:

- *Not available in respect of material or a process that is known and not novel.* Traditional knowledge has been developed over time: by definition, it is not the new creation of an individual or group. Traditional knowledge does not meet the first criterion for patentability.
- *Limited in time.* Traditional knowledge is ancestral and held in trust for future generations. A time frame of 20 years protection is inconsistent with these obligations. When the patent expires, the knowledge is open for all to exploit, even if this transgresses tapu and degrades taonga and mana. Ngai Tahu Taua, Cath Brown, explained at our Christchurch hui that the Maori weavers group, Te Roopu Raranga-Whatu o Aotearoa, had applied to patent an extract from coprosma used to dye flax baskets yellow in order to head off a French company which was investigating its use as a hair dye. On the question of time limits she stated:

It has worked so far but then you lose your patents – they wear out after so many years and then what do we do?⁵⁰

- *Public*. For a patent to be granted, it must be fully and sufficiently described and that description published. This is in conflict with the Maori way of storing knowledge orally, with a few trusted people, protected by ritual and karakia. Publication undermines the integrity of traditional knowledge.

81. Issues of seeking to reconcile indigenous and Western IPR systems are becoming more pressing as rapid advances are made in biotechnology. The need for action, domestically or internationally or both, was raised by a wide range of submitters.⁵¹ We refer to the international aspect below.

82. Within New Zealand we consider there is room for both immediate and longer term change. Review of the current statutes governing IPR, for example the Patents Act 1953, has been under consideration for some time. In 1994 the then Ministry of Commerce established Maori focus groups to review such matters as trade marks and patenting of life forms. A discussion paper issued by the Maori Trade Marks Focus Group proposed:

- no registration if culturally inappropriate
- culturally aggrieved persons could oppose applications or apply to have trade marks removed from the register
- establishment of a Maori consultative committee to IPONZ
- applicants required to prove they had permission to use Maori symbols, words, sounds.⁵²

83. Some of these proposals do not need legislative change, for instance establishing a consultation process.⁵³ It seems that IPONZ does not yet have any formal system of consultation with Maori about applications it receives, although we understand that applicants must show that they have consent from relevant Maori sources, for instance an iwi authority, in appropriate cases. Given the concerns raised by submitters in relation to genetic modification, and patents and plant varieties in particular, we consider that an established system of consultation is overdue. We have discussed the general importance of consultation elsewhere in this Report. It is sufficient here to note that a systematic approach of consulting Maori who are mandated by, and accountable to, the Maori community is required in the area of applications to IPONZ as well. In relation to patents, any recourse to Toi te Taiao : the Bioethics Council as suggested in paragraph 56 would be an additional source of assistance if required.

84. More generally, both the Maori Congress [IP103] and the WAI 262 claimants proposed that protection for Maori intellectual heritage rights be developed, and developed primarily by Maori. Both parties suggested the elements for a protective framework must:

- recognise the tino rangatiratanga of hapu and iwi in relation to their own cultural heritage rights and taonga

- be flexible so that differences and shared interests between tribes can be reflected and accommodated
- contain protocols for dealing with internal issues between individuals and the collective based on appropriate tikanga of the group and for dealing with persons outside the collective wishing to gain access to knowledge and taonga
- include sanctions and penalties for infringement, procedures for prior informed consent, compensation/financial protocols where relevant, and enforcement procedures
- provide for special legislation developed to give effect to mechanisms and protocols.

Recommendation 10.3

that a Maori Consultative Committee be established by the Intellectual Property Office of New Zealand to develop procedures for assessing applications, and to facilitate consultation with the Maori community where appropriate.

International obligations

85. In the international context, there is discussion about the need to amend conventions and agreements on intellectual property to allow reservations on grounds of protecting cultural heritage. This includes safeguards against proposals that are culturally offensive to indigenous peoples. However, progress is slow.

86. One aspect is the issue of amendments to the TRIPS Agreement, Article 27, and similar provisions in associated conventions requiring reciprocal registration of trademarks, patents and industrial designs. As noted earlier Article 27(2) of TRIPS allows signatory countries to exclude inventions from patentability where this is necessary to protect “public order or morality”. The latter terms are not defined, but a central issue for Maori is that it is not clear that they allow signatory countries to exclude applications on the basis of cultural offence. An example might be an application to patent a process to extract and modify genes from tuatara for a product to promote longevity.

87. In 1993 New Zealand ratified the Convention on Biological Diversity (CBD) which provides for signatories to:

... respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity ...

88. But there are tensions between the CBD and TRIPS. The CBD, for example, states that access to genetic resources should be subject to “prior informed consent”, meaning that authorisation of the donor or community holding the resource or material should be sought and obtained in order to access the resource and/or the knowledge. TRIPS on the contrary, assumes free access and does not mention the concept of consent or consultation in accessing source material.

89. Moreover, TRIPS does not provide for collective rights. The Preamble states that “intellectual property rights are private rights”. This in itself appears incompatible with the communal approach common to many indigenous people. Again, TRIPS does not have any provision recognising the principle of benefit-sharing or acknowledging relationships or rights between donors of material and patent holders. The absence of provisions for acknowledgment or protection of sources of IPRs in TRIPS, and the incorporation of such a principle in the CBD, demonstrates a fundamental difference between the two agreements.⁵⁴

90. The need for reforms in this area, at home and internationally, clearly extends beyond the field of genetic modification. However, the specific categories of patents and PVRs are directly relevant to genetic modification. For this reason, and in response to the call we heard for reforms, we have considered the issues in some detail. Domestic law reform cannot proceed completely independently of international change. With the Mataatua Declaration of 1993 (see box page 292) members of the New Zealand community showed world leadership in the area of promoting international indigenous rights to intellectual property. We believe this initiative should be maintained to pursue progress in this area.

Recommendation 10.4

that New Zealand be proactive in pursuing cultural and intellectual property rights for indigenous peoples internationally.

Recommendation 10.5

that New Zealand pursue the amendment of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights and associated conventions to include a reference to the avoidance of cultural offence as a specific ground for exclusion or reservation.

Sovereignty over genetic resources: flora and fauna

91. The question submitters raised was who owns native flora and fauna? This led to issues about profits derived from exploiting native plants and animals, and whether and how Maori should share in such profits. Some took the view that any profits made should stay in New Zealand, rather than flow overseas to multinational corporations. The Federation of Maori Authorities (FoMA) [IP69] for instance, said there was concern in the Maori community about what was being sold in this country, and that the thought of purchase by foreign companies of assets here, of things belonging to Maori as a people, was abhorrent.⁵⁵

92. Most Maori submitters⁵⁶ saw patents, copyrights and plant variety rights as an extension of private ownership, with private economic benefits, that shut out Maori.

93. There was some confusion over what was patentable and what was not. Mr Calhoun (NZIPA) said:

A naturally occurring substance is not an invention. However, the discovery of a product of nature, and the industrial application of that discovery is an invention. Thus, water from the hot pool in Rotorua was not an invention, but the microorganism was when isolated in an artificial environment where it produced proteins.⁵⁷

94. When asked about the example we had been quoted of a patent on a variety of pohutukawa, Mr Calhoun said:

That seems to be one of those rural or urban myths. There was a story about a French company owning the plant variety right on the pohutukawa, and the Commissioner of Plant Varieties ... keeps a register and he says he has no Plant Variety Right which has that. I guess anybody who does state that as an example, ask them for the number of the PVR.⁵⁸

95. There was concern that Maori could be shut out by patents from using traditional materials such as plant-derived dyes. A case in point is that of the Maori weavers group referred to earlier and their application to patent a plant extract specifically to prevent its use by an overseas company.

96. There was also concern that Maori would see little in the way of benefit sharing of profits from the use of native flora and fauna under the current intellectual property regime. As Pare Bennett (Atihaunui-a-Paparangi, Muaupoko) at the hui at Wanganui said:

Ko te take kaore te hunga whai rawa i te tohatoha atu nga rawa ki te katoa no reira kaore matau te ropu i te whakapono i te korero kua whakaputa mai ma te katoa tenei hangarau hou. Ko te take, ko te whai moni, whai putea me te mana.⁵⁹

(The wealthy are not sharing the wealth with everyone, so we (the group) do not believe the statement that this new technology will benefit everyone. Their sole concern is the pursuit of money, wealth and power.)

97. She expanded this:

E ai ki a matau, kei nga hapu o Aotearoa nei te mana motuhake i runga i raro, i roto i waho, i nga ira tipu taketake, i nga ira kararehe taketake, o nga ira tangata whenua hoki.⁶⁰

(In our view, the hapu of Aotearoa have the mandate and last say over the control of the genes of indigenous plants, animals and indigenous people.)

Ownership and the Treaty of Waitangi

98. Article 2 of the Treaty of Waitangi guarantees Maori:

te tino rangatiratanga o ratou wenua o ratou kainga me o ratou taonga katoa.

(the full exclusive and undisturbed possession of their Lands and Estates Forests Fisheries and other properties which they may collectively or individually possess so long as it is their wish and desire to retain the same in their possession)

99. To what degree the Treaty of Waitangi gives Maori ownership and control over the exploitation of native flora and fauna is disputed, and is currently being heard in the Waitangi Tribunal as the WAI 262 claim.

100. In our formal process we received a submission from three hapu in Tai Tokerau who are joint claimants in WAI 262 along with Ngati Kahungunu, Ngati Porou and Ngati Koata. At two of our hui, Hastings and Blenheim, we heard from iwi members involved in other parts of the claim. We also heard from Fred Allen (Te Atiawa) at the Wellington hui, who has a parallel claim, WAI 740, being heard at the same time. There was concern from submitters about the need to resolve the claims and the issues as quickly as possible. As Tuwhakairiora Williams presenting for Maori Congress said:

The findings of the [Waitangi] Tribunal in relation to WAI 262 are absolutely critical to this whole debate, this whole issue of genetic modification.⁶¹

101. The Commission agrees. We were told that the WAI 262 claim was lodged with the Waitangi Tribunal in 1991, but traditional knowledge hearings commenced only in September 1997.

102. Mr Williams went on to say:

It's been difficult for the Tribunal to make further progress on WAI 262 due to a lack of resources that are required to ensure that this claim can be heard in a timely manner.⁶²

103. Whether or not lack of resources has been a factor in delaying progress with this claim, the fact that it is still unresolved means that even alternatives to the ownership model asked for by hapu in the WAI 262 claim cannot be considered. FoMA submitted that native flora and fauna should be owned in trust for all New Zealanders. Greenpeace and Maori Congress pointed out that other countries were investigating ways that economic benefits derived from their native flora

and fauna could be retained. The submission listed Costa Rica, Tonga and the countries bordering the Andes.

104. Currently, as a signatory of TRIPS, New Zealand is not permitted to make any distinction between exploitation by local and international applicants. Under Article 27(2), however, it may exclude patentability where prevention of commercial exploitation is necessary “to protect human, animal or plant life or health”, or to avoid “serious prejudice” to the environment. As far as New Zealand is concerned, it is not clear that any finding by the Waitangi Tribunal that Maori own or control access to particular material or information can, on its own, prevent others from using that material and information to generate their own novel inventions or

Mataatua declaration

In 1993, the nine tribes of Mataatua in Aotearoa New Zealand convened the First International Conference on the Cultural and Intellectual Property Rights of Indigenous Peoples.

Over 150 delegates from 14 nations attended, including indigenous representatives from Ainu (Japan), Australia, Cook Islands, Fiji, India, Panama, Peru, Philippines, Surinam, United States and Aotearoa.

The Conference met to discuss issues including the value of indigenous knowledge, biodiversity, biotechnology, customary environmental management.

Over the course of six days, delegates considered principles of the cultural and intellectual property rights of indigenous peoples.

On the final day, delegates agreed on the terms of a declaration, known as the Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous Peoples, June 1993.

In summary, the Preamble to the Declaration provides that the indigenous peoples of the world:

Declare they have the right to self determination and to be recognised as the exclusive owners of their cultural and intellectual property

Acknowledge a commonality of experience

Affirm that their knowledge is of benefit to all humanity

Recognise that they are capable of managing their traditional knowledge but offer it to all humanity provided their fundamental rights to define and control this knowledge are protected by the international community

Insist that the first beneficiaries of indigenous knowledge must be the indigenous descendants of such knowledge

Declare that all forms of discrimination and exploitation of indigenous peoples, their knowledge and cultural and intellectual property rights must cease.

processes. Nevertheless, resolution of the claim is likely to be a major element of any moves to reform the IPR system in this country.

Recommendation 10.6

that all parties concerned work to resolve the WAI 262 and WAI 740 claims currently before the Waitangi Tribunal as soon as possible.

Bioprospecting

105. Currently, there is no legislation specifically regulating bioprospecting in New Zealand, except to the extent that the Crown or private individuals could prevent or restrict entry on to Crown land or private property for the protection of particular plants or animals and their habitats. Some countries have developed systems to license and control such activity to protect their cultural heritage or to benefit the local peoples and communities, eg Costa Rica, Iceland and the Andean Community system. This is an area that ought to be considered in conjunction with the investigation and setting up of a framework to address the concerns raised by Maori before this Commission, and more generally by indigenous peoples around the world.

106. Furthermore, while ownership issues remain unsettled, it is difficult to prevent overseas companies seeking patents based on native flora and fauna which may not return any economic benefits to New Zealand. This is called biopiracy or bioprospecting, depending on whether one approves of it or not. Biopiracy was raised with the Commission by Maanu Paul, Chair of the New Zealand Maori Council [IP105], in regard to an indigenous purple forest berry, which has interesting hormone substances that may have medical uses.

Changes to current system

Confidentiality of data provided in applications to ERMA

107. Submitters raised concern regarding the confidentiality of data provided for the purposes of approvals to experiment with, or market, new compounds and organisms under HSNO and the Agricultural Compounds and Veterinary Medicines Act (ACVM).⁶³ NZIPA submitted that when such information is released it has a major adverse impact on the future patentability of products, especially in cases where approval is required at an early stage.⁶⁴ They were concerned that when HSNO came fully into force, and other pending legislative changes were in effect, current provisions protecting “confidential supporting

information” would disappear.⁶⁵ Consequently, any confidential information supplied to ERMA concerning genetically modified organisms would potentially be available to the public, including an applicant’s competitors.

108. The Commission recognises the importance of this matter to applicants before ERMA. The requirement to protect confidential information in the approval of pharmaceutical or agricultural chemical products that contain new chemical entities is recognised by Article 39(3) of the TRIPS Agreement. In 1994 such provisions were incorporated into the Medicines Act, the Pesticides Act 1979 and the Animal Remedies Act 1967. They provided that “confidential supporting information” should remain confidential to the regulating authority and should not be used by regulating authorities in assessing any subsequent application for the same chemical or biological entity.

109. The Pesticides and Animal Remedies Acts will both be repealed when the provisions of HSNO come into force for hazardous substances. The protection they currently give to confidential supporting information will disappear with them.

110. Section 55 of HSNO imports the provisions of sections 23A to 23C of the Medicines Act and sections 35A to 35C of the Animal Remedies Act. The protection for undisclosed information provided under these Acts will only apply where the information held by ERMA is in connection with an application for approval of a hazardous substance, and it is also the subject of an innovative medicine application or an innovative animal remedy application, respectively.

111. When ACVM comes into force, section 55 of HSNO will be amended to import the provisions of Part VI of ACVM. The protection for undisclosed information provided under ACVM will apply where the information held by ERMA is in connection with an application for approval of a hazardous substance, but only when it is also the subject of an innovative agricultural compound application.

112. Genetically modified organisms do not fall within the statutory definition of a hazardous substance. Even if they are also the subject of an innovative medicine or animal remedy/agricultural compound application, the provisions for protection of undisclosed information imported under section 55 will not apply.

113. The end result of these legislative changes is that confidential supporting information relating to genetically modified organisms submitted to ERMA is not given the protection under HSNO it formerly had under the Medicines Act, the Pesticides Act and the Animal Remedies Act. This protection should be restored so that New Zealand complies with its obligations under Article 39(3) of TRIPS.

Application of Official Information Act

114. HSNO section 57 provides for information, including trade secrets, submitted in support of an application to ERMA for approval to be withheld under section 9(2)(b) of the Official Information Act 1982 (OIA). Following public notification, if ERMA receives a request for information from a third party and ERMA is of the opinion that the requested information may be withheld under section 9(2)(b), or the supplier of the information has marked it as commercially sensitive, the applicant will be notified of the OIA request. The applicant is allowed 10 working days from receipt of the notice to respond. In the absence of a response, ERMA may release that information without further reference to the applicant.

115. Submitters and their advisors were concerned that a trade secret, perhaps worth millions of dollars, could be released and its value lost because of such a provision, with its potential for miscommunication and timing delays. The Commission considers this concern is valid.

116. It was submitted that section 57 should be repealed, and likewise section 12 of the ACVM Act, which is modelled on section 57.

Recommendation 10.7

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

Conclusion

117. The economic benefits of intellectual property systems are generally considered to be positive. Removing biotechnology developments from coverage by patent or property rights systems would not necessarily have the effect that opponents to such applications want. New inventions or ideas would probably be kept as trade secrets or “know how”, and, in the absence of the disclosure required by patents and PVRs, be held even more tightly. Not allowing New Zealand inventors and investors to protect their work under an IPR would leave them in an invidious position against the rest of the world. It would also place New Zealand in breach of its obligations under major trade agreements.

118. The Commission sees a need to address some tensions or gaps, notably in the exemption for patenting of human beings and their biological processes, and the development of an appropriate framework for the protection of traditional knowledge and taonga of Maori. However, we are not persuaded that the IPR system is antithetical to the appropriate development and regulation of genetic modification.

chapter |

11

Te Tiriti o Waitangi

11.

Te Tiriti o Waitangi

Key issues:

- The Commission and the Treaty
- Crown responsibilities under the Treaty
- Consultation with Maori
- Changes to statute.

Introduction

1. A significant element of the Commission’s processes was the consultation with Maori, described in detail in appendix 1, section 3.6 (Maori Consultation: the process). This chapter is not about the Maori response, which is recorded throughout the Report, notably in appendix 3, section 4 (Analysis of the Maori Consultation). The present chapter deals with the impact of the Treaty on present and future uses of genetic modification in this country. It also addresses the manner in which Maori and Treaty issues are dealt with in the Hazardous Substances and New Organisms Act 1996 (HSNO).

2. The Treaty of Waitangi is an agreement signed initially¹ on 6 February 1840 at Waitangi, in the Bay of Islands, by representatives of the British Crown and of Maori. Under the Treaty, Maori agreed to give the Crown rights to govern and promote British settlement, and the Crown guaranteed Maori protection of their interests, and full citizenship rights.²

3. The importance of the Treaty as a founding document in New Zealand history has been recognised from the beginning, particularly in the Maori community.³ However, as a matter of law and enforcement in the courts, it came to prominence in the latter half of last century. The courts have described the Treaty relationship as a partnership,⁴ and a jurisprudence of formulating “principles of the Treaty” has evolved. These principles have emerged from decisions of the Waitangi Tribunal (a standing commission of inquiry charged with investigating

breaches of the Treaty), from the courts, and, on occasion, from government publications.⁵ Agreement on what the principles are, and the precise form in which they should be stated, is still developing.

4. However, two fundamental principles were referred to in many of the submissions we received on this matter. For this reason, they are noted here as Treaty principles particularly relevant to the debate on genetic modification. They are:

- *active protection*: the Crown has a duty of active protection of Maori interests
- *cooperation*: the Treaty requires each party to act reasonably and in good faith towards the other; this requires the Crown to consult with Maori so as to make informed decisions about matters of significance.

The Treaty and the Commission

5. It became clear that some submitters saw the Commission itself, and its processes, as in breach of the Treaty of Waitangi. They referred to matters that preceded the establishment of the Commission, and on which we are therefore unable to comment, for instance lack of consultation with Maori about the terms of reference, and about who should be appointed as Commissioners.⁶ Others focused on matters outside the Warrant, such as a perceived obligation to “implement” the Treaty and effect constitutional change before examining any questions of genetic modification.⁷

6. Some submitters referred to the need to acknowledge rangatiratanga, particularly over Maori resources.⁸ Another submitter criticised the legislation governing the Commission (the Commissions of Inquiry Act 1908) as in breach of the Treaty because its provisions were seen as not permitting full and active consultation with Maori.⁹ It is beyond our brief to comment specifically on these points.

7. Criticism of the Commission’s processes was based on the propositions that the Commission was an agent of the Crown and, as such, obligated to take reasonable steps to consult with Maori, in terms of Treaty principles, so as to inform itself sufficiently. As to the first, legal advice from the Crown Law Office was that the Commission was not an “agent” of the Crown. The test of Crown agency has two parts:

- whether the functions of a body properly belong within the province of government, and
- the nature and degree of the control that Ministers and other central government agencies exercise over the body.¹⁰

8. Crown Law advised that, while the first part was satisfied, the second and more important test was not. From the terms of the Warrant and the manner of the Commission’s appointment (ie by the Governor-General in Council) it is clear that the Commission was expected to carry out its work and reach its conclusions independently of government, which is how, in fact, we have operated. The Commission’s independence, in the Crown Law Office’s opinion, precluded it from being an “agent” of the Crown.

9. However, even were the legal position otherwise, the Commission is confident that it more than fulfilled the requirements of reasonable consultation for the purpose of informing itself before preparing this Report. As previously indicated, the way in which we set out to do this is recorded in appendix 1, section 3. With the help of views obtained at an initial scoping hui, the Commission arranged an extensive programme of information workshops and hui. Maori also participated in public meetings, formal hearings and the public submissions process. Nevertheless, concerns were voiced that the time frame imposed by the Commission’s tight reporting requirements would impair the consultation process because of absence of sufficient information and knowledge about the issues, and the lack of time to consider and respond to them.

10. In part, the workshop programme was a response to these concerns, which the Commission heard less frequently as the consultation proceeded. The Commission wishes to add that, in the initial stages of the inquiry, it heard similar concerns at public meetings; again, they were voiced less often as the nature and extent of the Commission’s consultation process became apparent.

Crown responsibilities under the Treaty

11. The Warrant sought views on the Crown’s responsibilities in relation to genetic modification under the Treaty. There has been some divergence in submissions about what this part of the Warrant might mean:

- that Maori views have “no primacy” resulting from the Treaty, but that Maori had established a “community of interest”, which required their views to be taken into account along with others¹¹
- that the Crown’s obligations in this area were unclear¹²
- that it was premature to address this matter while such cases as the WAI262 claim to the Waitangi Tribunal, or the appeal to the High Court (the *Bleakley* case¹³), were still outstanding.¹⁴ Regardless of that, however, we are required to report on Treaty obligations. So far as the *Bleakley* case is

concerned, in fact the High Court decision became available before the Commission completed its work and has been taken into account.

12. There were written and oral comments, in both Maori and non-Maori submissions, that the Treaty is a relevant or essential consideration.¹⁵ For the Maori Congress [IP103] it was, in fact, the starting point for consideration. As far as the obligations arising from the Treaty are concerned, there has been a measure of consistency in submissions from Maori and non-Maori sources. Both have referred to the duty or responsibility for active protection of Maori interests, and the duty or responsibility to consult.¹⁶ Reference has also been made to duties of equity and redress, acting in good faith, reasonableness and cooperation.¹⁷ As one submitter has put it:

... the Crown's responsibilities under the Treaty of Waitangi mean relating issues about GM back to the principles of partnership, protection and participation ...¹⁸

13. Other submissions have referred to what could be called an economic element in applying the Treaty. For some, a perceived lack of clarity about the principles means that a pragmatic approach is needed, calling for Crown action on behalf of all New Zealanders to help secure national benefits through genetic modification.¹⁹ But there has also been comment that:

The Treaty of Waitangi requires the Crown to promote the well-being and economic prosperity of all New Zealand's peoples. A strategy in which the Crown approves and encourages the responsible research, development and application of genetic modification in New Zealand is consistent with this requirement. The desire of Maori to place genetic modification technologies under fair scrutiny should be supported.²⁰

14. As noted, certain points emerge as particularly relevant to our inquiry, namely the principles of consultation, active protection of Maori interests, and of partnership. In addition, there is the pervasive principle that the Treaty calls for reasonableness and cooperation.²¹ The obligation to consult requires reasonable steps to be taken to consult. The principle of partnership requires the Treaty partners to cooperate to make the partnership work.²²

15. We consider that the responsibilities to consult and to actively protect Maori interests are closely linked: consultation is needed, for instance, to identify the relevant interests and how best to protect them. We therefore discuss aspects of the process of consultation briefly here. Discussion of the cultural concepts underpinning the Maori approach to consultation is contained in chapter 3 (Cultural, ethical and spiritual issues).

Consultation

Consultation requirements

16. Crown consultation with the Maori Treaty partner is a fundamental part of any process for dealing with questions of genetic modification. Over a decade ago, the Court of Appeal stated:

We think it right to say that the good faith owed to each other by the parties to the Treaty must extend to consultation on truly major issues.²³

17. We have looked at what such consultation might involve. As a matter of law, the Courts have indicated that,²⁴ in general, consultation means:

- providing information
- providing an opportunity to comment on a proposal
- that the decision-maker maintains an open mind in order properly to consider the views expressed.

18. We note that the importance of consultation between the Treaty partners was raised at public meetings, and at every hui in our consultation process, for instance by Sir John Turei (Tuhoe) at Orakei Marae.

19. We were reminded at our formal hearings that consultation is not the same as agreement, or even negotiation.

20. The responsibility to consult is not unlimited. In 1987 the Court of Appeal said:

... the notion of an absolute open-ended and formless duty to consult is incapable of practical fulfilment and cannot be regarded as implicit in the Treaty. I think the better view is that the responsibility of one Treaty partner to act in good faith fairly and reasonably towards the other puts the onus on a partner, here the Crown, when acting within its sphere to make an informed decision, that is a decision where it is sufficiently informed as to the relevant facts and law to be able to say that it has had proper regard to the impact of the principles of the Treaty.²⁵

21. The amount of consultation required to meet this test will vary.²⁶

Practical difficulties

22. We have heard about the difficulties of applying these principles in practice. For instance, applicants to the Environmental Risk Management Authority (ERMA) who have been advised to consult with Maori about their proposals have spoken of their difficulty in knowing whom to consult. Cost has also been a concern.²⁷

23. On the other hand, there are Maori concerns that consultation is often carried out too late, is too brief and that, on occasion, isolated individuals have been expected to respond on behalf of one or more hapu or iwi, or sometimes on a national basis. Dr Mere Roberts, of Nga Kaihautu Tikanga Taiao, an advisory committee of ERMA, spoke of the “almost impossible task” of speaking on behalf of Maori given current time and resource constraints, and was also concerned about the pressures and difficulties of “the solitary Maori on an IBSC”.²⁸ Other submissions stressed the importance of acknowledging Maori scientific knowledge, and the need to avoid regarding Maori views solely as a “cultural” response to consultation.²⁹ Moana Jackson spoke of the perception that:

... the views of our people are at best a cultural clip-on, and at worst irrelevant to the “real” scientific, ethical, and intellectual issues that need to be resolved. Our people are being silenced even as they are overwhelmed with cultural sensitivity or embraced in Treaty partnership.³⁰

24. It is outside our brief to comment in a general way on consultation processes with Maori. However, in this chapter, and also in chapter 6 (Research), we comment on aspects of consultation with Maori specifically in the context of genetic modification issues.

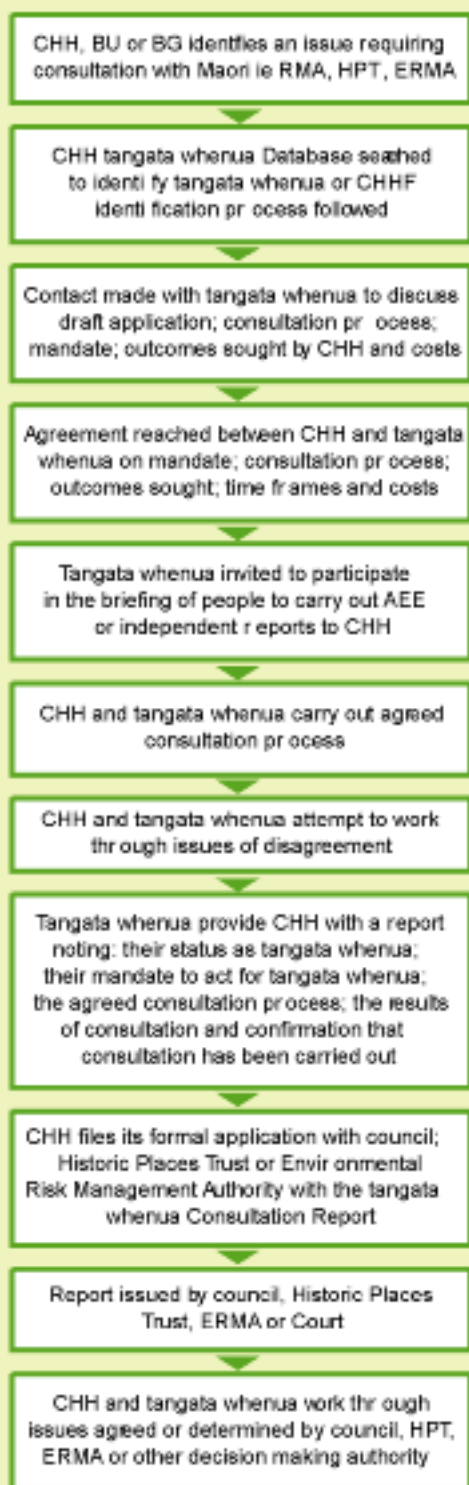
Successful consultation

25. We heard of successful consultation processes. An outline of the process used by Carter Holt Harvey is contained in the diagram overleaf, which was attached to the company’s submission [IP17].³¹ The key elements of the process are that:

- tangata whenua are identified with the assistance, where possible, of the consent authority, eg ERMA
- a consultation process is agreed with the tangata whenua including outcomes, time frames and costs
- consultation is carried out before an application is lodged with the consent authority
- where there is an “ongoing relationship” a memorandum of understanding is developed with the tangata whenua group.

26. The importance of consulting the group or groups with manawhenua over a relevant area is apparent from the background to the *Bleakley* case referred to in paragraphs 34 to 41. A valid mandate cannot be obtained from those who have no direct responsibility for the area in question. We have discussed this issue in chapter 6 (Research).

Best Practice Consultation Process as used by CHH and tangata whenua



Key Principles:

1. Both parties act with utmost good faith;
2. Tangata whenua confirm their mandate;
3. Tangata whenua define the appropriate consultation process and reach agreement with CHH;
4. CHH meets reasonable costs based on both internal and external benchmarks;
5. CHH provides all information that it will rely on during a formal application process;
6. Consultation is carried out before a formal application is lodged;
7. CHH attempts to resolve any areas of disagreement;
8. Tangata whenua confirm consultation has been carried out;
9. Unresolved issues are referred to the decision making authority for resolution.
10. A Memorandum of Understanding will be considered if there is more than one application, or there is a need for ongoing contact with tangata whenua.

Key:

- AEE - Assessment of environmental effects
- BG - Business group
- BU - Business unit
- CHH - Carter Holt Harvey
- CHHF - Carter Holt Harvey Forests
- ERMA - Environmental Risk Management Authority
- HPT - Historic Places Trust
- RMA - Resource Management Act

27. Equally, jointly building an adequate and agreed time frame for the consultation and discussing costs before they are incurred, together with consultation before a decision is made on an application or other project, are likely to be vital steps in a successful process. The significance of this last step was referred to by the Parliamentary Commissioner for the Environment [IP70] when he noted that in his experience, for many iwi and hapu, consultation is seen as “a reaction to someone else’s initiative” rather than “full and equal involvement from the outset in considering the options and determining the kaupapa”.³²

28. Attention to devising a jointly acceptable consultation process may be time-consuming initially, but, if done well, can result in direct responses in later cases as both trust and a knowledge base in each party is established. A memorandum of understanding is one way to formalise this. We were impressed by the example provided by Carter Holt Harvey.

29. There will be other examples of successful consultation by the Treaty partners, and certainly there are publications from the public sector with suggestions of how to approach consultation.³³ We think the time has passed when parties could credibly say that they do not know how to undertake appropriate consultation, or where to begin.

30. We envisage that Toi te Taiao : the Bioethics Council (for further details, see chapter 14: The biotechnology century) will have a role in drawing up a framework of principles for both Treaty partners. This framework may cover consultation to bring the elements of “best practice” together in one place. In addition, we envisage that Nga Kaihau Tikanga Taiao, the Maori advisory body of ERMA, will continue to look at specific applications made to that body, and that local iwi will be consulted both through IBSCs or their equivalent, and directly where any proposals affect their locality.

Giving statutory effect to the principles of the Treaty

31. So far as relevant, sections 5, 6 and 8 of HSNO provide:

5. Principles relevant to purpose of Act – All persons exercising functions, powers, and duties under this Act shall, to achieve the purpose of this Act, recognise and provide for the following principles:

(a) ...

(b) 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.

6. **Matters relevant to purpose of Act** – All persons exercising functions, powers, and duties under this Act shall, to achieve the purpose of this Act, take into account the following matters:

(a) ...

(b) ...

(c) ...

(d) the relationship of Maori and their culture and traditions with their ancestral lands, water, sites, wahi tapu, valued flora and fauna, and other taonga: ...

8. **Treaty of Waitangi** – All persons exercising powers and functions under this Act shall take into account the principles of the Treaty of Waitangi (Te Tiriti o Waitangi).

32. The Commission heard submissions regarding the expression “shall take into account”, for example from Te Runanga o Ngai Tahu [IP41], which in its written submission said:

... there needs to be a thorough review of HSN0 in relation (to) provision for tangata whenua. The minimum provision in relation to iwi concerns values should be to “recognise and provide for”.³⁴

33. Although this submission described “recognise and provide for” as the minimum acceptable formula, reference to cognate statutory provisions and case law shows that this would provide maximum protection. Further, discussion with Ngai Tahu representatives during their oral presentation failed to identify any intermediate position between “take into account” and “recognise and provide for” (or wording to similar effect).

34. In the *Bleakley* case, the High Court discussed the meaning of the statutory expressions in the sections set out above, and the distinctions between them. Justice McGechan said:

There is a deliberate legislative contrast between s.5 “recognise and provide for” and s.6 “take into account”. When Parliament intended that actual provision be made for a factor, Parliament said so. One does not “provide for” a factor by considering and then discarding it. In that light, the obligation “to take into account” in s6 was not intended to be higher than an obligation to consider the factor concerned in the course of making a decision – to weigh it up along with other factors – with the ability to give it considerable, moderate, little, or no weight at all as in the end in all the circumstances seemed appropriate.³⁵

35. Although written with reference to sections 5 and 6, this reasoning must apply equally to section 8, dealing with the principles of the Treaty. In this context, the wording “take into account” is a commonly used statutory formula, found also in section 8 of the Resource Management Act 1991. Sometimes, a stronger form of words has been used, the State-Owned

Enterprises Act 1986, for example, stating in section 9:

Nothing in this Act shall permit the Crown to act in a manner that is inconsistent with the principles of the Treaty of Waitangi.

while section 4 of the Conservation Act 1987 provides:

The Act shall be so interpreted and administered as to give effect to the principles of the Treaty of Waitangi.

36. Although semantically submitters may have been correct in saying that the last example is merely the State-Owned Enterprises Act formula stated affirmatively, it appears to represent the high-water mark of statutory recognition of Treaty principles to date.

37. In addressing the submissions seeking a stronger formula, a distinction needs to be drawn between section 8 considerations, and those dealt with in sections 5 and 6.

38. As noted, section 5(b) requires the Authority to “recognise and provide for”, among other things, the maintenance of the capacity of communities to provide for their economic, social and cultural wellbeing. Understandably, section 5(b) did not feature prominently in the judgments in the *Bleakley* case. It is not specific in its applicability to Maori or any ethnic group.

39. Regarding section 6, the High Court in *Bleakley* accepted that, in general, references to taonga would include intangible spiritual and cultural aspects, both as related to tangible taonga, and in their own right.³⁶ In relation, specifically, to the use of the term in section 6(d), Justice McGechan said the issue was not so simple. The concept had been transplanted from the Resource Management Act, with its emphasis on physical considerations rather than the need to consider intangible and spiritual beliefs in their own right. However, in accordance with usual concepts, and consistently with the Treaty, the Judge was satisfied that the reference to “other taonga” was meant to include intangible cultural and spiritual taonga. Justice Goddard reasoned that the addition of the words “and their culture and traditions” to “Maori” was designed deliberately to underscore the special nature of the relationship of Maori (“as opposed to any other group”) with the relevant matters listed in the subsection. However, like Justice McGechan, she made it clear that the matters to be taken into account under section 6(d) were not amenable to classification as purely physical entities: “some are essentially spiritual; some are also intangible; all have intrinsic value to Maori”.

40. In the result, the High Court interpreted section 6(d) as requiring those to whom the section is directed to take into account, not only the relationship of Maori to their ancestral lands, sites and other taonga of a tangible kind, but also

Maori cultural and spiritual values not specifically linked to physical or tangible features.

41. From the *Bleakley* judgments it is clear that, given the facts of the case, had the Authority accepted the evidence about particular spiritual and cultural values of an intangible kind, and decided to give effect to them, the only available outcome would have been to decline the application, regardless of whatever merit it might have had, such as research or health benefits. It follows that, had section 6 required the Authority to “give effect” to Maori spiritual and intangible values, and had the application been found to be in conflict with them, then, regardless of merit in other respects, the Authority would have been bound to decline the application.

42. We are unable to recommend that section 6 should be amended so as to afford even stronger protection for Maori values. It would be contrary to the spirit and the principles of the Treaty were the spiritual and cultural values of either Treaty partner given pre-emptive standing. In our view, the appropriate framework for the consideration of applications under HSNO is that the spiritual and cultural values of all New Zealanders ought to be taken into account, as envisaged by section 5.

Incorporating reference to the Treaty in legislation

43. The manner in which reference to the Treaty of Waitangi ought to be incorporated raises different issues. Legislation has given steadily increasing significance to the concept of the principles of the Treaty during the quarter century that has elapsed since enactment of the Treaty of Waitangi Act 1975. As indicated earlier in this chapter, definition of what constitutes the principles continues to evolve, mainly through pronouncements of the courts and the Waitangi Tribunal, and academic discussion. As stated, a number are regarded as well settled. We do not see why legislation seeking to incorporate such fundamental concepts need be half-hearted or ambiguous. In our view the principles should be incorporated in plain terms, and not left in the potentially token state of being “taken into account”. We would favour amendment of section 8 so that, on the precedent of the Conservation Act, it is clear that effect is to be given to the principles of the Treaty. We note the High Court has said that, since the Treaty was designed to have general application, such general application “must colour all matters to which it has relevance”,³⁷ so it may be that what we are proposing goes no further than what, in many cases, would be regarded as the appropriate legal interpretation.

Recommendation 11.1

that section 8 of the Hazardous Substances and New Organisms Act 1996 be amended to provide that effect is to be given to the principles of the Treaty of Waitangi.

chapter |

12.

Liability issues

12.

Liability issues

Key issues:

- Submitters' concerns
- What kinds of liability exist?
- Whether insurance is available
- How liability issues have been addressed overseas
- Are bonds a solution?
- Genetic discrimination.

Introduction

1. Who is, or is not, liable for damage caused by genetic modification? Who should be? To what extent? These questions were raised throughout the Commission's inquiry. There was particular concern about who would bear the responsibility for environmental damage, such as adverse effects on biodiversity if invasiveness turned out to be a characteristic of genetically modified plants.
2. This chapter of the Report examines the potential liability, under current New Zealand law, of those involved in creating, using or approving the use of genetically modified organisms or products, if harm is caused to others or the environment by such organisms or products. It also looks at whether the existing liability regime is adequate, and at the role of insurance.
3. An overriding concern was whether it was appropriate to leave liability to be decided according to the current regulatory and legal frameworks. For members of the general public wishing to claim for damage to health or property, major problems included establishment of liability and identification of liable parties.
4. The effects of genetic modification are expected to:
 - be likely to manifest only in the long term
 - be diffuse in nature
 - involve difficulties and expense in establishing proof of cause, nature and extent of any damage.

Choice of approach

5. Submitters maintained that a policy decision was needed to decide between two differing approaches to liability: whether liability was to be assumed by the state as a “socialisation of the risks” of genetic modification; or whether the producer or user should be responsible for any damage under a “polluter pays” approach.
6. A number of submitters argued that, as the state approved or regulated use of genetically modified organisms, it should assume the ultimate liability for genetic modification activities.

Types of liability

7. Submitters distinguished between harm that was foreseeable, or caused by negligence or failure to comply with regulatory requirements, and damage that was unanticipated, and occurred despite all requirements and precautions being followed.
8. Practical examples frequently mentioned included:
 - StarLink™ corn
 - genetic contamination of seeds in Europe
 - Monsanto damages claims for unlicensed use of patented genetically modified seeds
 - the BSE crisis in the United Kingdom.

While these illustrate situations giving rise to damages claims, they do not necessarily point to any specific deficiencies in the current New Zealand legal position.

9. A number of submitters raised the prospect of the loss of valuable markets or even the wholesale collapse of the organic farming sector, with no clear avenues of redress, in the event of general release of genetically modified crops.

Regulatory framework for liability

10. Submitters expressed varying views as to the appropriate framework for liability. Opinions spanned a continuum from the position that liability arising from genetic modification should be no different from liability for any non-genetic modification products or activities, through approval of the current regulatory framework of offences, penalties and powers to mitigate or remedy any adverse effects under the Hazardous Substances and New Organisms Act 1996 (HSNO), to the position that the current arrangements are inadequate,

given the potential risks and the difficulty of ensuring that those who benefited assumed the risk.

11. The following changes were advocated:

- legislation regulating genetic modification should include provision for liability and compensation
- there ought to be strict liability for environmental and economic damage
- “liability funds” should be established
- users of genetic modification technology should be required to give bonds for cleaning up adverse environmental effects, similar to those provided under the Resource Management Act 1991 (RMA).

Liability

Statutory liability

Hazardous Substances and New Organisms Act 1996

12. The use of genetic modification technology in New Zealand is controlled by HSNO and other statutes.

13. HSNO provides for strict liability for certain offences, and includes penalties and enforcement actions in the case of breaches of the legislation. The strict liability offences in HSNO are:¹

- developing a genetically modified organism in contravention of the Act (for example failure to obtain Environment Risk Management Authority (ERMA) approval to develop a genetically modified organism)
- failing to comply with any conditions imposed by ERMA on an approval under the Act
- non-observance of a compliance order.

14. In these cases, the prosecution does not need to prove that the defendant intended to commit the offence. However, as with other statutes imposing strict criminal liability, HSNO provides for limited defences, such as reasonable actions to protect human life or health or prevent serious damage to property or the environment, unforeseen events beyond the defendant’s control, or that all reasonable steps were taken to prevent an occurrence.² Other offences under HSNO include:³

- knowingly importing or releasing a genetically modified organism in contravention of the Act

- knowingly, recklessly or negligently possessing or disposing of a genetically modified organism imported, developed or released in contravention of the Act.

15. The above offences carry maximum penalties of three months imprisonment or a fine of \$500,000 plus \$50,000 a day for continuing offences. The Act confers wide-ranging inspection and enforcement powers upon authorised enforcement officers.

16. If a company is convicted of an offence under HSNO, every director and every person concerned in the management of that company will also be guilty of the same offence if it is proved:

- that the act constituting the offence took place with that person's authority, permission or consent; and
- that the person knew, or could reasonably be expected to have known, the offence was to be or was being committed and failed to take all reasonable steps to prevent it.

Compliance orders under HSNO

17. HSNO also provides for compliance orders requiring recipients to stop any dangerous conduct or actions contravening the Act, regulations, or controls under an approval. The orders can require a person to do anything necessary to ensure compliance, or to avoid or mitigate adverse effects on people or the environment. A compliance order is available to require remedying any adverse effects on people or the environment caused by a breach of the Act, for example an unauthorised release, or non-observance of conditions of a field trial approval.

18. Currently, ERMA has no power to impose conditions on general releases. Consequently, it is at present arguable (as New Zealand Life Sciences Network submitted [IP24])⁴ that any adverse effect on the environment or people arising from an approved release cannot be the subject of a compliance order. In Chapter 6 (Research), we have recommended the addition of a new category of conditional release.

Resource Management Act 1991

19. Remedies for damage through genetic modification may be available under RMA.

20. It is open to anyone to apply to the Environment Court for orders to prevent or stop any dangerous, offensive, objectionable or noxious activities that are or would be environmentally harmful.

21. The Court may also order that parties responsible for any actual or likely environmental damage must repair or mitigate the damage, or reimburse

anybody else who has taken action to remedy damage due to non-compliance with the Court's orders by the person responsible for the damage.⁵

22. It should be noted that these remedies are restricted to effects on the environment. They do not extend to personal damage or loss suffered by an individual. This is consistent with the approach in many other countries where reliance on laws of horizontal application (that is, laws that apply to all cases of contamination or pollution and do not discriminate between industries) is preferred to enacting laws creating specific liability for particular industries or activities.

Civil or common law liability

23. The Commission asked Professor Stephen Todd, Professor of Law, University of Canterbury⁶ for a formal opinion on the potential liability, under current law, of persons or bodies who develop, use or approve genetically modified organisms or products. The Commission adopts Professor Todd's descriptions and conclusions, which are summarised below. The Commission has placed the full text of the opinion on the Commission website.⁷

24. Broadly, there are three kinds of damage that may be caused by a genetically modified organism: personal injury, property damage and financial or economic loss. The existence or extent of any potential liability may differ according to the kind of damage claimed to have been suffered. In New Zealand, the possible application of the Accident Insurance Act 1998 needs to be considered at the outset, because all questions of liability for personal injury operate subject to the accident compensation regime that has been in force in New Zealand since 1974. Where the Act does not apply, the existing rules of liability for torts (civil wrongs) will determine whether and to what extent a defendant is subject to civil liability.

25. Since there is no New Zealand case law dealing with harm caused by genetically modified organisms, any assessment of the trends of future decisions is necessarily speculative.

Personal injury and the accident compensation scheme

26. Before any question can be answered as to the liability of any person for causing injury to another's health by a genetically modified organism, it has to be determined whether the injured person (the claimant) is covered by the accident compensation scheme. The Accident Insurance Act 1998 is the current statute. The Injury Prevention and Rehabilitation Bill now before Parliament is proposed to repeal and replace the 1998 Act. In its existing form, the Bill will make certain minor amendments to the ambit of cover, but the substance of the law will not

change, so the principles concerning cover and the scope for actions for damages for injury-related harm are likely to remain as discussed below.

Relationship with the common law

27. Where there is cover under the Act, it is not possible to bring a claim for damages in respect of personal injuries or death caused by another. Conversely, where there is no cover then an action for damages can still be brought.⁸

Personal injury by an accident

28. The first question is whether injury to health caused in some way by a genetically modified organism is personal injury within the meaning of the Act. Under section 29(1) “personal injury” means death or physical injury (and some forms of mental injury). “Physical injury” is not further defined but should be understood as meaning any condition involving harm to the human body, including harm by sickness or disease, that is more than merely trifling or fleeting.

29. For the purposes of the accident compensation scheme, it is likely that personal harm shown to have been caused by transgene technology, or some associated infection, would qualify as personal injury caused by an accident on a specific occasion. Damage caused by ingestion or exposure to genetically modified organisms or genetically modified products over time would not be covered under the scheme, but a common law action would be possible.

Medical misadventure

30. A second possibility is that there is cover for personal injury caused by medical misadventure. This means personal injury caused by medical error or medical mishap.⁹ As noted, in this context “personal injury” includes injury by disease or infection and any other form of bodily harm. It includes an existing condition that does not get better or gets worse, such as where a patient is not properly diagnosed or treated.

Work-related disease

31. A third possibility is when personal injury is suffered by practitioners or researchers in the field of genetic modification. For example, they may suffer an infection from picking up a virus associated with their work. There is cover under the scheme where a person suffers personal injury caused by a work-related gradual process, disease or infection.

Claims for personal injury not covered by the accident compensation scheme

Negligence

32. If the claimant is not prevented by the accident compensation scheme from taking a personal injury action, in principle the claimant can bring a damages action based on negligence (a form of tort) against the person or persons whose negligence contributed in some way to the damage sustained. Victims of personal injury must show that the defendant owed them a duty of care, that the duty was broken and that the breach caused damage of a reasonably foreseeable kind. On the duty issue, normally this is determined by asking whether the defendant should reasonably have foreseen that his or her negligence might cause injury to the claimant. On the issue of breach, the defendant must meet the standard of care reasonably and objectively to be expected of persons holding themselves out as possessing the relevant skill and experience. The claimant must also show that, on the balance of probabilities, any breach caused the harm in question.

33. A number of submitters drew attention to potential problems in establishing the cause of damage arising from genetic modification activities. They may be real and substantial, but probably are not so different from those that arise in other tort actions, for example those facing claimants in lung cancer actions against tobacco companies, or those bringing claims for asbestosis.

34. A claimant could also bring a negligence action for damage to property or for economic loss caused by genetic modification techniques or products. The same principles apply as with claims for personal injury. A claimant must show that there was a foreseeable risk of damage, that the defendant was negligent, and that the negligence caused the harm. Again, any difficulties will not necessarily be greater than those faced by claimants in negligence actions in other circumstances.

35. Negligence principles can apply in the case of damage to land, but, where possible, a claimant is likely to rely on stricter forms of liability. Where damage is done to land, this may give rise to liability in nuisance or under what is known as the rule in *Rylands v Fletcher*. These two related forms of civil liability are not founded on negligence and will usually be easier to establish.

Nuisance

36. Where people use their land to carry out an activity that causes harm to the land of a neighbour, they may commit the tort of nuisance. The activity may cause actual damage to the neighbouring land or it may interfere with the enjoyment of the land without physically damaging it. Liability depends on whether the

interference is reasonable or unreasonable: the law has to strike a balance between the conflicting interests of neighbouring occupiers.¹⁰ People must put up with the reasonable activities of their neighbours, but an interference becomes unreasonable and actionable where it exceeds what an ordinary neighbour could reasonably be expected to tolerate. Nuisance is a tort protecting the use of land, so claimants can sue only if they have an interest in land.¹¹ The defendant's liability is based upon possession and control of the land from which the nuisance emerges.¹²

*The rule in Rylands v Fletcher*¹³

37. This rule has been regarded as an extension of the law of nuisance to cases of an isolated event. The rule applies to the “escape” from the defendant's land of something likely to cause damage. Liability applies even if the defendant was not at fault or took all reasonable precautions to prevent the escape; the defendant must be in possession or control of the land from which the “harm” came and be making a “non-natural” use of the land; and the possibility of escape and the consequent harm must have been foreseeable, although the manner or immediate cause of the escape need not have been foreseeable. The effect of the rule is to impose a higher standard of responsibility for activities with inherent risks. Since, however, such activities generally have utility for the community, they should not be subjected to the kind of disincentive a rule of absolute liability would impose.

38. Courts have applied the forms of action discussed above (nuisance, and *Rylands v Fletcher*) to many different factual situations. Those having some analogy to present subject matter include damage caused by water,¹⁴ weeds,¹⁵ and sprays.¹⁶ If faced with a novel situation, such as a claim by a farmer for damage to a crop caused by contamination from a neighbour's genetically modified canola, the courts would deal with the issues by drawing on principles established by earlier cases.

Other liability problems

39. We have discussed the various forms of legal liability on which a claimant seeking to recover damages may rely. To succeed in establishing liability arising from genetic modification activity (typically against a manufacturer, vendor or user of genetically modified products, or an approving agency), the claimant must also establish that the defendant's activity or product caused the damage. For example, in the case of a motor accident or an explosion, it is a simple matter to prove a link between the event and the damage sustained. In other categories of claims it can be intensely difficult; those relating to liability arising from genetic modification are likely to be of the latter kind. Devising a new form of liability will not, however, resolve the difficulty; it is inherent in whatever kind of liability regime is adopted.

A claimant always has to establish a causative link between the activity or product and the damage sustained.

40. The same considerations apply to the final hurdle that faces any person seeking financial redress: having succeeded in the courts, will the claimant be able to obtain payment? The defendant may be a shell company without substantial assets, or may be insolvent. Indeed, by the time damage is discovered the potential defendant may no longer be in business. The problem is illustrated by the environmental damage at Mapua referred to by submitters.¹⁷ By the time the community started to address the issue, no target remained from which compensation could be recovered. Again, adopting some new category of liability would not mitigate the problem. Even bonds would be only a partial answer. Some of these problems are captured in a passage from a paper issued by the Commission of European Communities. After stating the expectation that liability would create incentives for more responsible behaviour, the paper continued:

However, a number of conditions need to be met for this effect to happen. For instance, experience with the US Superfund legislation (liability for cleaning up contaminated sites) shows the need to avoid loopholes for circumventing liability by transferring hazardous activities to thinly capitalised firms which become insolvent in the event of significant damage. If firms can cover themselves against liability risk by way of insurance, they will not tend to resort to this perverse route. Availability of financial security, such as insurance, is therefore important to ensure that liability is environmentally effective ...¹⁸

Environmental damage

41. Some forms of “environmental” damage are not, or not easily, remediable through a regime of individual liability. For an action in tort, there needs to be an identifiable defendant, quantifiable damage, and a causal connection between the defendant and the damage. Where damage is widespread and diffuse and the possible sources and their contribution to the damage uncertain, finding a remedy is no longer a matter for legal action between individuals. Some types of damage that may be caused by genetic modification, such as plants developing resistance to herbicides, or harm to beneficial insects, may raise this problem.

Liability of approving agencies

42. HSNO controls and manages the use in New Zealand of new organisms, including genetically modified organisms, which are living or viable. It does this by setting up mechanisms for processing and determining applications to manufacture, import or release new organisms. The Act lays down a process under which the approval of a tribunal, ERMA, is required:

- to import, develop or field trial any new organism in containment

- to import for release or release from containment any new organism
- to import any new organism for release in an emergency, or release any new organism from containment in an emergency.

43. As discussed in chapter 6 (Research), ERMA can delegate some low-risk applications. The only decisions it delegates externally are applications by research institutions such as universities and Crown Research Institutes to develop genetically modified organisms in containment. Such entities must set up Institutional Biological Safety Committees (IBSCs) to assess the applications.

44. As part of its responsibilities under the Biosecurity Act 1993, the Ministry of Agriculture and Forestry (MAF) approves the facilities where work is carried out.

45. The question arises whether ERMA or MAF could be held liable for negligence in giving or refusing approval. While Clause 33 of the First Schedule to HSNO exempts ERMA members and staff from liability that may be attributed to the organisation for any acts or omissions in the execution of its statutory functions, the statute does not confer any such exemption on ERMA itself. Thus ERMA could be held liable under the headings of negligence or nuisance (already discussed) or misfeasance of public office. This last form of action requires a deliberate and dishonest abuse of a decision-making power with the intention of harming a person or class of persons, or intentionally acting outside the statutory power knowing this would cause harm.

Limitation of actions

46. Civil claims for damage become barred by statute after a set time limit, commonly six years from the event giving rise to the damage. In personal injury cases, the period is only two years but an extension up to six years may be obtainable. Any harm caused by genetic modification technology may emerge only after an extended period of time. The nature of the damage and its cause may be concealed or may develop gradually, posing potential limitation problems. This raises the question whether any possible claim would be barred by the expiry of the relevant limitation period.

47. Current case law suggests that where harm caused by a genetically modified organism is latent the victim may still be able to bring a tort claim on discovering the harm. So in the case of personal injury any possible claim is unlikely to be barred before the victim has a chance to assert it. Where the claim is for property damage or financial loss the position is less certain, but recent case law trends suggest that the discoverability principle will replace the date of damage rule. In that case, the law of limitations is unlikely to cause special problems in the present context. The New Zealand Law Commission has recommended introducing a discoverability principle, but with a 10-year long stop from the date

the cause of action accrued, defined as the date when all facts necessary to establish the claim are in existence, whether or not their existence is known to the claimant. Claims after that date would become barred irrespective of any question of knowledge.¹⁹

Insurance

48. A report by the international insurance company Swiss Re²⁰ notes that only a handful of markets define special cover or exclusions for genetic engineering applications. This creates an impression that many insurers are treating genetic modification simply as a continuation of industrial activity using different gradually developing processes. As outlined above, organisations or persons causing harm by genetically modified organisms or products may be legally liable to the victims of the harm. The question arises whether insurance against such risk would be obtainable.²¹

49. Existing liability policies are likely to provide cover. As a general rule such policies have open wording, without specific exclusions for damage or injury caused by genetic modification. In taking out the insurance, the insured party would have given information about the risk to be covered in accordance with the requirements of the insurer, and provided there was full disclosure, and subject to standard exclusions, this type of liability would be covered.

50. However, the position may change quite soon. It appears that on present levels of understanding the leading overseas insurers cannot assess the level of any risk fully enough to accept and price it adequately or to spread the risk by reinsurance. Not enough is known about the degree of any danger and the extent, if any, to which there is a potential for widespread consequences. So it is likely that the insurance industry will introduce changes in liability policies excluding cover for harm caused by genetic modification. Whether or how widely this will affect liability policies is unpredictable but against at least some kinds of risks, insurance is likely to become unobtainable. This may be more likely in relation to personal injury liability than property damage.

51. For the insurance industry, genetic modification is potentially one of the most exposed technologies of the future. This is not only because the loss experience for traditional insurance models is unavailable, but also because there is widespread scepticism in society, as increasingly complex scientific developments are feared to be associated with massive potential for destruction. The more concern the public shows towards new risks, the less trust is placed in the traditional means to deal with them.

52. The Swiss Re report identifies four elements relevant to this possibility of a change of attitude by the insurance industry. They are:

- The socio-political and cultural element; genetic modification is a public issue in terms of structures and values.
- The socio-economic factor; pharmaceutical, agricultural and nutritional sectors are growing disproportionately in the area of genetic modification applications. Their products are entering new markets where reactions from consumers cannot be predicted.
- The coming omnipresence of genetic modification; genetically engineered applications and products are penetrating areas such as health, nutrition, and the environment, which are particularly sensitive because they are essential to everyday life.
- The time factor; the values, laws and risks acceptance relating to genetic modification are subject to constant change, which has no predictable direction or speed. The future risk component for genetic modification is prominent, particularly exposed and long term.

53. In conclusion, the Swiss Re report notes that the decisive factor is not whether genetic modification is dangerous, but rather how dangerous it is perceived to be. The report concludes that the development of social and legal frameworks unfavourable to genetic modification could lead to impossibly high liability risks that cannot be carried either by the genetic modification industry or the insurance industry alone.

Bond system

54. Resource consents under the RMA may impose conditions, including:

- a requirement that a bond be given in respect of the performance of any one or more conditions of the consent (including conditions as to the removal of structures on expiry of the consent)²²
- a financial contribution, works or services for purposes specified in the plan.²³

55. The Ministry for the Environment [IP101] proposed amending the RMA to provide for these ‘bonds’ be able to be extended beyond the period of the consent in order to deal with events or problems arising later.²⁴ The Ministry also submitted that bonds should be able to be imposed on any approval for developing or trialling a release of a GMO.²⁵

56. Where substantial bonds are required by Act of Parliament, they are rarely provided in cash.²⁶ Commonly, the person who has to give the bond provides a

performance bond, underwritten by an insurance company. Such bonds are obtainable from insurers operating in New Zealand. The bond guarantees the performance of the person who is required to fulfil the statutory requirements, for example a manufacturer of genetically modified products obliged (let us assume) to give a bond guaranteeing compliance with various safety regulations. Failure to comply will trigger forfeiture of the bond.

57. The question arises whether insurers would be prepared to issue bonds involving risks arising from genetic modification activities. For the insurance industry, this raises the same issues as discussed earlier (see paragraphs 48 to 53). At the present time, having regard to the difficulty in assessing the risk because of limited knowledge and experience about genetic modification, and the unlikelihood that reinsurance could be obtained, it is improbable that insurers would take on such risks. The situation could change were there fewer imponderables, but whether and when this might happen is unpredictable.

58. The Commission sees other problems with a bond system. The substantial premiums involved would equate to a penalty on a particular activity or product, disadvantaging those wishing to trade in the field, compared with other industries. If, as seems likely, insurance bonds would be unavailable, effectively the activity would be prohibited, contrary to the Commission's wish to maintain options.

Liability fund

59. GE Free New Zealand (RAGE) in Food and Environment [IP63] suggested the instigation of a liability fund, into which all companies concerned with carrying out any biotechnology activities in the environment are legally bound to contribute.²⁷ We were told Spain has such a fund.²⁸

Environmental user charge

60. Our attention was drawn to HSNO section 96. On an application relating to a hazardous substance, where ERMA considers a reduction in the likely adverse effects could be achieved by imposing an environmental user charge, it may report to the Minister on matters relevant to such a charge. The possibility arose that this provision might be enlarged to encompass new organisms as well as hazardous substances.

61. As presently framed, section 96 is of limited practical effect. As we read it, further legislation would be required if, following receipt of a report, the Minister was minded to pursue the imposition of a charge. In the event of further legislation, the possibility of amending the provision to include new organisms could be kept in mind.

Overseas approaches

62. Dealing with liability for damage caused by the use of genetic modification and genetically modified organisms is proving difficult and time consuming the world over. The Cartagena Protocol on Biosafety is a protocol of the Convention on Biological Diversity. It covers the safe transfer, handling and use of living modified organisms that might have an adverse effect on biodiversity. Article 27, which requires the parties to adopt a process to set out rules and procedures for liability and redress for damage arising from the transboundary movements of genetically modified organisms, sets a time frame of four years for this undertaking. The European Union has been working on the issue of environment liability, including genetic modification, since the publication of a Commission of European Communities (EC) Green Paper in 1993. In contrast, biotechnology is evolving rapidly and expanding into previously unimagined areas of everyday life. This rapidity creates a fluid situation where liability issues are concerned.

63. Solutions to the problem may appear simple enough at one level: there seems to be general agreement that the polluter should pay, for example, but how this response is to be translated into an effective and practical liability regime raises problems.

United States “Superfund”

64. Chris Webster, appearing for the Maori Congress [IP103], referred the Commission to information on the United States Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA) which created “Superfund,” a trust fund administered by the Environmental Protection Agency (EPA). Superfund was intended to provide temporary emergency federal funding for the cleanup of chemical waste if responsible parties could not be found or were unable to pay. It is funded by taxes levied on crude oil and chemical feedstock production, an environmental income tax at a certain level of company profits, and general appropriations.

65. In theory, Superfund is supposed to enforce a “polluter pays” policy. That is, if culpable parties can be linked to a polluted site, they must pay for cleanup efforts. In practice, Superfund’s rule of “retroactive, joint and several and strict liability” has been claimed to result in lengthy and expensive litigation, delays and inefficiency in clean ups, waste and even fraud; there are claims that 36 to 60 cents of every dollar put into Superfund has gone in legal and other transaction costs.

European Union position on liability

66. Early in 2001, the European Parliament completed a process of amending directive 90/220/EEC, regulating the deliberate release into the environment of genetically modified organisms.²⁹ The objective of the amendment (first submitted in February 1998) was to extend and clarify the scope of 90/220/EEC and to include all direct and indirect ecological aspects. The amendment proposed mandatory monitoring of genetic modification products after being placed on the market, and an expiry date of 10 years for first consents for such products. It also sought to increase the transparency and efficiency of the decision-making process, harmonise risk assessment processes, and introduce labelling and traceability requirements for all genetically modified organisms placed on the market.

67. The formal adoption process resulted in a number of compromises and amendments. In respect of liability issues, an important outcome was that the EC gave an undertaking to bring forward before the end of 2001 a legislative proposal on environmental liability, covering damage resulting from genetically modified organisms.

68. The EC has published a White Paper proposing the following system of liability for environmental damage, including damage from biotechnology products:

- classes of damage covered are biodiversity damage, contaminated sites, and traditional damage (personal, property damage and economic loss)
 - the polluter pays for damage, not society as a whole
 - there should be a single piece of legislation covering all sectors
 - there is strict liability (with defences) for damage caused by regulated “dangerous activities” including biotechnology
 - there is fault-based liability for damage caused by non-dangerous activities, with some alleviation of the burden of proof on the claimant
 - where no fault can be established, states will be responsible for restoration or compensation.
69. Limitations to the proposals include:
- biodiversity or sites must have sustained “significant damage” before liability applies
 - the extent of liability is restoration to prior state
 - producers’ exposure under the strict liability regime may be capped to enhance availability of insurance cover

- provision for biodiversity damage will apply only to particular protected areas (estimated to be about 10% of EU territory).
70. However, to date the European Parliament has not accepted the proposals.

Genetic discrimination in relation to insurance and employment

71. A number of submitters and commentators³⁰ raised the issue of diagnostic tests for genetic disorders being used by the insurance industry to limit or exclude insurance cover for persons suffering from, or with the potential to develop, such disorders. This would be unfair discrimination. There were even suggestions that such action could create a disadvantaged genetic “sub-class”.

72. Part II of the Human Rights Act 1993 (HRA) prohibits discrimination in areas of public life in relation to a number of conditions; those most relevant to gene technology include gender, disability, race and colour. Discrimination is also prohibited under section 19 of the New Zealand Bill of Rights Act 1990.

73. Developments in gene technology increase the potential for selecting children on the grounds of sex, race and colour (as well as other attributes not covered by the Act). Potentially, gene technology also increases the likelihood of direct and indirect discrimination against those who do not fit preferred genetic criteria.

74. United States experience shows that “genetic discrimination”, that is, discrimination against individuals because of their genetic make-up, already exists, particularly on the part of employers and the health insurance industry. A United States watchdog organisation, the Council for Responsible Genetics (CRG), has documented more than 200 cases of genetic discrimination by employers, while a survey by the Shriver Center for Public Health in Massachusetts reported 582 cases of people who were turned down for jobs or health insurance because of particular aspects of their genetic makeup.³¹

75. In some of the cases, the discrimination by employers and the health insurance industry resulted from the identification of an individual’s genetic propensity toward such conditions as breast and ovarian cancer. The same source reported that researchers generally believe these figures are merely the tip of the iceberg, given there are relatively few genetic screening tests in common use. With developments in gene technology and the human genome project, genetic discrimination is likely to increase. On the other hand, there is hope that developments in gene technology and the human genome project will reduce and eventually eliminate genetic conditions presently impairing human well-being.

The wish to improve human health needs, however, to be balanced against the danger of a resurgence of a eugenicist philosophy. Dr Mae-wan Ho, a witness for GE Free New Zealand,³² described rising genetic discrimination and a resurgence of eugenics as two worrying trends among the biomedical applications of genetic technology.

76. The Commission was urged to consider the necessary legislative and regulatory measures that would prevent the possibility of a “genetic underclass” developing in New Zealand. The World Medical Association has expressed the opinion that it may be desirable to adopt, in respect of genetic factors, the same consensus that prohibits the use of race discrimination in employment or insurance.³³

77. A significant consideration is the need to determine which groups are most likely to be advantaged or disadvantaged by the use and avoidance of genetic modification. This has particular relevance to issues concerning access to medical applications that prevent certain inherited genetic disorders. As the Human Rights Commission said, all individuals must have equal rights to access available treatments (that is, “goods and services” as defined by the HRA) without discrimination.³⁴

78. The Commission emphasises that genetic discrimination is a separate topic unconnected with the question of liability for damage caused by the use of genetic modification techniques or products.

Conclusions

79. To summarise, during our consultation processes there were submissions in favour of legislation to enable recovery of the expense of remedying damage caused by genetically modified organisms or products. Proposals included:

- the imposition of strict liability, meaning that third parties sustaining injury or damage could recover damages if they could prove a causative link with the genetically modified product, without having to establish conventional legal elements such as negligence or nuisance
- the establishment of some fund providing compensation for persons sustaining injury or damage
- those using or selling genetic modification technology or products should be required to enter into a bond for the benefit of persons sustaining injury or damage.

80. The Commission considers it is unnecessary to recommend legislation providing special remedies for third parties, where they may have been affected by the release of a genetically modified organism. As technology advanced with ever-increasing pace throughout the 20th century, the common law (that is, law based on court decisions, as distinct from statute law) showed it was well able to mould new remedies for novel situations. Parliamentary intervention has rarely been needed in this area. From a legal liability perspective we have not been persuaded there is anything so radically different in genetic modification as to require new or special remedies.

81. Strict liability can be a barrier to innovation and progress, and the weight of international precedent is against setting up such a regime: the United States, Canada, the United Kingdom and Japan do not impose strict liability and instead rely on the common law or general environment protection legislation for those seeking recourse. Significantly, the first three countries all have a legal background largely similar to our own. On the information before us, the only major countries with a strict liability regime are Germany and Austria.

82. The Commission's recommendations include enhanced filters for field trials and release of genetically modified organisms. The emphasis is on preventing damage or injury in the first place, rather than creating a liability regime additional to that already in place.

83. Given these recommendations, the Commission's conclusion in respect of liability issues in relation to genetic modification and genetically modified organisms is that it is best to leave the regime as it currently stands, at least in the short term, subject to the specific recommendations made below. We appreciate this means there is the potential for some socialisation of unforeseen or unanticipated loss or damage, but we consider that, with the emphasis on prevention, this is appropriate.

84. In making the recommendations below, we acknowledge the liability issues are difficult. In addition to the technical legal issues, other considerations require delicate balancing: on the one hand, protection of the public and the environment, and on the other the need, in the public interest, not to stifle innovation or drive away investors by imposing overly stringent conditions on research or economic activity. For these reasons, Government may wish to refer the liability issues to the Law Commission for more intensive study.

Recommendation 12.1

that Toi te Taiao : the Bioethics Council, in association with the Human Rights Commission, address the issue of genetic discrimination.

Recommendation 12.2

that for the time being there be no change in the liability system.

chapter

13.

Major conclusion:
preserving opportunities

13.

Major conclusion: preserving opportunities

Introduction

1. New Zealand is fortunate to be in a situation where we can benefit from a variety of technologies. Some of the benefits derive from the selective use of genetic modification, others from existing and developing uses that do not depend on genetic modification. The Commission considers it would be unwise to pin ourselves irretrievably to any one approach at this time as this would limit our future options.
2. Genetic modification technology offers many advantages, but the field is far from fully researched and continues to develop rapidly. Global trends and future consumer preferences cannot be predicted with any confidence. It would be premature to commit all our resources to the new technology at this time.

Our conclusion

3. There are aspects of genetic modification we consider positive and useful, and hence to have an important place in New Zealand's future in certain defined situations. We also want to maintain non-genetic modification options as effective choices. We favour a strategy of preserving opportunities and proceeding selectively with appropriate care.
4. The Commission considers that genetic modification technology should be used only in ways that are carefully managed. All opportunities to use the new technology should be seen in terms of the net contribution they will make to New Zealand. This would allow controlled use of genetic modification, the degree of control varying with the situation.
5. It is our view that an appropriate regulatory and institutional framework for the controlled use of genetic modification is already provided by the Hazardous Substances and New Organisms Act 1996 (HSNO). Nevertheless throughout the Report we have made recommendations for additional controls to make the existing system more robust. These are listed in the appropriate chapter, and numbered according to the chapter in which they were developed.

Positions we did not choose

6. In reaching this conclusion, the Commission considered all positions, including those at each end of the spectrum.

A New Zealand free of all genetically modified material

7. At one extreme New Zealand could become free of all genetically modified material, with no genetically modified products either in use or able to be brought into the country. We regard this option as impractical in light of all the evidence. Current medical uses would have to cease, including the use of genetically modified insulin by diabetics. The economy would contract as skilled scientists emigrated and academic and industry standards ceased to be internationally competitive. We would lose the opportunity to export the intellectual property gained through research employing genetic modification. Nor would our national border controls guarantee that no genetically modified material entered the country. Audit trail procedures and testing, which involve the use of genetic modification technology, would have to be stepped up for all imported foods and seeds, and this would ultimately raise the prices to consumers.

8. We heard of increasing consumer resistance to genetic modification technology in Europe. There was also evidence that the “clean green New Zealand” image and New Zealand’s “natural” environment are well recognised among consumers of our exports. We consider that a “clean green New Zealand” is an important image to maintain. However, although it is possible world consumer resistance may remain high, there could also be a shift towards increased tolerance of new forms of genetically modified food.

9. We consider there are advantages to be had from using genetic modification technology selectively, in a way that does not threaten New Zealand’s “clean green” image. This conforms with our preserving opportunities strategy.

10. Some submitters called for New Zealand to become 100% organic. In our opinion this subset of a “genetic modification free New Zealand” is not economically viable. Organic foods may indeed attract a premium. However, world markets are uncertain, and it is unlikely that organic exports would attract a sufficient premium in the near or medium future to offset to any degree the contractionary effect of not allowing any genetic modification in the country.

11. Premiums gained for organic exports may also diminish in the long run as they attract other countries into producing and exporting organics, increasing supply and lowering price. We note that the organic sectors of many of the economies around the world that allow genetic modification are expanding.

12. Further evidence suggested the range of organic foods that can be successfully exported from New Zealand in any volume is relatively narrow because of the shorter shelf life and increased perishability of fresh organic food. In addition, the substantial distances between New Zealand and its major export markets make it difficult to deliver products in premium condition.

13. Nevertheless we consider the organic economy important to New Zealand's future and regard it a key component of a preserving opportunities strategy.

Unrestricted use of genetic modification

14. At the opposite end of the spectrum, we also reject the option that New Zealand allow completely unrestricted use of genetic modification technology. Unregulated use would involve taking unacceptable risks with human and environmental health and with our cultural heritage. It would also compromise consumer choice and our export market options. In the event, no submitters suggested such an approach to us.

15. In short, either of the extreme options would significantly restrict New Zealand's future choices and has the potential to impose considerable costs. All sectors of our economy should remain viable and be able to expand to their full potential within the constraints of a competitive environment.

Preserving opportunities in research, food and medicine

Research

16. The Commission considers that a strong research base is essential if New Zealand is to be able to pursue all possible opportunities. The acquisition and application of new knowledge, to develop new technologies and new processes, is basic to the establishment of a knowledge economy. A skilled research workforce contributes to an internationally recognised education system and the growth of the economy in diverse areas. Without a cutting-edge research capability, New Zealand's ability to develop biosecurity systems or environmental impact analyses would be limited.

17. The Commission supports the continuation of genetic modification research within the regulatory framework set out in chapter 6 (Research), as a part of New Zealand's overall research programme.

Food

18. New Zealand imports a great variety of processed foods, many of which contain genetically modified components. It is not realistic, and would compromise

freedom of consumer choice, for such foods to be banned. In the future there will be more genetically modified foods available, with the potential to bring nutritional, health and price benefits to consumers. At the same time the content and safety of such foods must be rigorously assessed, and each product adequately labelled to ensure the well-being of consumers, and informed choice.

Medicine

19. Genetic modification in medicine is already proving of benefit in terms of the production of drugs such as insulin, and in the diagnosis of disease or disability.

20. To regulate the use of genetically modified medicines, we recommend the enhancement of our drug approval agency, Medsafe. This will enable it to better conduct the risk assessment needed to protect our environment. For drugs and vaccines containing live genetically modified organisms, this will avoid the necessity for Environmental Risk Management Authority (ERMA) evaluation as well, and safely preserve opportunities for appropriate use.

21. Gene therapy is on the horizon with the first treatments being given to patients in New Zealand as part of international medical trials. For afflicted families this therapy promises hope and abatement of guilt; for our community it raises deep anxiety about eugenics, disability and discrimination. Toi te Taiao : the Bioethics Council will develop guidelines to help patients, health professionals and regulatory agencies manage these challenges posed by the rapidly expanding understanding of the genome.

Preserving opportunities in crops and other field uses

22. The Commission concluded that genetic modification has a role in the development of food crops, forest trees, flowers and garden plants, subject to a range of controls designed to allow New Zealand to develop a mixed strategy of production systems. We also see that benefits might be derived from the use of genetic modification in other field uses such as pest control, bioremediation and bioreactors. However, we have adopted a careful approach, which requires each application for a genetically modified crop or field use to be treated on a case-by-case basis. This approach imposes conditions to mitigate potential risks. A range of mitigation measures has been proposed in order to reduce the risk of cross-contamination of other production systems, including the use of physical barriers and separation distances, and the adoption of sterilising technology.

23. Four broad categories of agricultural production were presented to the Commission: genetically modified crops, conventional farming, Integrated Pest

Management (IPM) and organics. To preserve and indeed enhance our opportunities in agriculture, all these forms of production should continue to be viable.

24. The four categories are not mutually exclusive, but each has a particular place. The genetic modification of crops provides opportunities to develop new products in new markets and improve commodity crops. Conventional farming and horticulture remain major sectors of New Zealand's economy, but producers are seeking to reduce costs, improve productivity and use more sustainable techniques. IPM aims to reduce the level of chemical usage in agriculture and promote ecologically sustainable methods. Organic farming likewise focuses on a sustainable production process, to meet a growing market demand for organically grown products.

25. As noted in chapter 5 (Economic and strategic issues), all forms of agriculture are evolving. The different methods should be seen not in opposition to each other, but rather as contributing in different ways to the same overall outcome.

26. That outcome is the achievement of the three sets of goals outlined in chapters 3, 4 and 5: cultural, ethical and spiritual; environmental and health; economic and strategic. The preserving opportunities strategy makes this possible by supporting viability and strength in the different types of farming. This concept is expressed in the diagram below.



Is compatibility possible?

27. A recommendation to preserve opportunities is only as good as the means put in place to give it effect. In this next section, therefore, the Commission addresses both the complexity and the diversity of the various strategies available to provide for compatibility between genetic modification and non-genetic modification land uses. We do not see that any one strategy, or combination of strategies, will fit every situation. Rather, implementation of our major conclusion requires a selection of strategies that ensures the release of any particular crop does not threaten the overarching goal of preserving opportunities.

29. To accomplish this, an essential change is needed to HSNO. Currently HSNO does not provide for any intermediate step between field testing (which under the Act is regarded as being in containment), and open release. Field testing means a crop is still in the process of being assessed, perhaps for environmental safety, and ERMA can require containment provisions such as fences, plastic sheet coverings or netting. “Open release” means that a new crop may be used freely without restriction: HSNO section 38 prescribes that any such release must be “without controls”.

30. This latter requirement supports an “all or nothing” approach: genetically modified crops may be anywhere or nowhere. If the Commission’s major strategy of preserving opportunities is to be effective, there needs to be a greater range of options.

31. We have therefore recommended a new category of “conditional release”, the conditions (which could include monitoring) being those necessary to achieve crop compatibility and to protect environmental and cultural values. Recommendation 6.8 from chapter 6 (Research), also set out below, is designed to achieve such a legislative change.

32. With that new general provision in place, some of the subsequent recommendations below set out specific strategies that may constitute the conditions attached to a release. We do not suggest these strategies are an exhaustive list. Others may be available, now or in the future, to preserve opportunities.

33. Nor do we suggest that every release must be with conditions. Section 38 remains in place, so that a genetically modified crop posing no threat to coexistence may proceed to open release. Others released initially with conditions may have those conditions modified or removed in the light of changing circumstances. The timely monitoring of the effects of released crops will increase the ability to make changes, withdraw approval or repair any damage quickly.

34. Recommendations 7.1, 7.3 and 7.7 have been discussed in chapter 7 and are repeated here to provide an overview of the total strategy for compatibility between genetically modified and non-genetically modified crops.

35. Recommendation 13.1, however, introduces a new element. HSNO section 6(e) directs that “economic and related benefits” are to be taken into account before any “new organism” is used, in this case a genetically modified crop. Much of the evidence we heard set out the advantage to New Zealand’s overall economic well-being of preserving the marketing advantages of our “clean green” image, as well as being open to benefits to be derived from selective use of genetic modification technology.

36. As a case study we discussed at length the kiwifruit industry, which dominates land use in the Bay of Plenty. ZESPRI International [IP46], in its submissions on behalf of the kiwifruit industry, emphasised the value of genetic modification-free kiwifruit for its marketing strategy in Europe. This strategy would be put at risk should a genetically modified version of kiwifruit be developed and grown in the same area and cross-pollinate with the established non-genetically modified variety.

37. It is to prevent such a consequence that the Commission puts forward Recommendation 13.1, whereby one of the strategies available under “conditional release” would be the exclusion of a genetically modified crop from a district where its presence would be a threat to an established industry. Some of the evidence we heard suggested that this condition would also be of value to the pip fruit and wine industries.

38. The concept of regional genetic modification-free zones was raised with the Commission. Such a proposal might be achievable under the Resource Management Act 1991. We discussed this idea extensively but saw difficulty in its implementation. First, it would require widespread acceptance in a given region before it could be put in place without impinging unduly on the rights of those who wished to avail themselves of selected genetic modification technologies. Second, and for the same reasons that we found an “all or nothing” approach to be too inflexible, a blanket ban on applications of genetic modification would be a blunt instrument when a genetically modified form of Crop A might be quite compatible with a non-genetically modified form of Crop B.

39. The Commission also discussed a more selective concept relating to the Resource Management Act provisions for different land uses. Genetically modified and non-genetically modified crops might be permitted or prohibited on a crop-by-crop and region-by-region basis. This would require a genetically modified crop to be designated as a different use from a non-genetically modified

crop of the same species. It may also be that over a period of time an aggregation of genetic modification or non-genetic modification uses became characteristic of particular regions and that identifiable regional differences emerged. These distinctions in land use might be written into regional or district plans, just as industrial use is separated from residential use. At the same time, the Commission acknowledges there are considerable practical difficulties with such proposals, which have the potential for dividing communities. Because of these difficulties the Commission is unable to reach a decision but notes the possibilities.

40. We have preferred the approach set out under recommendation 13.1 as a means of ensuring the preservation of established genetic modification-free industries such as kiwifruit. In a situation where we seek to provide for a diversity of crops, it is inevitable that there will be some restrictions on both genetic modification and non-genetic modification uses in the cause of preserving opportunities.

41. In recommendation 13.2 we consider that the Minister for the Environment should exercise the call-in powers laid down in HSNO before the first release of any genetically modified crop. We make this recommendation because the first release would be very much a watershed decision. At that point we would no longer be a genetic modification-free nation in terms of crops. Because of the significance attached to this event by many, the Commission recommends that a final overview be exercised at ministerial level.

42. Recommendation 6.13 underlines the need for adequate research funding for each of the agricultural options exercised under a preserving opportunities strategy. Research is essential for each form of agriculture to develop in a robust and responsible manner. Under-funding in any area would disadvantage that sector of our overall national strategy. The use of the word “adequate” does not suggest that the research dollar should be divided into four equal amounts. Many of the areas overlap, and some forms of research are more costly than others. But a disproportionate allocation to one area, so that others falter through lack of support, would undermine the strategy to preserve opportunities.

Recommendations

Recommendation 6.8 (Conditional Release)

that the Hazardous Substances and New Organisms Act 1996 be amended to provide for a further level of approval called conditional release.

Recommendation 13.1 (Benefit assessment)

that the methodology for implementing section 6(e) of the Hazardous Substances and New Organisms Act 1996 be made more specific to:

- include an assessment of the economic impact the release of any genetically modified crop or organism would have on the proposed national strategy of preserving opportunities in genetically modified and unmodified agricultural systems
- allow for specified categories of genetically modified crops to be excluded from districts where their presence would be a significant threat to an established non-genetically modified crop use.

Recommendation 13.2 (First release)

that before the controlled or open release of the first genetically modified crop, the Minister exercise the call-in powers available under section 68 of the Hazardous Substances and New Organisms Act 1996 in order to assess the likely overall economic and environmental impact on the preserving opportunities strategy.

Recommendation 7.7 (Separation distances)

that the Ministry of Agriculture and Forestry develop an industry code of practice to ensure effective separation distances between genetically modified and unmodified crops (including those grown for seed production), such a code:

- to be established on a crop-by-crop basis
- to take into account
 - existing separation distances for seed certification in New Zealand
 - developments in international certification standards for organic farming
 - emerging strategies for coexistence between genetically modified and unmodified crops in other countries
- to identify how the costs of establishment and maintenance of buffer zones are to be borne.

Recommendation 13.3 (Communication Networks)

that the Ministry of Agriculture and Forestry develop formalised local networks to encourage constructive dialogue and communication between farmers using different production methods, and to provide for mediation where necessary.

Recommendation 13.4 (Sterility Technology)

that sterility technologies be one tool in the strategy to preserve opportunities, especially in the case of those genetically modified crops most likely to cross-pollinate with non-genetically modified crops in the New Zealand context (eg, brassicas, ryegrass, ornamentals).

Recommendation 7.1 (Bt Strategy)

that prior to the release of any Bt-modified crops, the appropriate agencies develop a strategy for the use of the Bt toxin in sprays and genetically modified plants, taking into account:

- the concept of refugia
- limitations on total planted area
- home gardener use.

Recommendation 7.3 (Bees)

that the Ministry of Agriculture and Forestry develop a strategy to allow for the continued production of genetic modification-free honey and other bee products, and to avoid cross-pollination by bees between genetically modified and modification-free crops, that takes into account both geographical factors (in terms of crop separation strategies) and differences in crop flowering times.

Recommendation 6.13 (Research)

that public research funding be allocated to ensure organic and other sustainable agricultural systems are adequately supported.

chapter |

14.

The biotechnology
century: three major
proposals

14.

The biotechnology century: three major proposals

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

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

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 HSN 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

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.

chapter |

15.

Recommendations

15. Recommendations

In this chapter, we set out all our recommendations in a consolidated list, noting the chapters in which they appear.

Chapter 6: Research

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.

Recommendation 6.2

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

Recommendation 6.3

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

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.

Recommendation 6.5

that approvals to develop or import genetically modified organisms be deemed to cover their holding and breeding.

Recommendation 6.6

that HSN0 be amended to clarify that research involving genetic modification of human cell lines or tissue cultures is covered by the Act.

Recommendation 6.7

that approval for development of genetically modified animal cell lines be delegated to the IBSCs.

Recommendation 6.8

that HSN0 be amended to provide for a further level of approval called conditional release.

Recommendation 6.9

that HSN0 be amended to cover procedures used in mammalian cloning, such as nuclear transfer or cell fusion.

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.

Recommendation 6.11

that the funders of research portfolios be resourced to include the costs of compliance with HSN0.

Recommendation 6.12

that the Environmental Risk Management Authority (ERMA) require research on environmental impacts on soil and ecosystems before release of genetically modified crops is approved.

Recommendation 6.13

that public research funding be allocated to ensure organic and other sustainable agricultural systems are adequately supported.

Recommendation 6.14

that public research funding portfolios be resourced to include research on the socio-economic and ethical impacts of the release of genetically modified organisms.

Chapter 7: Crops and other field uses

Recommendation 7.1

that, prior to the release of any Bt-modified crops, the appropriate agencies develop a strategy for the use of the Bt toxin in sprays and genetically modified plants, taking into account:

- the concept of refugia
- limitations on total planted area
- home gardener use.

Recommendation 7.2

that the appropriate agencies develop a labelling regime to identify genetically modified seed, nursery stock and propagative material at point of sale.

Recommendation 7.3

that the Ministry of Agriculture and Forestry (MAF) develop a strategy to allow continued production of genetic modification-free honey and other bee products, and to avoid cross-pollination by bees between genetically modified and modification-free crops, that takes into account both geographical factors (in terms of crop separation strategies) and differences in crop flowering times.

Recommendation 7.4

that, in connection with any proposal to develop genetically modified forest trees, an ecological assessment be required to determine the effects of the modification on the soil and environmental ecology, including effects on soil microorganisms, weediness, insect and animal life, and biodiversity.

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.

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.

Recommendation 7.7

that MAF develop an industry code of practice to ensure effective separation distances between genetically modified and unmodified crops (including those grown for seed production), such a code:

- to be established on a crop-by-crop basis
- to take into account
 - existing separation distances for seed certification in New Zealand
 - developments in international certification standards for organic farming
 - emerging strategies for coexistence between genetically modified and unmodified crops in other countries
- to identify how the costs of establishment and maintenance of buffer zones are to be borne.

Chapter 8: Food

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.

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.

Recommendation 8.3

that, as a matter of priority, the Food Administration Authority 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.

Recommendation 8.4

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

Chapter 9: Medicine

Recommendation 9.1

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

Recommendation 9.2

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

Recommendation 9.3

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

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.

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.

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.

Chapter 10: Intellectual property

Recommendation 10.1

that the New Zealand Plant Variety Rights Act 1987 be amended to introduce the concept of essential derivation.

Recommendation 10.2

that the Patents Act 1953 be amended by adding a specific exclusion of the patentability of human beings and the biological processes for their generation, in line with section 18 of the Patents Act 1990 (Commonwealth).

Recommendation 10.3

that a Maori Consultative Committee be established by the Intellectual Property Office of New Zealand to develop procedures for assessing applications, and to facilitate consultation with the Maori community where appropriate.

Recommendation 10.4

that New Zealand be proactive in pursuing cultural and intellectual property rights for indigenous peoples internationally.

Recommendation 10.5

that New Zealand pursue the amendment of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights and associated conventions to include a reference to the avoidance of cultural offence as a specific ground for exclusion or reservation.

Recommendation 10.6

that all parties concerned work to resolve the WAI 262 and WAI 740 claims currently before the Waitangi Tribunal as soon as possible.

Recommendation 10.7

that HSN0 and ACVM be amended to give appropriate protection to all commercially sensitive or confidential supporting information provided with applications for approval.

Chapter 11: Te Tiriti o Waitangi

Recommendation 11.1

that section 8 of HSN0 be amended to provide that effect is to be given to the principles of the Treaty of Waitangi.

Chapter 12: Liability issues

Recommendation 12.1

that Toi te Taiao : the Bioethics Council, in association with the Human Rights Commission, address the issue of genetic discrimination.

Recommendation 12.2

that for the time being there be no change in the liability system.

Chapter 13: Major conclusion

Recommendation 13.1

that the methodology for implementing HSN0 section 6(e) be made more specific to:

- include an assessment of the economic impact the release of any genetically modified crop or organism would have on the proposed national strategy of preserving opportunities in genetically modified and unmodified agricultural systems
- allow for specified categories of genetically modified crops to be excluded from districts where their presence would be a significant threat to an established non-genetically modified crop use.

Recommendation 13.2

that before the controlled or open release of the first genetically modified crop, the Minister exercise the call-in powers available under HSN0 section 68 in order to assess the likely overall economic and environmental impact on the preserving opportunities strategy.

Recommendation 13.3

that MAF develop formalised local networks to encourage constructive dialogue and communication between farmers using different production methods, and to provide for mediation where necessary.

Recommendation 13.4

that sterility technologies be one tool in the strategy to preserve opportunities, especially in the case of those genetically modified crops most likely to cross-pollinate with non-genetically modified crops in the New Zealand context (eg, brassicas, ryegrass, ornamentals).

Chapter 14: The biotechnology century

Recommendation 14.1

that HSN0 section 68 be extended to include significant cultural, ethical and spiritual issues as grounds for the Minister's call-in powers.

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.

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.

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.

Genetic modification: an overview for non-scientists

What is genetic modification?

For centuries farmers have used selective breeding to improve both crops and stock by breeding from the plants or animals that had the qualities they wanted to bring out and strengthen. This was the only way they had to develop animals and crops that were more productive and resistant to disease, and could cope better with extremes of climate.

Today, scientists can find individual genes that control particular characteristics, separate them out, change them, and transfer them directly into the cells of an animal, plant, bacterium or virus. Because the DNA code is known and is common to all life, it is also possible to produce synthetic genes. This technology is called genetic modification or genetic engineering.

There are three major differences between selective breeding and genetic modification:

- In genetic modification, scientists take individual genes from one plant or animal and put them into the DNA of the cells of another. They may also make changes to (modify) an existing gene.
- Genetic modification provides a way of giving a plant or animal new, inheritable qualities that is much faster than traditional breeding methods; these qualities may themselves be entirely new.
- Genes can be transferred in ways that are not found in nature, between different species and even between animals and plants.

History

The knowledge on which the techniques of genetic modification are based dates from the 1950s, when James Watson, Francis Crick and Maurice Wilkin discovered the structure of DNA, the now-familiar double helix of nucleotides that forms the blueprint of life. This new understanding opened up the possibility that the genetic coding of organisms could be altered to give them new characteristics in ways that natural evolution or selective breeding could not produce.

When in the 1970s it became possible to isolate individual genes, refashion them and copy them in cells, huge commercial possibilities opened up. Ways of applying this new technology to medicine were developed quite rapidly. Applying these methods successfully to plants took longer; the first genetically altered whole food, Flav'r Sav'r tomatoes, came on the market in 1994. Since then the growth in the number and range of genetically modified products has been explosive. As the general public has become more aware of the impact of these discoveries, concerns over the use and safety of genetic modification have also been raised. As always, new technology brings with it new possibilities and new questions.

How genetic modification works

Cells that contain a gene to be isolated are broken open and the strands of DNA are extracted. Then proteins called restriction enzymes are added to break the DNA at particular points, until the short lengths that are individual genes are obtained.

The wanted gene is added to plasmids, small molecules in bacterial cells that contain DNA that is not part of the chromosomes of the cell. It is the discovery that plasmids can move between cells, taking their DNA with them, that has made this technology possible. The plasmids to which the wanted gene has been added are put in with the cells (usually bacteria) where the wanted gene is to go. The plasmids get inside the bacteria and add their genes to the genes of the bacteria. This means the bacteria now have the wanted gene as well as their own. These bacteria are then used to transfer the new genes into plant or animal cells. This process of gene splicing creates recombinant DNA.

The ability to separate out single genes and study them is a vital part of biological and medical research.

Another way to create genetically modified products is to use the bacteria themselves as factories for the introduced genes, producing such things as enzymes used in food production (eg, chymosin for cheese making) and vitamins for use in making processed foods, or hormones for use in medicine and animal husbandry.

The future

Genetic modification means that for the first time humans can make living things to our own design, without relying on nature. The implications are vast. Although any new technology may have its risks, this one has special features. They need to be addressed with wisdom and discernment.

Terms of Reference (the Warrant)

Royal Commission on Genetic Modification

Elizabeth the Second, by the Grace of God Queen of New Zealand and Her Other Realms and Territories, Head of the Commonwealth, Defender of the Faith:

To The Right Honourable Sir Thomas Eichelbaum, G.B.E., of Wellington, formerly Chief Justice of New Zealand; Jacqueline Allan, of Auckland, medical practitioner; Jean Sutherland Fleming, of Dunedin, scientist; and the Right Reverend Richard Randerson, of Auckland, Bishop of the Anglican Church:

Greeting:

Appointment and order of reference

Know ye that We, reposing trust and confidence in your integrity, knowledge, and ability, do, by this Our Commission, nominate, constitute, and appoint you, The Right Honourable Sir Thomas Eichelbaum, Jacqueline Allan, Jean Sutherland Fleming, and The Right Reverend Richard Randerson, to be a Commission to receive representations upon, inquire into, investigate, and report upon the following matters:

1. the strategic options available to enable New Zealand to address, now and in the future, genetic modification, genetically modified organisms, and products; and
2. any changes considered desirable to the current legislative, regulatory, policy, or institutional arrangements for addressing, in New Zealand, genetic modification, genetically modified organisms, and products:

Relevant matters

And, without limiting the order of reference set out above, We declare that, in conducting the inquiry, you may, under this Our Commission, investigate and receive representations upon the following matters:

- a. where, how, and for what purpose genetic modification, genetically modified organisms, and products are being used in New Zealand at present:
- b. the evidence (including the scientific evidence), and the level of uncertainty, about the present and possible future use, in New Zealand, of genetic modification, genetically modified organisms, and products:
- c. the risks of, and the benefits to be derived from, the use or avoidance of genetic modification, genetically modified organisms, and products in New Zealand, including:
 - i. the groups of persons who are likely to be advantaged by each of those benefits; and
 - ii. the groups of persons who are likely to be disadvantaged by each of those risks:
- d. the international legal obligations of New Zealand in relation to genetic modification, genetically modified organisms, and products:

e. the liability issues involved, or likely to be involved, now or in the future, in relation to the use, in New Zealand, of genetic modification, genetically modified organisms, and products:

f. the intellectual property issues involved, or likely to be involved, now or in the future, in relation to the use in New Zealand of genetic modification, genetically modified organisms, and products:

g. the Crown's responsibilities under the Treaty of Waitangi in relation to genetic modification, genetically modified organisms, and products:

h. the global developments and issues that may influence the manner in which New Zealand may use, or limit the use of, genetic modification, genetically modified organisms, and products:

i. the opportunities that may be open to New Zealand from the use or avoidance of genetic modification, genetically modified organisms, and products:

j. the main areas of public interest in genetic modification, genetically modified organisms, and products, including those related to-

i. human health (including biomedical, food safety, and consumer choice):

ii. environmental matters (including biodiversity, biosecurity issues, and the health of ecosystems):

iii. economic matters (including research and innovation, business development, primary production, and exports):

iv. cultural and ethical concerns:

k. the key strategic issues drawing on ethical, cultural, environmental, social, and economic risks and benefits arising from the use of genetic modification, genetically modified organisms, and products:

l. the international implications, in relation to both New Zealand's binding international obligations and New Zealand's foreign and trade policy, of any measures that New Zealand might take with regard to genetic modification, genetically modified organisms, and products, including the costs and risks associated with particular options:

m. the range of strategic outcomes for the future application or avoidance of genetic modification, genetically modified organisms, and products in New Zealand:

n. whether the statutory and regulatory processes controlling genetic modification, genetically modified organisms, and products in New Zealand are adequate to address the strategic outcomes that, in your opinion, are desirable, and whether any legislative, regulatory, policy, or other changes are needed to enable New Zealand to achieve these outcomes:

Definitions

And We declare that, in this Our Commission, unless the context otherwise requires,- genetic modification means the use of genetic engineering techniques in a laboratory, being a use that involves-

- a. the deletion, multiplication, modification, or moving of genes within a living organism; or
- b. the transfer of genes from one organism to another; or
- c. the modification of existing genes or the construction of novel genes and their incorporation in any organisms; or
- d. the utilisation of subsequent generations or offspring of organisms modified by any of the activities described in paragraphs (a) to (c)

genetically modified organism means an organism that is produced by genetic modification

organism includes a human being

product includes every medicinal, commercial, chemical, and food product that (while not itself capable of replicating genetic material) is derived from, or is likely to be derived from, genetic modification:

Exclusions from inquiry

But We declare that you are not, under this Our Commission, to inquire into the generation of organisms or products using modern standard breeding techniques (including cloning, mutagenesis, protoplast fusions, controlled pollination, hybridisation, hybridomas and monoclonal antibodies):

Appointment of chairperson

And We appoint you, The Right Honourable Sir Thomas Eichelbaum, to be the Chairperson of the Commission:

Power to adjourn

And for better enabling you to carry this Our Commission into effect you are authorised and empowered, subject to the provisions of this Our Commission, to make and conduct any inquiry or investigation under this Our Commission in such manner and at such time and place as you think expedient, with power to adjourn from time to time and from place to place as you think fit, and so that this Our Commission will continue in force and any such inquiry may at any time and place be resumed although not regularly adjourned from time to time or from place to place:

Consultation and procedures

And you are required, in carrying this Our Commission into effect,-

- to consult with the public in a way that allows people to express clearly their views, including ethical, cultural, environmental, and scientific perspectives, on the use, in New Zealand, of genetic modification, genetically modified organisms, and products; and

- to adopt procedures that will encourage people to express their views in relation to any of the matters referred to in the immediately preceding paragraph; and
- to consult and engage with Maori in a manner that specifically provides for their needs; and
- to use relevant expertise, including consultancy and secretarial services, and to conduct, where appropriate, your own research:

And you are empowered, in carrying this Our Commission into effect,-

a. to prepare and publish discussion papers from time to time on topics relevant to the inquiry; and

b. unless you think it proper in any case to withhold any evidence or information obtained by you in the exercise of the powers conferred upon you,-

i. to include in any discussion papers prepared and published by you all or any of that evidence or information; and

ii. to publish or otherwise disclose in such other ways as you think fit all or any of that evidence or information:

General provisions

And, without limiting any of your other powers to hear proceedings in private or to exclude any person from any of your proceedings, you are empowered to exclude any person from any hearing, including a hearing at which evidence is being taken, if you think it proper to do so:

And you are strictly charged and directed that you may not at any time publish or otherwise disclose, except to His Excellency the Governor-General in pursuance of this Our Commission or by His Excellency's direction, the contents or purport of any report so made or to be made by you:

And it is declared that the powers conferred by this Our Commission are exercisable despite the absence at any time of any 1 or any 2 of the members appointed by this Our Commission so long as the Chairperson, or a member deputed by the Chairperson to act in the place of the Chairperson, and at least 1 other member, are present and concur in the exercise of the powers:

And We do further declare that you have liberty to report your proceedings and findings under this Our Commission from time to time if you judge it expedient to do so:

Reporting date

And, using all due diligence, you are required to report to His Excellency the Governor-General in writing under your hands, not later than 1 June 2001, your findings and opinions on the matters aforesaid, together with such recommendations as you think fit to make in respect of them:

And, lastly, it is declared that these presents are issued under the authority of the Letters Patent of Her Majesty Queen Elizabeth the Second constituting the office of Governor-

General of New Zealand, dated 28 October 1983, and under the authority of and subject to the provisions of the Commissions of Inquiry Act 1908, and with the advice and consent of the Executive Council of New Zealand.

In witness whereof We have caused this Our Commission to be issued and the Seal of New Zealand to be hereunto affixed at Wellington this 8th day of May 2000.

Witness Our Right Trusty and Well-beloved Counsellor Sir Michael Hardie Boys, Principal Knight Companion of Our New Zealand Order of Merit, Knight Grand Cross of the Most Distinguished Order of Saint Michael and Saint George, Principal Companion of Our Service Order, Governor-General and Commander-in-Chief in and over New Zealand.

Michael Hardie Boys, Governor-General.

By His Excellency's Command-

Helen Clark, Prime Minister.

Approved in Council-

Marie Shroff, Clerk of the Executive Council.

1SR 1983/225

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Extending Time Within Which Royal Commission on Genetic Modification May Report

Elizabeth the Second, by the Grace of God Queen of New Zealand and Her Other Realms and Territories, Head of the Commonwealth, Defender of the Faith: To The Right Honourable Sir Thomas Eichelbaum, G.B.E., of Wellington, formerly Chief Justice of New Zealand; Jacqueline Allan, of Auckland, medical practitioner; Jean Sutherland Fleming, of Dunedin, scientist; and the Right Reverend Richard Randerson, of Auckland, Bishop of the Anglican Church:

Greeting:

Whereas by Our Warrant, dated 8 May 2000*, issued under the authority of the Letters Patent of Her Majesty Queen Elizabeth the Second constituting the office of Governor-General of New Zealand, dated 28 October 1983**, and under the authority of and subject to the provisions of the Commissions of Inquiry Act 1908, and with the advice and consent of the Executive Council of New Zealand, we nominated, constituted, and appointed you, the said The Right Honourable Sir Thomas Eichelbaum, Jacqueline Allan, Jean Sutherland Fleming, and the Right Reverend Richard Randerson to be a Commission to inquire into, investigate, and report upon certain matters relating to genetic modification:

And whereas by Our said Warrant you are required to report to Her Excellency the Governor-General, not later than 1 June 2001, your findings and opinions on those matters, together with such recommendations as you think fit to make in respect of those matters:

And whereas it is expedient that the time for so reporting should be extended as hereinafter provided:

Now, therefore, We do by these presents extend, until 27 July 2001, the time within which you are so required to report without prejudice to the continuation of the liberty conferred

on you by Our said Warrant to report your proceedings and findings from time to time if you should judge it expedient to do so:

And we do hereby confirm Our said Warrant, dated 8 May 2000*, and the Commission constituted by that Warrant save as modified by these presents:

And, lastly, it is declared that these presents are issued under the authority of the Letters Patent of Her Majesty Queen Elizabeth the Second constituting the office of Governor-General of New Zealand, dated 28 October 1983**, and under the authority of and subject to the provisions of the Commissions of Inquiry Act 1908, and with the advice and consent of the Executive Council of New Zealand.

In Witness whereof We have caused these presents to be issued and the Seal of New Zealand to be hereunto affixed at Wellington this 14th day of May 2001.

Witness Our Trusty and Well-beloved The Honourable Dame Silvia Rose Cartwright, Chancellor and Principal Companion of Our New Zealand Order of Merit, Dame Commander of Our Most Excellent Order of the British Empire, Principal Companion of Our Service Order, Governor-General and Commander-in-Chief in and over New Zealand.

[L.S.]

Silvia Cartwright, Governor-General.

By Her Excellency's Command-

Jim Anderton, for Prime Minister. Approved in Council-

Marie Shroff, Clerk of the Executive Council.

* New Zealand Gazette, 11 May 2000, No. 49, page 1072.

** SR 1983/225.

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Terms of Reference (the Warrant)

Te Komihana Tapairu mo Te Kaupapa Whakarereke Ira Momo Whakaheke

Ko Irihapeti te Tuarua, i raro i te Maru o Te Atua, te Kuini o Aotearoa me ana ake Rohe me ana Whenua, te Upoko o Nga Herenga ki Ingarangi, te Kaiwaowao o te Whakapono:

Ki te Tino Honore ki a Ta Thomas Eichelbaum, G.B. E.o Te Whanganui-a-Tara, te Kaiwhakawa Matua mo Aotearoa o mua; Jacqueline Allan, no Tamaki-makau-rau, he rata, Jean Sutherland Fleming, no Otepoti, he kauputaiao; me te Kaikarakia a Richard Randerson, no Tamaki-makau-rau, te Pihopa o te Hahi Mihinare:

Kia Ora

Nga tangata jua tohua me nga whakaritenga

Kia Mohio Mai Koutou, ara, ko matau e whakapono nei, a, e whiwhi whakamanawatanga nei ki to ngakau tapatahi, to matauranga me to pumanawa, kei te mahi matau i tenei, Ta matau Whakaritenga, ki te whakaingoa, te whakatu me te tohu i a koutou, Ta Thomas Eichelbaum, Jacqueline Allan, Jean Sutherland Fleming me te Kaikarakia a Richard Randerson, kia noho hei Komihana, a, kia whiwhi i nga whakaputanga whakaaro mo, te uiui, te tuhura me te whakatakoto purongo mo nga take e whai ake nei:

a. nga kowhiringa rautaki kei te watea, kia taea ai e Aotearoa te titiro inaianei me nga ra kei mua ki te Kaupapa Whakarereke Ira Momo Whakaheke, nga mahi whakarereke ira momo whakaheke mo nga kaiao me nga huanga; me

b. nga rereketanga e whakaarohia ana he pai ki te mahi, e pa ana ki nga ture o naianei, nga whakaritenga, nga kaupapahere, nga whakahaere a-ropu hei titiro ki nga nga mahi whakarereke ira momo whakaheke, nga mahi whakarereke ira momo whakaheke mo nga kaiao, me nga huanga i roto o Aotearoa:

Nga take e whai panga ana

A, ahakoa kaore he here kei runga i nga whakapuakanga kei runga ake nei, e ki tuturu ana Matau, i a koutou e whakahaere ana i te uiuitanga e ahei ana koutou i raro i tenei, Ta Matau Whakaritenga, ki te tuhura me te whiwhi i nga whakaputanga whakaaro mo enei take, ara:

a. ki whea nga wahi hei mahi i te mahi nei, te ahua o te mahi me te take mo nga mahi whakarereke ira momo whakaheke, nga mahi whakarereke ira momo whakaheke mo nga kaiao, me nga huanga e whakamahia ana i roto i Aotearoa inaianei:

b. nga taunakitanga (tae atu ana ki nga taunakitanga putaiao), me nga awangawanga mo te whakamahi i nga tikanga whakarereke ira momo whakaheke, nga mahi whakarereke ira momo whakaheke mo nga kaiao, me nga huanga, e whakamahia ana i roto i Aotearoa inaianei me nga ra kei mua:

c. nga morearea me nga painga i pu mai, i te whakamahi, i te pare ranei i nga mahi whakarereke ira momo whakaheke, nga mahi whakarereke ira momo whakaheke mo nga kaiao, me nga huanga e whakamahia ana i roto i Aotearoa, tae atu ana -

i. ki nga ropu tera ka whai hua mai i nga painga nei; me

ii. nga ropu tera ka rawakoretia e aua morearea:

d. nga herenga ture a-taiao a Aotearoa e pa ana ki nga mahi whakarereke ira momo whakaheke, nga mahi whakarereke ira momo whakaheke mo nga kaiao, me nga huanga:

e. nga here kei roto, nga here tera ka puta ake ranei inaianei, i nga ra kei mua hoki, e pa ana ki te whakamahi i nga tikanga whakarereke ira momo whakaheke, nga mahi whakarereke ira momo whakaheke mo nga kaiao, me nga huanga e whakamahia ana i roto i Aotearoa:

f. nga take kei roto e pa ana ki nga rawa punenga, tera ranei ka whai panga inaianei, i nga ra kei mua ranei, mo te ahua o te whakamahi i nga tikanga whakarereke ira momo whakaheke, nga mahi whakarereke ira momo whakaheke mo nga kaiao, me nga huanga e whakamahia ana i roto i Aotearoa:

g. nga kawenga a te Karauna i raro i te Tiriti o Waitangi e pa ana ki nga tikanga whakarereke ira momo whakaheke, nga mahi whakarereke ira momo whakaheke mo nga kaiao, me nga huanga:

h. nga whakahaere me nga take kei te ao whanui tera ka whai panga ki te ahua o te whakamahi, te whakatiki ranei i te whakamahi a Aotearoa i nga tikanga whakarereke ira momo whakaheke, nga mahi whakarereke ira momo whakaheke mo nga kaiao, me nga huanga:

i. nga huarahi tera ka watea ki Aotearoa mai i te whakamahi, te pare ranei i nga tikanga whakarereke ira momo whakaheke, nga mahi whakarereke ira momo whakaheke mo nga kaiao, me nga huanga:

j. nga tino wahi e paingia ana e te iwi e pa ana ki nga tikanga whakarereke ira momo whakaheke, nga mahi whakarereke ira momo whakaheke mo nga kaiao, me nga huanga, a, ka uru atu -

i. te hauora o te tangata (tae atu ana ki nga take biomedical, te tiaki kai me nga kowhiringa e watea ana ki nga kaiutu):

ii. nga take taiao (tae atu ana ki nga take biodiversity, biosecurity me nga take hauora e pa ana ki nga ecosystem):

iii. nga take ohanga (tae atu ana ki nga mahi rangahau me nga mahi auaha, te whakapakari kaipakihī, nga hua ahuhenua me nga rawa e tukuna ana ki rawahi):

iv. nga take e pa ana ki nga tikanga a-iwi me nga tika:

k. nga tino rautaki e titiro ana ki nga morearea e pa ana ki nga tika, nga tikanga a-iwi, te taiao, te hāpori me te ohanga, tae atu ana ki nga painga e puta ake ana i te whakamahi i nga tikanga whakarereke ira momo whakaheke, nga mahi whakarereke ira momo whakaheke mo nga kaiao, me nga huanga:

l. nga whakataunga ki te ao whanui e whai panga ana ki nga kawenga e here ana i a Aotearoa ki te ao whanui, me nga kaupapahere o Aotearoa e pa ana ki nga whenua o rawahi me nga mahi tauhokohoko, o nga mahi tera ka mahia e Aotearoa ki te whakarereke ira momo whakaheke, nga mahi whakarereke ira momo whakaheke mo nga kaiao, me nga huanga, tae atu ana ki nga whakapaunga me nga morearea e pa ana ki etahi ake kowhiringa:

m. te whanuitanga o nga hua, e ahu ake ana i nga rautaki, o nga tikanga whakarereke ira momo whakaheke, nga mahi whakarereke ira momo whakaheke mo nga kaiao, me nga huanga, ara, ka taea te whakamahi, te pare ranei i nga ra kei mua i a Aotearoa:

n. mehemea he rawaka nga ture me nga whakaritenga e whakahaere ana i nga tikanga whakarereke ira momo whakaheke, nga mahi whakarereke ira momo whakaheke mo nga kaiao, me nga huanga, hei titiro ki nga hua e ahu ake ana i nga rautaki, ara, ki to whakaaro he pai, a mena e hiahiatia ana etahi atu whakarereketanga ki nga ture, ki nga whakaritenga, ki nga kaupapahere, me etahi atu whakarereketanga ranei e hiahiatia ana kia tatu ai i a Aotearoa enei hua:

Nga Tautuhinga

A, e whakapuaka ana Matau, i roto i tenei Ta Matau Whakaritenga, engari koa he rereke te whakahau a te horopaki, -

ko te kaupapa whakarereke ira momo whakaheke, he whakamahi tenei i nga hangarau tatai tikanga i roto i tetahi whare rangahau, ara, he mahi e uru ana -

a. te whakakoretanga, te whakarautanga, te whakangohetanga, te neketanga o nga momo ira ranei i roto i te kaiora ora; ko tenei ranei

b. te whakawhititanga o nga ira mai i tetahi kaiao ki tetahi atu; ko tenei ranei

c. te whakangohetanga o nga ira o naianei, te hanga ira hou ranei me te whakatopu i enei ki roto ki etahi kaiao; ko tenei ranei

te whakamahi i nga whakatipuranga o muri, nga uri ranei o nga kaiao he mea whakangohe ma etahi o nga mahi i whakamaramatia i nga kowae (a) ki (c)

ko te kaiao he mea whakarereke tona ira momo whakaheke, he kaiao tenei na te mahi whakarereke ira momo whakaheke i whakaputa

ka uru atu te tangata ki te kupu kaiao

ka uru ki te kupu huanga, nga mea e whai ake nei; nga huanga rongoa katoa, nga huanga hokohoko, nga huanga matu me nga huanga kai (ahakoa kaore e ahei ana ia ki te whakatauiria ira) i pu mai, tera ranei i pu mai i nga mahi whakarereke ira momo whakaheke.

Nga mea ka mahue ki waho i te uiuitanga

Engari e whakapuaka ana matau kaua koe, i raro i tenei Ta Matau Whakaritenga, e uiui i te mahi whakato kaiao, whakato huanga ranei e whakamahi ana i nga hangarau whakatipu (tae atu ana ki te cloning, mutagenesis, protoplast fusions, (controlled pollinations), hybridisation, hybridomas me nga monoclonal antibody):

Te tohu i te tumuaki

A, e tohu ana Matau i a koe, te Honore Matau Ta Thomas Eichelbaum hei Tumuaki mo te Komihana:

Te Mana Hiki Hui

A, kia pai ake ai to whakahaere i tenei Ta Matau Whakaritenga kia tatu ai, e whakamanahia ana, e whakakahatia ana koe, i raro i nga wahanga o tenei Ta Matau Whakaritenga, ki te whakahaere i tetahi uiuitanga, tetahi tuhuratanga ranei i raro i Ta Matau Whakaritenga ki te ahua, te wa me te wahi e pai ana ki a koe, a, kei a koe te mana ki te hiki i te hui ia wa, ia wa, mai i tetahi wahi ki tetahi atu e ai ki tau e hiahia ana, a, kia haere tonu ai te mahi a tenei Ta Matau Whakaritenga, a, kia taea ai te timata ano tetahi uiuitanga ahakoa ehara i te mea ka rite tonu te hiki i te hui ia wa, ia wa, mai i tetahi wahi ki tetahi atu ranei:

Mahi whakawhiti whakaaro me nga whakahaere

A, e whakahautia ana koe i roto i o mahi whakahaere i tenei Ta Matau Whakaritenga,

- kia whakahaeretia e koe o mahi whakawhiti whakaaro me te iwi, kia watea ai ratau ki te ata whakamarama i o ratau whakaaro, tae atu ana ki nga tirohanga e pa ana ki te tika, nga tikanga a-iwi, te taiao me nga mahi putaiao, mo te whakamahi i nga tikanga whakarereke ira momo whakaheke, nga mahi whakarereke ira momo whakaheke mo nga kaiao, me nga huanga; a
- kia whakapumautia e koe nga tikanga whakahaere hei whakatenatena i nga tangata ki te whakaputa i o ratau whakaaro e pa ana ki nga take i roto i te kowae o mua atu nei; a
- kia whakawhiti whakaaro koe me te iwi Maori kia tino mohiotia ai kei te tiakina o ratau nei hiahiatanga; a
- kia whakamahia e koe nga pukenga e whai panga ana, tae atu ana ki nga ratonga whakawhiti whakaaro me nga ratonga mahi hekeretari, me te whakahaere i au ake rangahau i nga wa e tika ana:

A, e whakakahatia ana koe, i a koe e mahi ana kia tatu tenei Ta Matau Whakaritenga, -

a. ki te whakatika me te whakaputa i nga pepa whakawhiti korero ia wa, ia wa mo nga take e whai panga ki te uiuitanga; a

b. engari koa e whakaaro ana koe he tika ki te pupuri i etahi taunakitanga, etahi parongo ranei i whiwhi koe i a koe e mahi ana i raro i te mana kua tukuna ki a koe, -

i. ki te whakauru ki nga pepa whakawhiti korero nau i whakatika, nau i whakaputa, te katoa, etahi ranei o aua taunakitanga, aua parongo ranei; a

ii. ki te whakaputa, te mahi ke ranei ki te panui ma etahi atu tikanga e whakaaro ana koe he tika, te katoa, etahi ranei o aua taunakitanga, aua parongo ranei:

Nga wahanga whanui

A, ahakoa kaore he here kei runga i etahi atu o o mana whakahaere ki te whakarongo ki nga take e whakahaeretia ana i tetahi wahi muna, ki te aukati ranei i tetahi tangata mai i o hui, kei a koe te mana ki te aukati i te tangata ahakoa ko wai mai i nga whakahaere, tae atu ana ki nga hui kei reira e tangohia ana nga taunakitanga, mehemea e tika ana tenei ki to whakaaro:

A, e tino whakahautia ana, e tohutohutia ana koe kia kaua koe e noho ka whakaputa, ka panui ranei i nga take kei roto i nga purongo, te huarahi ranei e whaia ana e aua purongo, he mea hanga, e mea ana ranei koe ki te hanga, haunga ia ki te Kawana Tianara e ai ki tenei Ta Matau Whakaritenga, ki te whakahau ranei a te Kawana Tianara:

A, e whakapuaka ana matau ko nga mana whakahaere i whakamaua e tenei Ta Matau Whakaritenga, ka taea te whakahaere enei ahakoa kei te ngaro tetahi mema kotahi, etahi mema e rua ranei i tohua ki tenei Ta Matau Whakaritenga meana kei reira te Tiamana, tetahi mema ranei he mea whakarite e te Tiamana hei kawe i tana turanga, me tetahi atu mema, i runga i ta ratau whakaae ki te whakamahi i enei mana whakahaere:

A, i tua atu e whakapuaka ana Matau kei te watea koe ki te whakapurongo i o whakahaere me o kitenga i raro i tenei Ta Matau Whakaritenga, ia wa, ia wa mehemea ki to whakaaro he pai ki te mahi penei:

Te Ra Whakapurongo

A, ma te whakamahi i nga tikanga mamahi me hoatu e koe tetahi purongo ki te Kawana Tianara, mahau tonu e tuhi, a, kia kaua e tae atu ki a ia i muri i te 1 o nga ra o Hune 2001, mo o kitenga me o whakaaro mo nga take kua whakahuatia i mua atu nei, i te taha o etahi tutohutanga e whakaaro ana koe he tika ki te whakatakoto, e pa ana ki aua take:

A, ko te mea whakamutunga, e whakapuakatia ana enei tapanetanga i raro i te mana o nga Reta Arai a Kuini Irihapeti te Tuarua e whakatu ana i te tari o te Kawana Tianara o Aotearoa, he mea haina i te 28 o nga ra o Oketopa 1983, a, i raro i te mana o, a, e whakataka ana ki nga wahanga o te Ture o te Komihana Uiuitunga 1908, me nga whakamaherehere me nga whakaaetanga o te Kaunihera Whakahaere o Aotearoa.

Hei whakatuturutanga kua tukuna e Matau tenei Ta Matau Whakaritenga, me te Hira o Aotearoa kia whakamaua i naianei tonu ki Te Whanganui-a-ara i tenei te 8 o nga ra o Mei 2000.

Tirohia Ta Matau Tino Pou me Ta Matau Tumu Korero Kaiwhakatakoto Aroha a Ta Michael Hardie Boys, Principal Knight Companion of Our New Zealand Order of Merit, Knight Grand Cross of the Most Distinguished Order of Saint Michael and Saint George, Principal Companion of Our Service Order, Governor-General and Commander-in-Chief in and over New Zealand.

Michael Hardie Boys, Kawana Tianara.

I raro i tana whakahau -

Helen Clark, Pirimia.

I whakaaetia i roto i te Kaunihera -

Marie Shroff, Kaituhi o te Kaunihera Whakahaere Kaupapa.

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Treaty of Waitangi

Summary of the Treaty's history and images at the National Archives

The Treaty of Waitangi is seen as the founding document of the nation of New Zealand. It was signed in 1840 by representatives of the British Crown and Maori chiefs.

There are three copies of the treaty here:

- the English version as signed;
- the Maori version as signed; and
- a modern English translation of the Maori version.

The Treaty of Waitangi 1840

[English text of the Treaty]

Her Majesty Victoria Queen of the United Kingdom of Great Britain and Ireland regarding with Her Royal Favour the Native Chiefs and Tribes of New Zealand and anxious to protect their just Rights and Property and to secure to them the enjoyment of Peace and Good Order has deemed it necessary in consequence of the great number of Her Majesty's Subjects who have already settled in New Zealand and the rapid extension of Emigration both from Europe and Australia which is still in progress to constitute and appoint a functionary properly authorized to treat with the Aborigines of New Zealand for the recognition of Her Majesty's Sovereign authority over the whole or any part of those islands.

Her Majesty therefore being desirous to establish a settled form of Civil Government with a view to avert the evil consequences which must result from the absence of the necessary Laws and Institutions alike to the native population and to Her subjects has been graciously pleased to empower and to authorize "me William Hobson a Captain" in Her Majesty's Royal Navy Consul and Lieutenant Governor of such parts of New Zealand as may be or hereafter shall be ceded to Her Majesty to invite the confederated and independent Chiefs of New Zealand to concur in the following Articles and Conditions.

ARTICLE THE FIRST

The Chiefs of the Confederation of the United Tribes of New Zealand and the separate and independent Chiefs who have not become members of the Confederation cede to Her Majesty the Queen of England absolutely and without reservation all the rights and powers of Sovereignty which the said Confederation or Individual Chiefs respectively exercise or possess, or may be supposed to exercise or to possess, over their respective Territories as the sole Sovereigns thereof.

ARTICLE THE SECOND

Her Majesty the Queen of England confirms and guarantees to the Chiefs and Tribes of New Zealand and to the respective families and individuals thereof the full exclusive and undisturbed possession of their Lands and Estates Forests Fisheries and other properties which they may collectively or individually possess so long as it is their wish and desire to retain the same in their possession; but the Chiefs of the United Tribes and the individual Chiefs yield to Her Majesty the exclusive right of Preemption over such lands as the proprietors thereof may be disposed to alienate at such prices as may be agreed upon between the respective Proprietors and persons appointed by Her Majesty to treat with them in that behalf.

ARTICLE THE THIRD

In consideration thereof Her Majesty the Queen of England extends to the Natives of New Zealand Her royal protection and imparts to them all the Rights and Privileges of British Subjects.

[Signed] W Hobson Lieutenant Governor

Now therefore We the Chiefs of the Confederation of the United Tribes of New Zealand being assembled in Congress at Victoria in Waitangi and We the Separate and Independent Chiefs of New Zealand claiming authority over the Tribes and Territories which are specified after our respective names, having been made fully to understand the Provisions of the foregoing Treaty, accept and enter into the same in the full spirit and meaning thereof in witness of which we have attached our signatures or marks at the places and the dates respectively specified

Done at Waitangi this Sixth day of February in the year of Our Lord one thousand eight hundred and forty.

Tiriti o Waitangi 1840

[Maori text of the Treaty]

Ko Wikitoria te Kuini o Ingarani i tana mahara atawai ki nga Rangatira me nga Hapu o Nu Tirani i tana hiahia hoki kia tohungia ki a ratou o ratou rangatiratanga me to ratou wenua, a kia mau tonu hoki te Rongo ki a ratou me te Atanoho hoki kua wakaaro ia he mea tika kia tukua mai tetahi Rangatira—hei kai wakarite ki nga Tangata maori o Nu Tirani—kia wakaaetia e nga Rangatira maori te Kawanatanga o te Kuini ki nga wahikatoa o te Wenua nei me nga Motu—na te mea hoki he tokomaha ke nga tangata o tona Iwi Kua noho ki tenei wenua, a e haere mai nei.

Na ko te Kuini e hiahia ana kia wakaritea te Kawanatanga kia kaua ai nga kino e puta mai ki te tangata Maori ki te Pakeha e noho ture kore ana.

Na, kua pai te Kuini kia tukua a hau a Wiremu Hopihona he Kapitana i te Roiara Nawi hei Kawana mo nga wahi katoa o Nu Tirani e tukua aiane, amoa atu ki te Kuini, e mea atu ana ia ki nga Rangatira o te wakaminenga o nga hapu o Nu Tirani me era Rangatira atu enei ture ka korerotia nei.

KO TE TUATAHI

Ko nga Rangatira o te wakaminenga me nga Rangatira katoa hoki ki hai i uru ki taua wakaminenga ka tuku rawa atu ki te Kuini o Ingarani ake tonu atu—te Kawanatanga katoa o ratou wenua.

KO TE TUARUA

Ko te Kuini o Ingarani ka wakarite ka wakaae ki nga Rangatira ki nga hapu—ki nga tangata katoa o Nu Tirani te tino rangatiratanga o ratou wenua o ratou kainga me o ratou taonga katoa. Otiia ko nga Rangatira o te wakaminenga me nga Rangatira katoa atu ka tuku ki te Kuini te hokonga o era wahi wenua e pai ai te tangata nona te Wenua—ki te ritenga o te utu e wakaritea ai e ratou ko te kai hoko e meatia nei e te Kuini hei kai hoko mona.

KO TE TUATORU

Hei wakaritenga mai hoki tenei mo te wakaaetanga ki te Kawanatanga o te Kuini—Ka tiakina e te Kuini o Ingarani nga tangata maori katoa o Nu Tirani ka tukua ki a ratou nga tikanga katoa rite tahi ki ana mea ki nga tangata o Ingarani.

[signed] William Hobson Consul & Lieutenant Governor

Na ko matou ko nga Rangatira o te Wakaminenga o nga hapu o Nu Tirani ka huihui nei ki Waitangi ko matou hoki ko nga Rangatira o Nu Tirani ka kite nei i te ritenga o enei kupu, ka tangohia ka wakaaetia katoatia e matou, koia ka tohungia ai o matou ingoa o matou tohu.

Ka meatia tenei ki Waitangi i te ono o nga ra o Pepueri i te tau kotahi mano, e waru rau e wa te kau o to tatou Ariki.

Treaty of Waitangi 1840

[Translation of the Maori text of the Treaty,
by Professor Sir Hugh Kawharu, used with permission]

Victoria, the Queen of England, in her concern to protect the chiefs and the subtribes of New Zealand and in her desire to preserve their chieftainship (1) and their lands to them and to maintain peace (2) and good order considers it just to appoint an administrator (3) one who will negotiate with the people of New Zealand to the end that their chiefs will agree to the Queen's Government being established over all parts of this land and (adjoining) islands (4) and also because there are many of her subjects already living on this land and others yet to come. So the Queen desires to establish a government so that no evil will come to Maori and European living in a state of lawlessness. So the Queen has appointed "me, William Hobson a Captain" in the Royal Navy to be Governor for all parts of New Zealand (both those) shortly to be received by the Queen and (those) to be received hereafter and presents (5) to the chiefs of the Confederation chiefs of the subtribes of New Zealand and other chiefs these laws set out here.

THE FIRST

The Chiefs of the Confederation and all the Chiefs who have not joined that Confederation give absolutely to the Queen of England for ever the complete government (6) over their land.

THE SECOND

The Queen of England agrees to protect the chiefs, the subtribes and all the people of New Zealand in the unqualified exercise (7) of their chieftainship over their lands, villages and all their treasures (8). But on the other hand the Chiefs of the Confederation and all the Chiefs will sell (9) land to the Queen at a price agreed to by the person owning it and by the person buying it (the latter being) appointed by the Queen as her purchase agent.

THE THIRD

For this agreed arrangement therefore concerning the Government of the Queen, the Queen of England will protect all the ordinary people of New Zealand and will give them the same rights and duties (10) of citizenship as the people of England (11).

[signed] William Hobson Consul & Lieut. Governor

So we, the Chiefs of the Confederation of the subtribes of New Zealand meeting here at Waitangi having seen the shape of these words which we accept and agree to record our names and our marks thus.

Was done at Waitangi on the sixth of February in the year of our Lord 1840.

Footnotes

- (1) “Chieftainship”: this concept has to be understood in the context of Maori social and political organisation as at 1840. The accepted approximation today is “trusteeship”.
- (2) “Peace”: Maori “Rongo”, seemingly a missionary usage (rongo – to hear ie hear the “Word” – the “message” of peace and goodwill, etc).
- (3) Literally “Chief” (“Rangatira”) here is of course ambiguous. Clearly a European could not be a Maori, but the word could well have implied a trustee-like role rather than that of a mere “functionary”. Maori speeches at Waitangi in 1840 refer to Hobson being or becoming a “father” for the Maori people. Certainly this attitude has been held towards the person of the Crown down to the present day – hence the continued expectations and commitments entailed in the Treaty.
- (4) “Islands” ie coastal, not of the Pacific.
- (5) Literally “making” ie “offering” or “saying” – but not “inviting to concur”.
- (6) “Government”: “kawanatanga”. There could be no possibility of the Maori signatories having any understanding of government in the sense of “sovereignty” ie any understanding on the basis of experience or cultural precedent.
- (7) “Unqualified exercise” of the chieftainship – would emphasise to a chief the Queen’s intention to give them complete control according to their customs. “Tino” has the connotation of “quintessential”.
- (8) “Treasures”: “taonga”. As submissions to the Waitangi Tribunal concerning the Maori language have made clear, “taonga” refers to all dimensions of a tribal group’s estate, material and non-material – heirlooms and wahi tapu (sacred places), ancestral lore and whakapapa (genealogies), etc.
- (9) Maori “hokonga”, literally “sale and purchase”. Hoko means to buy or sell.
- (10) “Rights and duties”: Maori “tikanga”. While tika means right, correct, (eg “e tika hoke” means “that is right”), “tikanga” most commonly refers to custom(s), for example of the marae (ritual forum); and custom(s) clearly includes the notion of duty and obligation.
- (11) There is, however, a more profound problem about “tikanga”. There is a real sense here of the Queen “protecting” (ie allowing the preservation of) the Maori people’s tikanga (ie customs) since no Maori could have had any understanding whatever of British tikanga (ie rights and duties of British subjects.) This, then, reinforces the guarantees in Article 2.

Notes for readers

Quotations and macrons

This volume includes numerous direct quotations from our consultation process. Many quotations are sentence fragments. Minor changes have been made to direct quotations for the sake of readability and consistency. Thus:

- *realize, eg, 1990's, GMO's* have been changed to *realise, eg, 1990s, GMOs* respectively, in line with the Report style
- abbreviation of *NZ* in quoted material has been replaced by *New Zealand* and *biotech* by *biotechnology*, but other abbreviations (such as *GE, GMO, IP*) have been retained
- punctuation has sometimes been altered so that an initial capital is replaced by a lower-case letter when the direct quotation functions as a sentence fragment in the text, rather than a complete sentence
- ellipses (...), normally indicating the omission of words or sentences within the quotation, are used at the opening or closing of the quotation only if it is relevant to signal a continuing argument or theme.

No changes to quotations affect the meaning intended by the submitter.

The format for quotations depends on their extent or context in the Report structure. Two formats have been used:

- Short quotations, including sentence fragments, are incorporated in normal paragraphs and are indicated by quotation marks.
- Longer quotations, usually passages of several sentences or paragraphs, are presented as an indented paragraph or paragraphs below a colon. They are in a smaller type size and indented on the left. These quotations do not use quotation marks.

The choice of format is determined by the context and does not indicate that one quotation is considered more important than any other.

The printed version of the Report of the Commission adopts the common modern usage of macrons over long vowels in Maori terms.

Interested Persons

The Report uses the term ‘Interested Person’ to refer to those who were entitled to take part in the formal hearings because, in terms of section 4 of the Commissions of Inquiry Act 1908, they satisfied the Commission they had an interest in the Inquiry apart from any interest in common with the public (see Appendix 1: Section 3.3 for further details).

Abbreviations

This Report uses the title of an organisation in full at first mention in each chapter of the Report and thereafter uses any designated abbreviated form or acronym. This procedure is repeated for each chapter. Thus, in chapter 3, under “Religious world views from the Judaeo-Christian tradition”, “Anglican Church in Aotearoa New Zealand and Polynesia” is subsequently referred to as “Anglican Church”, and where the “Environmental Risk Management Authority” (ERMA) appears, it will be followed in that chapter by “ERMA”. The choices for abbreviated forms of Interested Persons are listed in table 1 of Appendix 2. A few names of Interested Persons were abbreviated further in this volume for the sake of readability.

References

Endnotes to chapters in this Report often make reference to transcripts, submissions and other documents received by the Commission during the course of its inquiry. Many of these are available on the Commission website, www.gmcommission.govt.nz, which will be maintained until 30 June 2002.

Reference notes

Chapter 1: Introduction

- 1 See pages 364-369 (English) & pages 369-374 (Maori) for Her Majesty the Queen's full instructions, called "The Warrant".
- 2 In the inquiry process under the Commissions of Inquiry Act 1908, those accorded Interested Persons status had the right to appear before the Commission in person (or by counsel or agent) and give oral evidence. For further detail, see appendix 1, section 3.3, "Formal Hearings: the process".

Chapter 3: Cultural, ethical and spiritual issues

- 1 For example, Royal Society of New Zealand [IP77b] Interested Person submission: Executive Summary, para 1. New Zealand Life Sciences Network [IP24]. Interested Person submission: Name of Organisation/Person section. Crop and Food Research [IP4]. Interested Person submission: sB(j), Summary, para 67.
- 2 Friends of the Earth [IP78] Interested Person submission: sB(j), (Summary), para 1.7.
- 3 Moana Jackson (Kahungunu), 10 February, 2001. Hastings regional hui. Omahu Pa, Fernhill. Transcript.
- 4 The Anglican Church in Aotearoa New Zealand and Polynesia [IP42]. Evidence of Stephanie McIntyre, 19 February, 2001. Transcript of proceedings: page 3825.
- 5 Terehia Kipa (Tuhoe, Te Arawa), 24 February, 2001. Christchurch regional hui. Te Waipounamu House, Christchurch. Transcript.
- 6 Sir John Turei (Tuhoe), 10 March, 2001. Auckland regional hui. Orakei Marae. Transcript.
- 7 Te Runanga o Ngai Tahu [IP41]. Interested Person submission: sB(j)(ii), para 31.
- 8 Ngati Wairere were the occupiers of the land at Ruakura from around 1840. The land subsequently passed into Crown ownership, but was finally returned to the Waikato Raupatu Lands Trust as part of the Deed of Settlement between the Crown and Waikato Tainui signed in 1995. Through all this Ngati Wairere have made the point that they continue to hold and have never relinquished manawhenua over the land.
- 9 John Hohapata-Oke (Ngati Awa), 2 December, 2000. Rotorua regional hui. Tamatekapua Marae, Rotorua. Transcript.
- 10 Donald M Bruce. The Importance of Public Values in the Safety and Risk Assessment of GM Foods. OECD Conference on Biotechnology and Food Safety, Edinburgh, 2000. Reprinted in Appendix 4: Professor Brian Jordan. *OECD Conference on the Scientific and Health Aspects of Genetically Modified Foods. A report prepared for The Ministry of Research, Science and Technology. Edinburgh, 28 February - 1 March 2000.* Massey University, April 2000.
- 11 Friends of the Earth [IP78]. Interested Person submission: sB(j), Summary, para 1.7.
- 12 Friends of the Earth: sB(j)(ii), para 1.1.
- 13 Green Party of Aotearoa/New Zealand [IP83]. Interested Person submission: sB(j)(iv), para 12.
- 14 Friends of the Earth [IP78]. Interested Person submission: sB(j), Summary, para 1.7.
- 15 World scientists' statement calling for a moratorium on GM crops and ban on patents: This statement was issued during the 1999 meeting on the UN Convention on Biodiversity held in Cartagena, Columbia to consider the Biosafety Protocol. It was issued by 125 scientists from 24 countries; by April 2000 the number of signatories had risen to 310 scientists from 36 countries. Quoted in: *Work in progress: proceed with caution. Primary Producer Access to Gene Technology.* House of Representatives Standing Committee on Primary Industries and Regional Services, Australia.

- 16 Koanga Gardens Charitable Trust [IP72]. Interested Person submission: sA(1), para 11.
- 17 New Zealand Catholic Bishops' Conference [IP98]. Evidence of Dr Michael McCabe, 22 February 2001. Transcript of proceedings: page 4004.
- 18 Quaker Spiritual Ecology Group, Religious Society of Friends [IP50]. Evidence of Joanna Paul, 22 February 2001. Transcript of proceedings: page 3955.
- 19 Anglican Church in Aotearoa New Zealand and Polynesia [IP42]. Interested Person submission: Executive Summary.
- 20 Public Questions Committee [IP93]. Interested Person submission: Executive Summary, para 4.15.
- 21 New Zealand Jewish Community [IP80]. Interested Person submission: para 7.
- 22 Anglican Church in Aotearoa New Zealand and Polynesia [IP42]. Evidence of Stephanie McIntyre, 19 February, 2001. Transcript of Proceedings: page 3824.
- 23 New Zealand Catholic Bishops' Conference [IP38]. Evidence of Anne Dickinson, 22 February 2001. Transcript of proceedings: page 4005.
- 24 New Zealand Catholic Bishops' Conference [IP38]. Interested Person submission: Executive Summary, para 7.
- 25 New Zealand Catholic Bishops' Conference [IP38]. Interested Person submission: sB(j)(i), para 2.
- 26 Anglican Church in Aotearoa New Zealand and Polynesia [IP42]. Interested Person submission: sB(j)(iv).
- 27 Anglican Church in Aotearoa New Zealand and Polynesia [IP42]: sB(j)(iv).
- 28 *Bleakley v ERMA* AP177/00 HC, Wellington 2 May 2001 unreported.
- 29 University of Auckland [IP16]. Evidence of Dr Ingrid Winship, 25 October 2000. Transcript of proceedings: page 472.
- 30 Environmental Risk Management Authority [IP76]. Interested Person submission: sB(j)(iv), para 4.
- 31 New Zealand Catholic Bishops' Conference [IP38]. Interested Person submission: s B(j)(iv), para 27.
- 32 New Zealand Catholic Bishops' Conference [IP38]: Executive Summary, para 15.
- 33 Dr Maurice Ormsby. Called by New Zealand Wool Board [IP30]. Witness brief: sB(j)(iv), para 4.
- 34 Dr Maurice Ormsby. Witness brief: sB(j)(iv), para 5.5.
- 35 Save Animals from Exploitation (SAFE) [IP85]. Interested Person submission: sB(k), paragraph 204.
- 36 New Zealand Catholic Bishops' Conference [IP38]. Interested Person submission. Executive Summary, para 5.
- 37 Friends of the Earth [IP78]. Interested Person submission: sB(k), para 1.4.
- 38 Bevan Tipene Matua (Ngai Tahu, Kahungunu), 24 February 2001. Christchurch regional hui. Te Waipounamu House, Christchurch. Transcript.
- 39 Moana Jackson (Kahungunu), 10 February, 2001. Hastings regional hui. Omaha Marae. Transcript.
- 40 Muaupoko Co-operative Society [IP57]. Evidence of Vivienne Taueki, 27 February, 2001. Transcript of proceedings: page 4217.
- 41 Reverend Edward Ellison (Ngai Tahu), 6 March, 2001. Dunedin regional hui. Otakou Marae, Otakou. Transcript.
- 42 Sir John Turei (Tuhoë). 10 March, 2001. Auckland regional hui, Orakei Marae. Transcript.
- 43 Save Animals From Exploitation (SAFE) [IP85]. Interested Person submission: sB(k), para 197.
- 44 New Zealand Transgenic Animal Users [IP45]. Interested Person submission: sB(j)(v), para 91.
- 45 Mere McGarvey (Tainui), 17 February, 2001. Gisborne regional hui. Poho-o-Rawiri Marae, Gisborne. Transcript.
- 46 Angeline Ngahina Greensill (Tainui). Called by Nga Wahine Tiaki o te Ao [IP64]. Witness brief: Executive Summary.
- 47 Te Manawanui Pauro (Atihaunui-a-Paparangi), 4 November, 2000. Wanganui regional hui. Te Ao Hou Marae, Wanganui. Transcript.

- 48 Tamati Cairns and Paora Ammunsen. Called by New Zealand Life Sciences Network Incorporated [IP24]. Witness brief: sB(g), s2, para 49.
- 49 Tamati Cairns and Paora Ammunsen. Witness brief: sB(g), s2, para 46.
- 50 Tamati Cairns and Paora Ammunsen. Witness brief: sB(g), s2, para 47.
- 51 George Ria (Rongowhakata), 17 February, 2001. Gisborne regional hui. Poho-o-Rawiri Marae, Gisborne. Transcript.
- 52 Nici Gibbs. *Genetically Modified Organisms and Maori Cultural and Ethical Issues*. Background paper presented to the Royal Commission on Genetic Modification, commissioned by the Ministry for the Environment June 1996.
- 53 Unknown speaker, 6-8 April, 2001. National hui. Turangawaewae Marae, Ngaruawahia. Transcript.
- 54 Environmental Risk Management Authority [IP76]. Interested Person submission: Executive Summary, sA(2), para 5.
- 55 Environmental Risk Management Authority [IP76]. Interested Person submission: Executive Summary, sA(2), para 7.
- 56 Parliamentary Commissioner for the Environment [IP70]. Evidence of Dr Morgan Williams in cross-examination, 28 February 2001. Transcript of proceedings: page 4336.

Chapter 4: Environment and health issues

- 1 Information drawn from:
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Chapter 9: Medicine

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Chapter 10: Intellectual property

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Chapter 11: Te Tiriti o Waitangi

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Glossary of Māori terms

Maori term	English equivalent in context
Aotearoa	New Zealand
atua	divinity, god
hapu	clan
harakeke	New Zealand flax, <i>Phormium tenax</i>
hauoratanga	good health
hua	result, fruit
hui	conferences
ika	fish
ira tangata	human element of life
iwi	kin groups, public, communities
kai	food
kaik	village
kaihautu	host
kaikorero	representative, speaker
kaitiaki	guardian
kaitiakitanga	guardianship
kanohi ki te kanohi	face to face
kaumatua	male elder, elders
kaupapa	topic, project
kawa	ritual
kawai whakaheke	lines of descent
kirehe	animals, creatures
kokako	blue-wattled crow, <i>Callaeas cinerea cinerea</i>
korero	communicate
kuia	female elder, elders
kumara	sweet potato
kura kaupapa	school using Maori as the medium of instructions
mana	authority, control; prestige, standing

mana tangata tiaki	standing as a custodian for cultural matters
marae	meeting house
matauranga	knowledge
mauri	life principle, principle
mihimihi	welcome
Pakeha	European, non-Maori
papatipu	land with Maori title
Po	night, the underworld, the after-life
pohutukawa	a tree, <i>Metrosideros excelsa</i>
powhiri	opening ceremony
puharakeke	a land snail
pukenga	skilled, a repository
rangatahi	young Maori
rangatira	chief
rangatiratanga	independence, dominion
rawaho	an outsider
reo	language
reo irirangi Maori	Maori radio
riwai	potato
rohe	area
rongoa	medicine
runanga	councils, boards
taiao	environment, world view
take	subject of discussion
takiwa	district
tamariki	children
tangata tiriti	persons of cultures other than Maori
tangata whenua	local people, native people
taonga	assets, belongings
taonga tuku iho	treasures handed down from the ancestors
tapu	inviolable
Te ao Maori	the Maori world

te reo (te reo Maori)	the Maori language
Te Tiriti o Waitangi	Treaty of Waitangi
teina	younger sister of a female, younger brother of a male
tika	correct
tikanga	culture, cultural, customs
tino rangatiratanga	independence
toku	my
tu	to stand
tuakana	older sister of a female, older brother of a male
tupuna	ancestor
w'akapapa	Wanganui and Taranaki dialect for whakapapa
wairua	spirit
wananga	seminar, workshop
whakapapa	genealogy, heredity
whanau	family
whanui	broad, a group or people in general
whenua	land

Glossary of abbreviations

ACABQ	Advisory Committee on Administrative and Budgetary Questions
ACGNT	Advisory Committee on Novel Genetic Techniques
ACVM Act	Agricultural Compounds and Veterinary Medicines Act
ADB	Asian Development Bank
AIA	advance informed agreement
AIDS	acquired immune deficiency syndrome
ANZCERTA	Australia New Zealand Closer Economic Relations Trade Agreement
ANZECC	Australia and New Zealand Environment and Conservation Council
ANZFA	Australia New Zealand Food Authority
ANZFSC	Australia New Zealand Food Standards Council
APEC	Asia-Pacific Economic Cooperation
ASEAN	Association of South-East Asian Nations
ATC	Agricultural Technical Cooperation
BLIS	bacteriocin-like inhibitory substances
BNP	brain natriuretic peptide
BSE	bovine spongiform encephalopathy
Bt	<i>Bacillus thuringiensis</i>
CAC	Codex Alimentarius Commission
CBD	Convention on Biological Diversity
CCFL	Codex Committee on Food Labelling
CCGP	Codex Committee on General Principles
CER	Closer Economic Relations [with Australia] (CER includes ANZCERTA)
CGD	chronic granulomatous disease
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
CRESA	Centre for Research Evaluation and Social Assessment

CRI	Crown Research Institute
DDT	dichlorodiphenyltrichloroethane
DHB	District Health Board
DIA	Department of Internal Affairs
DNA	deoxyribonucleic acid
DOC	Department of Conservation
ECOSOC	Economic and Social Council
ERMA	Environmental Risk Management Authority
ESR	Institute of Environmental Science and Research
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration
FeLV	feline leukaemia virus
FRST	Foundation for Research, Science and Technology
GATT	General Agreement on Tariffs and Trade
G-CSF	granulocyte-colony stimulating factor
GDP	gross domestic product
GE	genetic engineering
GM	genetic modification
GMAC	Genetic Modifications Approval Committee
GMO	genetically modified organism
GMP	genetically modified product
GST	Goods and Services Tax
GTAC	Genetic Technology Advisory Committee
hAAT	human alpha-1-antitrypsin
HCV	hepatitis C virus
HDC	Health and Disability Commissioner
HFA	Health Funding Authority
HGT	horizontal gene transfer
HHS	Hospital and Health Service
HIV	human immunodeficiency virus
HRC	Health Research Council

HSNO	Hazardous Substances and New Organisms Act 1996
IBAC	Independent Biotechnology Advisory Committee
IBRD	International Bank for Reconstruction and Development
IBSC	Institutional Biological Safety Committee
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights
ICSID	International Centre for Settlement of Investment Disputes
IDA	International Development Association
IFC	International Finance Corporation
IP	(a) Interested Person
IP	(b) intellectual property
IPM	Integrated Pest Management
IPONZ	Intellectual Property Office of New Zealand
IPPC	International Plant Protection Convention
IPR	intellectual property right
ISE	International Society of Ethnobiologists
ISPM	International Standard for Phytosanitary Measures
LMO	living modified organism
MAAC	Medicines Assessment Advisory Committee
MAF	Ministry of Agriculture and Forestry
MAS	marker assisted selection
MCA	Ministry of Consumer Affairs
MED	Ministry of Economic Development
MFAT	Ministry of Foreign Affairs and Trade
MfE	Ministry for the Environment
MH	malignant hypothermia
MIGA	Multilateral Investment Guarantee Agency
MMP	Mixed Member Proportional
MOH	Ministry of Health
MoRST	Ministry of Research, Science and Technology
MOU	Memorandum of Understanding

mRNA	messenger RNA
NACHD	National Advisory Committee on Health and Disability
NAEAC	National Animal Ethics Advisory Committee
NAWAC	National Animal Welfare Advisory Committee
NECHAR	National Ethics Committee on Human Assisted Reproductions
NPPO	National Plant Protection Organization
NZHIS	New Zealand Health Information Service
NZODA	New Zealand Official Development Assistance
OCR	Official Cash Rate
OECD	Organisation for Economic Co-operation and Development
OEEC	Organisation for European Economic Co-operation
OIE	Office International des Epizooties
OSH	Occupational Safety and Health Service
PCE	Parliamentary Commissioner for the Environment
PKU	phenylketonuria
PS	public submission
PVR	Plant Variety Rights
R&D	research and development
RCGM	Royal Commission on Genetic Modification
RMA	Resource Management Act 1991
RNA	ribonucleic acid
RPPO	Regional Plant Protection Organization
SCOTT	Standing Committee on Therapeutic Trials
SPS Agreement	Agreement on the Application of Sanitary and Phytosanitary Measures
SPSS	Statistical Package for the Social Sciences
TBT Agreement	Agreement on Technical Barriers to Trade
TGA	Therapeutic Goods Administration
TRIPS Agreement	Agreement on Trade-Related Aspects of Intellectual Property Rights
TTMRA	Trans-Tasman Mutual Recognition Arrangement

UDHR	Universal Declaration of Human Rights
UN	United Nations
UNEP	United Nations Environment Programme
UNESCO	United Nations Educational, Scientific and Cultural Organization
UPOV	International Union for the Protection of New Varieties of Plants
UPOV	Union Internationale pour la Protection des Obtentions Vegetale
VAT	Value Added Tax
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Glossary of technical terms

This glossary of technical terms indicates the source of the definition. It presents, in some instances, more than one definition of a term, with the second entry providing an expanded explanation. Expanded definitions may also focus on the application of the terms in the field of genetic modification rather than in their widest context. Entries have been edited to conform with Report style if necessary. Some entries, marked [New Zealand], provide an explanation particularly applicable to New Zealand circumstances.

a-amylase, alpha-amylase

Alpha amylase breaks the alpha-1,4-glucosidic bonds of starch to yield oligosaccharides. Slightly different versions of this enzyme are produced by the bacteria *Bacillus amyloliquefaciens*, *B. licheniformis*, *B. subtilis* and the fungus *Aspergillus oryzae*. Alpha amylase is used to make corn syrup, beer, wallpaper removers, cold-soluble laundry starch, and digestive aids.

BioTech Life Sciences Dictionary

Any of a group of enzymes that are present in saliva, pancreatic juice, and parts of plants and catalyze the hydrolysis of starch to sugar to produce carbohydrate derivatives.

The American Heritage Dictionary of the English Language

b-carotene, beta-carotene

An antioxidant which protects cells against oxidation damage that can lead to cancer. Beta carotene is converted, as needed, to vitamin A.

A yellow carotenoid pigment that gives a reddish colour to plants such as carrots and tomatoes. It is often used as a vitamin supplement because the liver can convert it into Vitamin A.

Nutritional and Metabolic Diseases.

The isomeric form of carotene that is widely distributed in nature and most efficiently converted to vitamin A by the body.

The American Heritage Dictionary of the English Language

allergen

A substance that causes an allergic reaction.

Waiter, there's a Gene in My Food

also **allergic reaction, allergy**: an exaggerated physical response to some

antigen, typically a common environmental substance, that produces little or no response in the general population, resulting when histamine or histamine-like substances are released from injured cells. It involves various respiratory and dermatological symptoms, such as sneezing or itching.

Academic Press Dictionary of Science and Technology

also **allergenicity**: Ability to induce various types of allergic responses (also known as hypersensitivity responses).

Virology/Immunology

amino acid

The basic subunit of a protein, coded by triplets of bases in the DNA blueprint. There are 20 amino acids universally found in proteins.

Bernie May

The fundamental building blocks of a protein molecule. A protein is composed of a chain of hundreds or thousands of amino acids. Our bodies can synthesise most of the amino acids. However, eight amino acids (called “essential amino acids”) must be obtained from food.

About Biotechnology

antibiotic resistance

The ability of a bacterium to synthesise a protein that neutralises an antibiotic.

BioTech Life Sciences Dictionary

also **antibiotic resistance genes**: Genes in a microorganism that confer resistance to antibiotics, for example by coding for enzymes that destroy it, by coding for surface proteins that prevent it from entering the microorganism, or by being a mutant form of the antibiotic’s target so that it can ignore it.

BioTech Life Sciences Dictionary

antibody

A protein produced in response to the presence of a specific antigen.

About Biotechnology

antigen

A usually protein or carbohydrate substance (as a toxin or enzyme) capable of stimulating an immune response.

Merriam-Webster’s Collegiate Dictionary

antimetabolite

A substance that replaces or inhibits an organism’s utilization of a metabolite

Merriam-Webster’s Collegiate Dictionary

aquaculture

The cultivation of the natural produce of water (as fish or shellfish).

Merriam-Webster's Collegiate Dictionary

1. The cultivation of aquatic plants and animals for human food consumption or other human use.
2. Specifically, freshwater cultivation, as opposed to marine cultivation (mariculture).

Academic Press Dictionary of Science and Technology

aspartame

An artificial sweetener, $C_{14}H_{18}N_2O_5$, formed from aspartic acid.

The American Heritage Dictionary of the English Language

autoimmune

A condition where the body's immune system is unable to distinguish between foreign particles and the body's own cells and as a result attacks normal body tissue.

BioTech Life Sciences Dictionary

bacteriophage

see phage

base pair

One of the pairs of chemical bases composed of a purine on one strand of DNA joined by hydrogen bonds to a pyrimidine on the other that hold together the two complementary strands much like the rungs of a ladder and include adenine linked to thymine or sometimes to uracil and guanine linked to cytosine

Merriam-Webster's Collegiate Dictionary

The pair of nitrogenous bases, consisting of a purine linked by hydrogen bonds to a pyrimidine, that connects the complementary strands of DNA or of hybrid molecules joining DNA and RNA. The base pairs are adenine-thymine and guanine-cytosine in DNA, and adenine-uracil and guanine-cytosine in RNA.

The American Heritage Dictionary of the English Language

biocontrol, biological control

The use of one organism to control the population size of another organism.

About Biotechnology

The agricultural use of living things, such as parasites, diseases, and predators, to control or eliminate others, such as weeds and pests, rather than by using chemicals (herbicides and pesticides).

BioTech Life Sciences Dictionary

biodiversity, biological diversity

The existence of a wide range of different types of organisms in a given place at a given time.

BioTech Life Sciences Dictionary

The variability among living organisms from all sources including, among other things, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are a part; this includes diversity within species, between species and of ecosystems.

World Foundation for Environment and Development

also **biodiversity prospecting** or **'bioprospecting'**: The search for useful genetic and biochemical compounds and materials and related information in nature.

bioinformatics

The newly developed computer-based discipline that organises biological data, particularly genetic data.

The Current Uses of Genetic Modification

The use of computers in solving information problems in the life sciences; mainly, it involves the creation of extensive electronic databases on genomes, protein sequences, etc. Secondly, it involves techniques such as the three-dimensional modelling of biomolecules and biological systems.

BioTech Life Sciences Dictionary

biomedicine

Medicine based on the application of the principles of the natural sciences and especially biology and biochemistry.

Merriam-Webster's Collegiate Dictionary

also **biomedical engineering**: The use of engineering technology, instrumentation and methods to solve medical problems, such as improving our understanding of physiology and the manufacture of artificial limbs and organs.

BioTech Life Sciences Dictionary

biopiracy

The commercial development of naturally occurring biological materials, such as plant substances or genetic cell lines, by a technologically advanced

country or organisation without fair compensation to the peoples or nations in whose territory the materials were originally discovered.

The American Heritage Dictionary of the English Language

The unauthorised and uncompensated taking of biological resources.

World Foundation for Environment and Development

bioreactor

A device or apparatus in which living organisms and especially bacteria synthesise useful substances (as interferon) or break down harmful ones (as in sewage)

Merriam-Webster's Collegiate Dictionary

An apparatus, such as a large fermentation chamber, for growing organisms such as bacteria or yeast that are used in the biotechnological production of substances such as pharmaceuticals, antibodies, or vaccines, or for the bioconversion of organic waste.

The American Heritage Dictionary of the English Language

bioremediation

The use of plants or microorganisms to clean up pollution or to solve other environmental problems.

BioTech Life Sciences Dictionary

biosecurity

The protection of people and natural resources from unwanted organisms capable of causing harm.

Environmental Performance Indicators Programme

[New Zealand] The cost effective protection of any natural resources from organisms capable of causing unwanted harm. The Biosecurity Act 1993 is the main act dealing with biosecurity issues. It has resulted in changes to the way biosecurity is managed and viewed.

Previously, pest management largely had an agricultural or horticultural focus. But this tended to overlook other pests, like environmental pests. With the passing of the Biosecurity Act, when we now talk about biosecurity pests, we mean a wide range of organisms that are harmful, not only to production industries, but also to the environment (including the land, freshwater and marine environments, as well as to people). That includes undesirable animals, undesirable plants such as weeds, and organisms that attack animals and plants (including disease-causing microorganisms).

MAF Rural Bulletin May 1999

biosphere

The part of the Earth's environment where life exists

Cambridge International Dictionary of English

- (1) The part of the world in which life can exist
- (2) Living beings together with their environment

Merriam-Webster's Collegiate Dictionary

biotechnology

Any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

World Foundation for Environment and Development

The industrial use of living organisms or biological techniques developed through basic research. Biotechnology products include antibiotics, insulin, interferon, recombinant DNA, and techniques such as waste recycling. Much older forms of biotechnology include breadmaking, cheesemaking and brewing wine and beer.

BioTech Life Sciences Dictionary

bovine spongiform encephalopathy (BSE)

An infectious degenerative brain disease occurring in cattle. Also called *mad cow disease*.

The American Heritage Dictionary of the English Language

bovine somatotropin (bovine growth hormone, bST, BGH)

A growth hormone found in cattle; a version of this hormone is also found in all mammals, including humans. Injections of this hormone dramatically increase the milk production of lactating cows. In past years, the hormone was very expensive because it could only be taken from slaughtered cows, but in the early '90s researchers learned how to genetically engineer the bacterium *E. coli* to produce it. Now, many dairy producers use the hormone, but the practice is controversial because the use of bST may increase the incidence of mastitis (udder infection) in cows, and the long-term human health effects of the slightly increased hormone levels in the milk from treated cows have not been established.

BioTech Life Sciences Dictionary

carbohydrate

Any of various neutral compounds of carbon, hydrogen, and oxygen (as sugars, starches, and celluloses), most of which are formed by green plants and which constitute a major class of animal foods.

Merriam-Webster's Collegiate Dictionary

cell

The smallest basic unit of a plant or animal.

Cambridge International Dictionary of English

A small usually microscopic mass of protoplasm bounded externally by a semipermeable membrane, usually including one or more nuclei and various other organelles with their products, capable alone or interacting with other cells of performing all the fundamental functions of life, and forming the smallest structural unit of living matter capable of functioning independently.

Merriam-Webster's Collegiate Dictionary

chromosome

Structure containing DNA and proteins in the cell nucleus.

Bernie May

Components in a cell that contain genetic information. Each chromosome contains numerous genes. Chromosomes occur in pairs: one obtained from the mother; the other from the father. Chromosomes of different pairs are often visibly different from each other.

About Biotechnology

chymosin

See rennin

clone

(of DNA): An identical copy. The term may be applied to a fragment of DNA, a plasmid that contains a single fragment of DNA, or a bacterium that contains such a plasmid.

(of animal): An identical offspring, generally created by transfer of an identical nucleus into a recipient egg.

The Current Uses of Genetic Modification

1. To insert a piece of DNA into a vector for subsequent amplification and isolation of that specific piece;
2. A piece of DNA composed of a vector and its insert.

Bernie May

also cloning vector: Biological carriers such as plasmids, bacteriophages, or cosmids used to amplify an inserted DNA sequence.

Bernie May

containment

(biological): Containment based on a biological barrier that prevents the transmission or escape of an organism.

(physical): Containment achieved by the control of access, restriction of air circulation, and/or the provision of other secure physical barriers.

The Current Uses of Genetic Modification

also **containment facility**: [*New Zealand*] A place approved in accordance with section 39 of the Biosecurity Act, for holding organisms that should not become established in New Zealand.

MAF Biosecurity Authority

copyright

The exclusive legal right to reproduce, publish, and sell the matter and form (as of a literary, musical, or artistic work).

Merriam-Webster's Collegiate Dictionary

Creutzfeld-Jakob disease (CJD)

A rare, usually fatal disease of the brain, characterised by progressive dementia and gradual loss of muscle control, that occurs most often in middle age and is caused by a slow virus.

The American Heritage Dictionary of the English Language

crippled bacteria, viruses

Bacteria and viruses that have had parts of their genomes that would make them infective, removed.

David Heaf

cross-pollination

The transfer of pollen from an anther of the flower of one plant to a stigma of the flower of another plant.

The American Heritage Dictionary of the English Language

cultivar

A cultivated plant or animal that has no known wild ancestor.

BioTech Life Sciences Dictionary

A variety of plant produced through selective breeding by humans and maintained by cultivation.

The Genomics Lexicon

cytogenetics

Study that relates the appearance and behavior of chromosomes to genetic phenomenon.

An Agricultural and Environmental Biotechnology Annotated Dictionary

Demeter Association

The international accreditation agency for Biodynamic agriculture.

Demeter Association, Inc

DNA

Deoxyribonucleic acid, the chemical at the centre of the cells of living things which controls the structure and purpose of each cell and carries genetic information during reproduction.

Cambridge International Dictionary of English

A nucleic acid that constitutes the genetic material of all cellular organisms and the DNA viruses; DNA replicates and controls through messenger RNA the inheritable characteristics of all organisms. A molecule of DNA is made up of two parallel twisted chains of alternating units of phosphoric acid and deoxyribose, linked by crosspieces of the purine bases and the pyrimidine bases, resulting in a right-handed helical structure, that carries genetic information encoded in the sequence of the bases.

Academic Press Dictionary of Science and Technology

ecology

(The relationships between) the air, land, water, animals, plants, etc., usually of a particular area, or the scientific study of this

Cambridge International Dictionary of English

1. Of or relating to the environment or to the science of ecology.of or relating to the environment or to the science of ecology.
2. Relating to the prudent use or beneficial management of natural resources and the natural environment.relatng to the prudent use or beneficial management of natural resources and the natural environment

Harcourt Academic Press Dictionary of Science and Technology

ecosystem

The complex of a community of organisms and its environment functioning as an ecological unit.

Merriam-Webster's Collegiate Dictionary

endosperm

A nutritive tissue in seed plants formed within the embryo sac

Merriam-Webster's Collegiate Dictionary

The nutritive tissue within seeds of flowering plants, surrounding and absorbed by the embryo.

The American Heritage Dictionary of the English Language

endotoxin

A toxin of internal origin; *specifically*: a poisonous substance present in bacteria (as the causative agent of typhoid fever) but separable from the cell body only on its disintegration.

Merriam-Webster's Collegiate Dictionary

enzymes

Proteins that control the various steps in all chemical reactions.

An Agricultural and Environmental Biotechnology Annotated Dictionary

Any of numerous complex proteins that are produced by living cells and catalyse specific biochemical reactions at body temperatures.

Merriam-Webster's Collegiate Dictionary

also **restriction enzyme**: any of various enzymes that break DNA into fragments at specific sites in the interior of the molecule — called also restriction endonuclease.

Merriam-Webster's Collegiate Dictionary

epigenetic

Of, relating to, or produced by the chain of developmental processes in epigenesis that lead from genotype to phenotype after the initial action of the genes.

Merriam-Webster's Collegiate Dictionary

eukaryote

an organism composed of one or more cells containing visibly evident nuclei and organelles — compare prokaryote.

Merriam-Webster's Collegiate Dictionary

expression (gene)

The process by which proteins are made from the instructions encoded in DNA.

NHGRI Glossary of Genetic Terms

The process by which a gene's coded information is converted into the structures present and operating in the cell. Expressed genes include those that are transcribed into mRNA and then translated into protein and those that are transcribed into RNA but not translated into protein (eg, transfer and ribosomal RNAs).

BioTech Life Sciences Dictionary

field trial

A trial of a new product in actual situations for which it is intended.

Merriam-Webster's Collegiate Dictionary

gene

A unit of hereditary information. A gene is a section of a DNA molecule that specifies the production of a particular protein.

About Biotechnology

A locus on a chromosome that encodes a specific protein or several related proteins. It is considered the functional unit of heredity.

An Agricultural and Environmental Biotechnology Annotated Dictionary

gene construct

A sequence of genes made by joining several genes together artificially in the laboratory.

Genewatch

gene deletion

The total loss or absence of a gene.

Office of Rare Diseases, National Institutes of Health

The total loss (or absence) of a gene. Gene deletion plays a role in birth defects and in the development of cancer.

On-line Medical Dictionary

gene expression

The process by which a gene's coded information is translated into the structures present and operating in the cell (either proteins or RNAs).

Office of Rare Diseases

The full use of the information in a gene via transcription and translation leading to production of a protein and hence the appearance of the phenotype determined by that gene. Gene expression is assumed to be controlled at various points in the sequence leading to protein synthesis and this control is thought to be the major determinant of cellular differentiation in eukaryotes.

On-line Medical Dictionary

gene insertion

The addition of one or more genes into a genome from an external source.

On-line Medical Dictionary

gene knockout

Inactivation of specific genes. Knockouts are often created in laboratory organisms such as yeast or mice so that scientists can study the knockout organism as a model for a particular disease.

NHGRI Glossary of Genetic Terms

gene product

The protein produced by a gene.

The Genomics Lexicon

gene sequencing

Determination of the sequence of nucleotide bases in a strand of DNA.

On-line Medical Dictionary

gene therapy

The process of introducing new genes into the DNA of ... cells to correct a genetic disease or flaw. (1) Human gene therapy: Insertion of normal DNA directly into cells to correct a genetic defect. (2) Somatic cell gene therapy: The repair or replacement of a defective gene within somatic tissue.

BioTech Life Sciences Dictionary

(3) Germ line (gene) therapy: The repair or replacement of a defective gene within the gamete-forming tissues, which produces a heritable change in an organism's genetic constitution.

An Agricultural and Environmental Biotechnology Annotated Dictionary

gene transfer

The transfer of genes into a cell by any of a number of different methods available.

BioTech Life Sciences Dictionary

Insertion of unrelated DNA into the cells of an organism. There are many different reasons for gene transfer: for example, attempting to treat disease by supplying patients with therapeutic genes. There are also many possible ways to transfer genes. Most involve the use of a vector, such as a specially modified virus that can take the gene along when it enters the cell.

NHGRI Glossary of Genetic Terms

genetic code

The way genetic information is stored in living organisms.

About Biotechnology

The biochemical basis of heredity consisting of codons in DNA and RNA that determine the specific amino acid sequence in proteins and appear to be uniform for all known forms of life.

Merriam-Webster's Collegiate Dictionary

genetic drift

Random variation in gene frequency from one generation to another.

An Agricultural and Environmental Biotechnology Annotated Dictionary

The random change of the occurrence of a particular gene in a population; genetic drift is thought to be one cause of speciation when a group of organisms is separated from its parent population.

BioTech Life Sciences Dictionary

genetic engineering (GE)

see **genetic modification**

genetic marker

A usually dominant gene or trait that serves especially to identify genes or traits linked with it.

Merriam-Webster's Collegiate Dictionary

A segment of DNA with an identifiable physical location on a chromosome and whose inheritance can be followed. A marker can be a gene, or it can be some section of DNA with no known function. Because DNA segments that lie near each other on a chromosome tend to be inherited together, markers are often used as indirect ways of tracking the inheritance pattern of a gene that has not yet been identified, but whose approximate location is known.

NHGRI Glossary of Genetic Terms

genetic modification (GM)

Altering the genetic material of cells or organisms in order to make them capable of making new substances or performing new functions.

The Genomics Lexicon

The technique of removing, modifying or adding genes to a DNA molecule in order to change the information it contains. By changing this information, genetic engineering changes the type or amount of proteins an organism is capable of producing.

About Biotechnology

genetically modified organism (GMO)

Organisms that have had genes from other species inserted into their genome.

Functional Genomics Glossary

An organism whose genome has been altered by the inclusion of foreign genetic material. This may be derived from other individuals of the same or wholly different species, or of an artificial nature. Foreign genetic information can be added to the organism during its early development and incorporated in cells of the entire organism. Genetic information can also be added later in development to selected portions of the organism.

Functional Genomics Glossary

genome

The total hereditary material of a cell.

About Biotechnology

The genetic complement contained in the chromosomes of a given organism, usually the haploid chromosome state.

An Agricultural and Environmental Biotechnology Annotated Dictionary

also **genome projects:** Research and technology development efforts aimed at mapping and sequencing some or all of the genome of human beings and other organisms.

BioTech Life Sciences Dictionary

genomics

The discipline involving the study of the collection of genes found in an organism.

The Current Uses of Genetic Modification

The study of genomes, which includes genome mapping, gene sequencing and gene function.

BioTech Life Sciences Dictionary

also **genomic healthcare:** Healthcare which utilises advances made by the science of genomics.

The Genomics Lexicon

also **genomic library:** A random collection of cloned DNA fragments (usually in viral or cosmid vectors) that together represent virtually all of an organism's DNA. Partial or subgenomic libraries contain only restriction fragments of a certain size range.

Bernie May

germ cell

Reproductive cell.

An Agricultural and Environmental Biotechnology Annotated Dictionary

Sperm and egg cells, and their precursors. Germ cells are haploid and have only one set of chromosomes (23 in all), while all other cells have two copies (46 in all).

The Genomics Lexicon

glyphosate

A white compound, $C_3H_8NO_5P$, that is soluble in water, used as a broad-spectrum herbicide.

The American Heritage Dictionary of the English Language

heavy metal

Metallurgy. any metal or alloy of high specific gravity, especially one that has a density higher than 5 grams per cubic centimetre.

Academic Press Dictionary of Science and Technology

herbicide

Any substance that is toxic to plants; usually used to kill specific unwanted plants.

An Agricultural and Environmental Biotechnology Annotated Dictionary

Any agent, either organic or inorganic, used to destroy unwanted vegetation, especially weeds and grasses; selective herbicides eliminate weeds without destroying desirable crop or garden plants; nonselective herbicides destroy all vegetation in the given area.

Academic Press Dictionary of Science and Technology

histology

The scientific study of the structure of tissue from plants, animals and other living things.

Histology involves looking at cells under a microscope.

Cambridge International Dictionary of English

homeopathy, homoeopathy

A system of medical practice that treats a disease especially by the administration of minute doses of a remedy that would in healthy persons produce symptoms similar to those of the disease.

Merriam-Webster's Collegiate Dictionary

A system of therapy advanced in the late eighteenth century by Dr Samuel Hahnemann, based on the theory that “like cures like”; if the conditions produced by giving large doses of a drug to a healthy person are similar to conditions occurring as a natural consequence of disease, then that disease may be treated by the same drug in much smaller doses.

Academic Press Dictionary of Science and Technology

homologous recombination

Genetics. The recombination of a piece of DNA into a homologous sequence.

Academic Press Dictionary of Science and Technology

horizontal gene transfer (HGT)

The transfer of genes or genetic material directly from one individual to another by processes similar to infection. It is distinct from the normal process of vertical gene transfer — from parents to offspring — which occurs

in reproduction. Natural agents exist which can transfer genes horizontally between individuals. These are viruses, many of which cause diseases, and other pieces of parasitic genetic material, called plasmids and transposons, many of which carry and spread antibiotic and drug resistance genes. These are able to get into cells and then make use of the cell's resources to multiply many copies or to jump into (as well as out of) the cell's genome. The natural agents are limited by species barriers, so that for example, pig viruses will infect pigs, but not human beings, and cauliflower viruses will not attack tomatoes. However, genetic engineers make artificial vectors (carriers of genes) by combining parts of the most infectious natural agents, with their disease-causing functions removed or disabled, and design them to overcome species barriers, so the same vector may now transfer, say, human genes, which are spliced into the vector, into the cells of all other mammals, or cells of plants.

ngin (Norfolk Genetic Information Network)

immunosuppression

Immunosuppression is intentionally stopping the body's immune system from working, or making it less effective, usually by drugs, especially in order to help the body accept an organ which has been taken from another person's body.

Cambridge International Dictionary of English

Suppression (as by drugs) of natural immune responses.

Merriam-Webster's Collegiate Dictionary

immune system

The bodily system that protects the body from foreign substances, cells, and tissues by producing the immune response and that includes especially the thymus, spleen, lymph nodes, special deposits of lymphoid tissue (as in the gastrointestinal tract and bone marrow), lymphocytes including the B cells and T cells, and antibodies.

Merriam-Webster's Collegiate Dictionary

immunotherapy

(1) A medical technique for stimulating a patient's immune system to attack and destroy disease-causing cells (viruses, bacteria, cancer cells, etc).

(2) A type of medical treatment which includes a combination of immunopotentiator and immunosuppressant agents, desensitisation to any allergens, bone marrow transplants, and thymus implantations.

BioTech Life Sciences Dictionary

insecticide

A chemical substance made and used for killing insects, especially those which eat plants.

Cambridge International Dictionary of English

'in silico'

In or by means of a computer simulation.

World Wide Words

informed consent

The process by which an individual willingly and voluntarily agrees to participate in an activity after first understanding the risks and benefits or participation (as against non-participation) in an activity or research study. In a genetic study, potential participants should be appraised of the study goals, risks, benefits, alternative to participation, disclosure policies, and financial and time commitments involved in study participation. The informed consent process should be documents, typically with a signed consent form approved by an Institutional Review Board. Special considerations apply to vulnerable populations (ie, minors, mentally handicapped individuals).

The Genomics Lexicon

intellectual property

Useful artistic and industrial information and knowledge.

International Law Dictionary and Directory

That area of the law involving patents, copyrights, trademarks, trade secrets, and plant variety protection.

Shaping Genes

Integrated Pest Management

An internationally recognised movement in which scientists attempt to create crop and livestock management systems that reduce reliance on broad spectrum chemical interventions and promote more ecologically integrated solutions to pest control (it is markedly closer to organic than to conventional production).

Ecologically based pest management that promotes the health of crops and animals, and makes full use of natural and cultural control processes and methods, including host resistance and biological control. It uses chemical pesticides only where and when the above measures fail to keep pests below damaging levels. All interventions are need-based and are applied in ways that minimise undesirable side-effects.

CGIAR Policy Statement on Integrated Pest Management

knockout (gene)

See gene knockout.

lactase

An enzyme capable of hydrolyzing lactose into glucose and galactose.

The Random House Webster's Unabridged Dictionary

lactose

A type of sugar which is found in milk

Cambridge International Dictionary of English

lectin

any of a group of proteins that bind to particular carbohydrates in the manner of an antibody and are commonly extracted from plants for use as an agglutinin, as in clumping red blood cells for blood typing.

The Random House Webster's Unabridged Dictionary

marker genes

Genes that identify which plants [or animals] have been successfully transformed.

About Biotechnology

metabolic disease

An inherited enzyme abnormality.

Nutritional and Metabolic Diseases.

monoculture

The agricultural practice of cultivating crops consisting of genetically similar organisms.

An Agricultural and Environmental Biotechnology Annotated Dictionary

mRNA (messenger RNA)

The class of RNA molecules that copies the genetic information from DNA, in the nucleus, and carries it to ribosomes, in the cytoplasm, where it is translated into protein.

An Agricultural and Environmental Biotechnology Annotated Dictionary

mutagenesis

The occurrence or induction of mutation.

Merriam-Webster's Collegiate Dictionary

The introduction of permanent heritable changes (ie, mutations) into the DNA of an organism. In the case of site-directed mutagenesis, the substitution or modification of a single amino acid at a defined location in a protein is

performed by changing one or more base pairs in the DNA using recombinant DNA technology.

Functional Genomics Glossary

non-tariff trade barriers

Economic, political, administrative or legal impediments to trade other than duties, taxes and import quotas.

World Cargo Alliance, Inc.

nucleus

The central part of an atom, usually made up of protons and neutrons, or the part of a cell that controls its growth. DNA is stored in the nucleus of a cell.

Cambridge Dictionaries Online

nutraceutical

Any substance that is a food or a part of a food and provides medical or health benefits, including the prevention and treatment of disease. [Note: “Nutraceutical” and “Nutriceutical” are frequently used interchangeably.]

Nutraceutical Alliance

nutriceutical

Nutriceutical is a term derived from the words “nutrition” and “pharmaceutical” A nutriceutical is a product that combines food and an active ingredient such as a drug or a vitamin or some other chemical substance. These products are on the leading edge of development and are a 1990s phenomenon. [Note: “Nutraceutical” and “Nutriceutical” are frequently used interchangeably.]

ScienceNet

oleic acid

An oily liquid, $C_{17}H_{33}COOH$, occurring in animal and vegetable oils and used in making soap.

The American Heritage Dictionary of the English Language

organic

Of, relating to, yielding, or involving the use of food produced with the use of feed or fertiliser of plant or animal origin without employment of chemically formulated fertilisers, growth stimulants, antibiotics, or pesticides.

Merriam-Webster’s Collegiate Dictionary

organism

An individual animal, plant, or single-celled life form.

Waiter, there’s a Gene in My Food

patent

Title by which a government grants the exclusive right to make use of an invention for a fixed time period.

Money Words

PC1–PC4 containment

Levels of containment. *See* **containment**

pesticide

A substance that kills harmful organisms (for example, an insecticide or fungicide).

An Agricultural and Environmental Biotechnology Annotated Dictionary

A chemical which is used to kill unwanted organisms such as rats, insects, nematodes, etc. Pesticides often act as nerve poisons, and they are hazardous to animals and humans (some pesticides can cause nerve or liver damage, birth defects and cancer).

BioTech Life Sciences Dictionary

phage, bacteriophage

A virus for which the natural host is a bacterial cell. Used as a vector for cloning segments of DNA.

Functional Genomics Glossary

(Bacteriophage) A virus that parasitises bacteria. It initiates infection by attaching itself by its tail to the wall of bacterial cell. Through enzyme action the bacteria wall is perforated and the bacteriophage DNA or RNA passes through into bacterial cell. It uses the cell's machinery to make more bacteriophage DNA and bacteriophages, which are released by breakage of the bacterial cell.

A Dictionary of Biology

pharmaco foods

A term coined by the Commission to mean a food genetically modified to deliver a particular therapeutic agent, such as a vaccine or a pharmaceutical.

phenotype

The observable characteristics of a genetically controlled trait.

Marine Biological Laboratory

The observable characteristics of an organism as opposed to the set of genes it possesses (its genotype). The phenotype that an organism manifests is a result of both genetic and environmental factors. Therefore, organisms with

the same genotype may display different phenotypes due to environmental factors. Conversely, organisms with the same phenotypes may have different genotypes.

About Biotechnology

Plant Variety Rights

[*New Zealand*] A grant of Plant Variety Rights for a new plant variety gives the holder the exclusive right to produce for sale and to sell propagating material of the variety. In the case of vegetatively propagated fruit and ornamental varieties Plant Variety Rights gives the holder the additional exclusive right to propagate the protected variety for the purpose of the commercial production of fruit, flowers or other products of the variety.

Plant Variety Rights Office

plasmid

A small, circular piece of DNA found outside the chromosome in bacteria. Plasmids are the principal tools for inserting new genetic information into microorganisms or plants.

About Biotechnology

A structure composed of DNA that is separate from the cell's genome. In bacteria, plasmids confer a variety of traits and can be exchanged between individuals — even those of different species. Plasmids can be manipulated in the laboratory to deliver specific genetic sequences into a cell.

The Genomics Lexicon

prokaryote

a unicellular organism having cells lacking membrane-bound nuclei; bacteria are the prime example but also included are blue-green algae and actinomycetes and mycoplasma.

WordNet Vocabulary Helper (NotreDame)

protein

A biological molecule which consists of many amino acids chained together by peptide bonds. The sequence of amino acids in a protein is determined by the sequence of nucleotides in a DNA molecule. As the chain of amino acids is being synthesised, it is also folded into higher order structures shaped, for example, like helices or like flat sheets. Proteins are required for the structure, function, and regulation of cells, tissues, and organs in the body.

The Genomics Lexicon

proteomics

The new discipline that aims to identify and characterise all the proteins present in a cell.

The Current Uses of Genetic Modification

recombinant DNA

DNA molecules that have been created by combining DNA from more than one source.

The Genomics Lexicon

Recombinant DNA is a fragment of DNA incorporated artificially into the DNA molecule of a suitable vector so that it can express itself many times. This way a large quantity of the DNA in question can be obtained. The DNA is usually one that contains genes of interest, such as interferon, insulin, or growth hormone. The DNA may also be intended to fix mutated genes causing diseases, such as haemophilia or sickle cell anaemia. The vector could be plasmids, bacteriophages, and cosmids (packaged plasmid DNA into a phage particle).

BioTech Life Sciences Dictionary

also recombinant clones: Clones containing recombinant DNA molecules.

BioTech Life Sciences Dictionary

also recombinant DNA technology: The technology upon which genetic engineering or genetic modification is based. The process involves DNA being joined together in novel combinations.

The Current Uses of Genetic Modification

rennet

A substance used for thickening milk, esp. to make cheese. Most cheese is made with rennet, which comes from the stomach lining of calves, and is therefore not vegetarian.

Cambridge International Dictionary of English

rennin

An enzyme that catalyzes the coagulation of milk, found in the gastric juice of the fourth stomach of young ruminants and used in making cheeses and junkets. Also called chymosin, rennet.

The American Heritage Dictionary of the English Language

seed bank

A facility designed for the ex situ conservation of individual plant varieties through seed preservation and storage.

World Resource Institute

also seeds naturally occurring on or in the soil.

sequencing

Determining the order of nucleotides in a DNA or RNA molecule, or determining the order of amino acids in a protein.

The Genomics Lexicon

service mark

A mark or device used to identify a service (as transportation or insurance) offered to customers.

Merriam-Webster's Collegiate Dictionary

A word, phrase, logo, symbol, color, sound or smell used by a business to identify a service and distinguish it from those of its competitors. If the business uses the name or logo to identify a product, such as a camera, it is called a trademark. In practice, the legal protections for trademarks and service marks are identical.

Nolo

substantial equivalence

A comparative technique recommended by the Organisation for Economic Co-operation and Development (OECD): when faced with a novel or modified food or food product, you search for its nearest equivalent amongst existing organisms used as food or sources of food. These can then be used as the basis for comparison to assess risk, given that there should be extensive knowledge available.

Waiter, there's a Gene in My Food

'super-weed'/'super-bug'

A weed or pest that has developed a resistance to a herbicide/pesticide that once destroyed it.

Waiter, there's a Gene in My Food

terminator technology

The current popular term applying to the methods used to render plant seeds sterile and unable to germinate.

The Current Uses of Genetic Modification

toxicity test

Controlled laboratory test to determine the toxicity of a chemical to an organism in terms of specific chemical concentrations.

An acute toxicity test establishes the concentration required to kill a predetermined proportion of test organisms within a relatively short period

of time, typically four days or less. A chronic toxicity test reveals the effects of a sublethal concentration applied throughout all or part of the life cycle.

On-line Medical Dictionary

trademark

Symbol, logo, or design that legally identifies a business or its product.

Money Words

A word, phrase, logo, symbol, color, sound or smell used by a business to identify a product and distinguish it from those of its competitors. If the business uses the name or logo to identify a service, such as photo copying, it is called a service mark. In practice, the legal protections for trademarks and service marks are identical.

Nolo

transformation

A change in the genetic structure of an organism as a result of the uptake and incorporation of foreign DNA.

About Biotechnology

transgene

A gene transferred to a recipient organism using recombinant technology.

The Current Uses of Genetic Modification

transgenic

An organism that has been genetically engineered to contain the genes from another species.

Waiter, there's a Gene in My Food

An organism whose genome has been altered by the inclusion of foreign genetic material. This foreign genetic material may be derived from other individuals of the same species or from wholly different species. Genetic material may also be of an artificial nature. Foreign genetic information can be added to the organism during its early development and incorporated in cells of the entire organism. As an example, mice embryos have been given the gene for rat growth hormone allowing mice to grow into large adults. Genetic information can also be added later in development to selected portions of the organism. As an example, experimental genetic therapy to treat cystic fibrosis involves selective addition of genes responsible for lung function and is administered directly to the lung tissue of children and adults.

The Genomics Lexicon

transposon

A [DNA] sequence that can move about in the genome of an organism.

Marine Biological Laboratory

A segment of DNA flanked by transposable elements that is capable of moving its location in the genome.

Bernie May

vaccine

A preparation of dead or weakened pathogen, or of derived antigenic determinants, that is used to induce formation of antibodies or immunity against the pathogen.

An Agricultural and Environmental Biotechnology Annotated Dictionary

vector

An organism or a biological molecule used to transfer material to a different organism or cell. In genetic modification, this refers to an organism, bacterium or plasmid able to transfer DNA.

The Current Uses of Genetic Modification

A self-replicating DNA molecule that exists with, but is separate from the genome of the host cell. Many different vectors have been identified and genetically engineered for use in molecular biology. DNA inserted into a vector will be replicated along with the vector. In this manner, DNA of interest can be obtained in large quantities, ie, cloned. For example, the human insulin gene can be cloned into the plasmid vector pBr 322 which, in turn, will replicate in *E. coli* cultures.

Bernie May

also cloning vector: DNA molecule originating from a virus, a plasmid, or the cell of a higher organism into which another DNA fragment of appropriate size can be integrated without loss of the vector's capacity for self-replication; vectors introduce foreign DNA into host cells, where it can be reproduced in large quantities. Examples are plasmids, cosmids, and yeast artificial chromosomes; vectors are often recombinant molecules containing DNA sequences from several sources.

The Genomics Lexicon

virus

An infectious agent composed of a single type of nucleic acid, DNA or RNA, enclosed in a coat of protein. Viruses can multiply only within living cells.

About Biotechnology

Viruses consist of a piece of nucleic acid covered by protein. Viruses can only reproduce by infecting a cell and using the cell's mechanisms for self-replication. They can cause disease; modified viruses can also be used as a tool in gene therapy to introduce new DNA into a cell's genome.

The Genomics Lexicon

xenotransplant

Transplantation of tissue or organs between organisms of different species, genus, or family. A common example is the use of pig heart valves in humans.

The Genomics Lexicon

yeast

A type of fungus which is used in making alcoholic drinks such as beer and wine, and for making bread swell and become light .

Cambridge Dictionaries Online

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