appendix 2

Outcomes of Consultation: Submissions from Interested Persons

Contents

Introduction to Appendix 2

This volume is one of the appendix volumes to the report of the Royal Commission on Genetic Modification to the New Zealand Government on its investigations into the strategic options and desirable changes to regulatory mechanisms to enable New Zealand to address genetic modification, genetically modified organisms, and products.

There are three appendix volumes covering the New Zealand context, the Commission's consultative processes and the outcomes of that consultation:

- Appendix 1 outlines the New Zealand context for the inquiry and records the major aspects of the processes of the Commission.
- Appendix 2 summarises and analyses submissions from Interested Persons.
- Appendix 3 summarises and analyses submissions from the Public.

This appendix volume (Appendix 2) covers the analysis of the written submissions of those granted Interested Person status for the purposes of the Commission's consultation. It also includes glossaries (technical terms, Maori terms and abbreviations) and an index.

Quotations, abbreviations and macrons

This volume includes numerous direct quotations from submissions in the 'IP report', which analyses submissions from Interested Persons. Many quotations are sentence fragments. Minor changes have been made to direct quotations for the sake of readability and consistency. Thus:

- *realize*, *e.g.*, *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- abbreviation of *NZ* in quoted material has been replaced by *New Zealand* and *biotech* by *biotechnology*, but other abbreviations (such as *GE*, *GMO*, *IP*) have been retained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. Three 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.
- Short quotations, indicated by quotation marks, occasionally form part of a bulleted list of examples. In these instances, the source of the quotation is provided in parentheses at the end of the paragraph.

The choice of format is determined by the context and does not indicate that one quotation is considered more important than any other.

In referring to the submissions by Interested Persons, this volume uses the title of the Interested Person in full at first mention in each subsection of the report and thereafter uses any designated abbreviated form or acronym. This procedure is repeated for each subsection. Thus, under section 3 "Analysis of written submissions by Interested Persons: Liability issues", *Green Party of Aotearoa/New Zealand* will be subsequently referred to as *Green Party*, and *Environmental Risk Management Authority (ERMA)* will be followed in that subsection by *ERMA*.

Table 1 provides a list, in alphabetical order, of those granted Interested Person status, together with their submission number and the abbreviated forms used throughout the text where appropriate.

The printed version of the report of the Commission adopts the common modern usage of macrons over long vowels in Maori terms. A glossary of Maori terms is included in this volume.

List of Interested Persons

Table 1 List of Interested Persons by name and submission number

Interested Person as referenced in report	Abbreviated form used (if any)	Interested Person as self-referenced in submission	IP Submission No
A2 Corporation		A2 Corporation Limited	IP26
Agcarm		Agcarm Incorporated	IP29
AgResearch		AgResearch	IP13
Anglican Church in Aotearoa New Zealand and Polynesia	Anglican Church	The Anglican Church in Aotearoa New Zealand and Polynesia	IP42
Association of Crown Research Institutes	ACRI	Association of Crown Research Institutes	IP22
Auckland Healthcare Services		Auckland Healthcare Services Limited	IP91
Auckland UniServices		Auckland UniServices	IP23
Aventis CropScience		Aventis CropScience	IP14
Bio Dynamic Farming and Gardening Association in New Zealand	Bio Dynamic Farming and Gardening Association	Bio Dynamic Farming and Gardening Association in New Zealand (Inc)	IP61
BIO-GRO New Zealand	BIO-GRO	BIO-GRO NZ	IP58
Biotenz		Biotenz Inc	IP25
Canterbury Commercial Organics Group		Canterbury Commercial Organics Group	IP65
Carter Holt Harvey/Fletcher Challenge Forests		Carter Holt Harvey Limited and Fletcher Challenge Forests Limited	IP17

Table 1 continued

Interested Person as referenced in report	Abbreviated form used (if any)	Interested Person as self-referenced in submission	IP Submission No
Commonsense Organics		Commonsense Organics	IP66
Comvita New Zealand	Comvita	Comvita NZ Ltd	IP74
Council of Medical Colleges in New Zealand		Council of Medical Colleges in New Zealand	IP37
Crop and Food Research		New Zealand Institute for Crop & Food Research ("Crop & Food Research")	IP4
Cystic Fibrosis Association of New Zealand	Cystic Fibrosis Association	Cystic Fibrosis Association of New Zealand	IP39
Diabetes Youth New Zealand	Diabetes Youth	Diabetes Youth New Zealand	IP60
DuPont New Zealand	DuPont	DuPont New Zealand Ltd	IP1
Environment and Conservation Organisations of New Zealand	ECO	ECO: Environment and Conservation Organisations of New Zealand (Inc)	IP102
Environmental Risk Management Authority	ERMA	Environmental Risk Management Authority	IP76
Eubios Ethics Institute		Eubios Ethics Institute	IP96
Federated Farmers of New Zealand	Federated Farmers	Federated Farmers of New Zealand (Inc)	IP34
Federation of Māori Authorities	FoMA	Federation of Māori Authorities Inc (FoMA)	IP69
Foundation for Research, Science and Technology	FRST	Foundation for Research, Science and Technology	IP21

Table 1 continued

Interested Person as referenced in report	Abbreviated form used (if any)	Interested Person as self-referenced in submission	IP Submission No
Friends of the Earth (New Zealand)	Friends of the Earth	Friends of the Earth (New Zealand) Ltd	IP78
GE Free New Zealand (RAGE) in Food and Environment	RAGE	GE Free New Zealand (RAGE) in Food and Environment Incorporated	IP63
Genesis Research and Development	Genesis	Genesis Research and Development Corporation Limited (Genesis)	IP11
Golden Bay Organic Employment and Education Trust		The Golden Bay Organic Employment and Education Trust	IP104
Green Party of Aotearoa/New Zealand	Green Party	The Green Party of Aotearoa/New Zealand	IP83
Greenpeace New Zealand	Greenpeace	Greenpeace New Zealand (Inc)	IP82
Haemophilia Foundation of New Zealand	Haemophilia Foundation	Haemophilia Foundation of New Zealand (Inc)	IP48
Hamilton City Council		Hamilton City Council	IP20
Health Research Council of New Zealand	Health Research Council	Health Research Council of New Zealand	IP27
HortResearch		The Horticulture and Food Research Institute of New Zealand Ltd (HortResearch)	IP5
Human Genetics Society of Australasia, New Zealand Branch	Human Genetics Society	Human Genetics Society of Australasia, New Zealand Branch	IP59

Table 1 continued

Interested Person as referenced in report	Abbreviated form used (if any)	Interested Person as self-referenced in submission	IP Submission No
Institute of Molecular BioSciences, Massey University	Institute of Molecular BioSciences	Institute of Molecular BioSciences, Massey University	IP15
Interchurch Commission on Genetic Engineering	Interchurch Commission	Interchurch Commission on Genetic Engineering	IP49
Koanga Gardens Trust		Koanga Gardens Trust Incorporated	IP72
Landcare Research		Landcare Research	IP12
Lincoln University		Lincoln University	IP8
Lysosomal Diseases New Zealand	Lysosomal Diseases	Lysosomal Diseases New Zealand	IP99
Malaghan Institute of Medical Research	Malaghan Institute	Malaghan Institute of Medical Research	IP10
Mäori Congress		Mäori Congress	IP103
Meat Industry Association of New Zealand	MIA	Meat Industry Association of New Zealand Inc ("MIA")	IP32
Meat New Zealand	MNZ	Meat New Zealand (MNZ)	IP31
Ministry for the Environment	MfE	Ministry for the Environment	IP101
Monsanto New Zealand	Monsanto	Monsanto New Zealand Limited	IP6
Muaupoko Co-operative Society		Muaupoko Co-operative Society	IP57

Table 1 continued

Interested Person as referenced in report	Abbreviated form used (if any)	Interested Person as self-referenced in submission	IP Submission No
National Beekeepers Association of New Zealand, Poverty Bay Branch	National Beekeepers Association, Poverty Bay	Poverty Bay Branch of the National Beekeepers Assoc of NZ Inc	IP62
National Nutritional Foods Association of New Zealand	NNFA	National Nutritional Foods Association of New Zealand (NNFA)	IP106
National Testing Centre		National Testing Centre	IP44
Nelson GE Free Awareness Group		Nelson GE Free Awareness Group	IP100
New Zealand Agritech	Agritech	New Zealand Agritech Inc Ltd	IP73
New Zealand Arable-Food Industry Council	Arable-Food Industry Council	The New Zealand Arable-Food Industry Council	IP56
New Zealand Association of Scientists	NZAS	New Zealand Association of Scientists (NZAS)	IP92
New Zealand Biotechnology Association	NZBA	New Zealand Biotechnology Association	IP47
New Zealand Catholic Bishops' Conference	Catholic Bishops' Conference	New Zealand Catholic Bishops' Conference	IP38
New Zealand Cooperative Dairy Company	Cooperative Dairy Company	New Zealand Cooperative Dairy Company	IP88
New Zealand Council of Trade Unions	Council of Trade Unions	New Zealand Council of Trade Unions	IP95
New Zealand Dairy Board	Dairy Board	New Zealand Dairy Board	IP67

Table 1 continued

Interested Person as referenced in report	Abbreviated form used (if any)	Interested Person as self-referenced in submission	IP Submission No
New Zealand Feed Manufacturers Association/Poultry Industry Association of New Zealand/Egg Producers Federation of New Zealand	Feed Manufacturers Association/Poultry Industry Association/Egg Producers Federation	New Zealand Feed Manufacturers Association (Inc); Poultry Industry Association of New Zealand (Inc); Egg Producers Federation of New Zealand (Inc)	IP35
New Zealand Forest Industries Council	NZFIC	New Zealand Forest Industries Council	IP9
New Zealand Forest Research Institute	Forest Research Institute	New Zealand Forest Research Institute Ltd	IP2
New Zealand Game Industry Board	NZGIB	New Zealand Game Industry Board	IP33
New Zealand Grocery Marketers Association	Grocery Marketers Association	New Zealand Grocery Marketers Association Inc	IP54
New Zealand Institute of Patent Attorneys	Institute of Patent Attorneys	New Zealand Institute of Patent Attorneys Inc	IP71
New Zealand Jewish Community		New Zealand Jewish Community	IP80
New Zealand Life Sciences Network	Life Sciences Network	New Zealand Life Sciences Network (Incorporated)	IP24
New Zealand Mäori Council	Mäori Council	New Zealand Mäori Council	IP105
New Zealand National Commission for UNESCO	National Commission for UNESCO	New Zealand National Commission for UNESCO	IP90

Table 1 continued

Interested Person as referenced in report	Abbreviated form used (if any)	Interested Person as self-referenced in submission	IP Submission No
New Zealand Organisation for Rare Diseases	Organisation for Rare Diseases	The New Zealand Organisation for Rare Diseases	IP98
New Zealand Plant Protection Society	Plant Protection Society	New Zealand Plant Protection Society	IP36
New Zealand Transgenic Animal Users	Transgenic Animal Users	New Zealand Transgenic Animal Users	IP45
New Zealand Vegetable and Potato Growers' Federation/New Zealand Fruitgrowers' Federation/ New Zealand Berryfruit Growers' Federation	Vegetable and Potato Growers' Federation/ Fruitgrowers' Federation/ Berryfruit Growers' Federation	New Zealand Vegetable and Potato Growers' Federation (Inc); New Zealand Fruitgrowers' Federation (Inc); New Zealand Berryfruit Growers' Federation (Inc)	IP75
New Zealand Veterinary Association	Veterinary Association	New Zealand Veterinary Association Incorporated	IP28
New Zealand Vice Chancellors Committee	Vice Chancellors Committee	New Zealand Vice Chancellors Committee	IP18
New Zealand Wool Board	Wool Board	New Zealand Wool Board	IP30
New Zealand Worm Federation	Worm Federation	NZ Worm Federation, Inc	IP94
Ngä Wähine Tiaki o te Ao		Ngä Wähine Tiaki o Te Ao	IP64
Northland Conservation Board		Northland Conservation Board	IP68
Organic Federation New Zealand	Organic Federation	Organic Federation New Zealand	IP81

Table 1 continued

Interested Person as referenced in report	Abbreviated form used (if any)	Interested Person as self-referenced in submission	IP Submission No
Organic Product Exporters Group	OPEG	Organic Product Exporters Group Inc	IP53
Pacific Institute of Resource Management		Pacific Institute of Resource Management	IP84
Parliamentary Commissioner for the Environment		Parliamentary Commissioner for the Environment	IP70
Pesticide Action Network New Zealand	Pesticide Action Network	Pesticide Action Network New Zealand	IP87
Physicians and Scientists for Responsible Genetics New Zealand	PSRG	Physicians and Scientists for Responsible Genetics New Zealand – Charitable Trust	IP107
Public Questions Committee (Methodist, Presbyterian, Churches of Christ, Quaker)	Public Questions Committee	Public Questions Committee (Methodist, Presbyterian, Churches of Christ, Quaker)	IP93
Quaker Spiritual Ecology Group, Religious Society of Friends	Quaker Spiritual Ecology Group	Quaker Spiritual Ecology Group of The Religious Society of Friends – Aotearoa/New Zealand Te Haahi Tuuhauwiri	IP50
Researched Medicines Industry Association of New Zealand	RMI	Researched Medicines Industry Association of New Zealand Incorporated (RMI)	IP55
Royal Forest and Bird Protection Society of New Zealand	Forest and Bird Protection Society	Royal Forest & Bird Protection Society of New Zealand Inc	IP79

Table 1 continued

Interested Person as referenced in report	Abbreviated form used (if any)	Interested Person as self-referenced in submission	IP Submission No
Royal Forest and Bird Protection Society, Marlborough Branch	Forest and Bird, Marlborough	Marlborough Branch Royal Forest & Bird Protection Society Inc	IP40
Royal Forest and Bird Protection Society, Nelson/Tasman Branch	Forest and Bird, Nelson/Tasman	Nelson/Tasman Branch Royal Forest & Bird Protection Society	IP43
Royal Society of New Zealand	Royal Society	Royal Society of New Zealand	IP77a[1] IP77b
Rural Women New Zealand	Rural Women	Rural Women New Zealand	IP52
SAFE (Save Animals From Exploitation)	SAFE	SAFE (Save Animals From Exploitation)	IP85
Safe Food Campaign		Safe Food Campaign	IP86
Soil and Health Association of New Zealand	Soil and Health Association	Soil and Health Association of New Zealand Inc	IP97
Sustainable Futures Trust		Sustainable Futures Trust	IP51
Te Rünanga o Ngäi Tahu		Te Rünanga o Ngäi Tahu	IP41
University of Auckland		University of Auckland	IP16
University of Canterbury		University of Canterbury	IP7
University of Otago		University of Otago	IP19

[1]Royal Society of New Zealand [IP77] presented two submissions. The submission designated [IP77a] was prepared on behalf of members affiliated to the biological sciences; submission [IP77b] represented the views of members from a social sciences background.

Table 1 continued

Interested Person as referenced in report	Abbreviated form used (if any)	Interested Person as self-referenced in submission	IP Submission No
WAI 262 claimants, Ngäti Wai, Ngäti Kuri, Te Rarawa	WAI 262 claimants	WAI 262 claimants, Ngäti Wai, Ngäti Kuri, Te Rarawa	IP89
Wrightson		Wrightson Limited	IP3
ZESPRI International	ZESPRI	ZESPRI International Ltd (ZESPRI)	IP46

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Outcomes of Consultation: Submissions from Interested Persons

Section contents

1. Methodology of analysis, report content and themes

Background

Purpose of the IP report

The analysis of written submissions by Interested Persons stands as a subsidiary report within the volumes constituting the complete report of the Royal Commission. It is referred to here as the "IP report". It provides a summary and analysis of the issues raised in 107 written submissions from organisations accorded Interested Person status as part of the Commission's process. Each of the written submissions has been given full consideration, and this report reflects the key points raised in those submissions. The report does not provide an in-depth analysis of every point raised in the submissions.

The purpose of the IP report was to provide a summary of issues raised by submitters to assist the Commissioners in their deliberations and to provide a public record of the key issues raised in the submissions from Interested Persons. The report was prepared relatively early on in the Commission process and formed one of first analyses of key issues identified by submitters.

Organisations granted Interested Person status

In total, 107 written submissions were received from 117 organisations that had been accorded Interested Person status. In some instances, several organisations grouped together to provide a joint submission; and in other instances, organisations that were given Interested Person status chose not to provide a written submission.

To fulfil the legal requirements for Interested Person status, an applicant had to satisfy the Commission that "he has an interest in the inquiry apart from any interest in common with the public". Further detail on the requirements for Interested Person status and the process by which this status was granted are described in Appendix 1 (see "Processes of the Commission: Formal Hearings: the process").

Submission format

Interested Persons wishing to make submissions were invited to respond using a standardised document based on the Warrant that set out the matters that the Commission had been appointed "to receive representations upon, inquire into, investigate, and report upon". The Warrant for the Commission is contained in Appendix 1 (see "Operational detail: Terms of reference").

The "Call for Submissions" documents (Forms 3 and 4) were provided on the Commission's website so that submitters would respond in the standardised format (preferably electronically). If requested, submitters were also emailed a copy of the Call for Submissions document or provided with hard copy. All submissions from Interested Persons were placed on the Commission's website 10 working days before the submitter presented oral evidence to the Commission at the Formal Hearings.

In most instances submitters followed the format set by the Commission in responding to the Warrant. They provided written submissions, usually accompanied by witness briefs, and sometimes by background documents. Some submitters responded only to selected Warrant items on which they wished to comment. In a few instances submitters preferred to provide their views in a different format, such as a letter or list of key points, and did not follow the Warrant format.

This IP report has analysed the "submission" only. The witness brief material has been used only where the submitter stated in the submission that the response to the particular Warrant item was contained in the witness brief. Oral presentations made by submitters at a later stage in the Commission process and the results of cross-examination of witnesses do not form part of the IP report.

Methodology

Project team

The project team for the IP report comprised a team of independent submission analysts employed by the Commission secretariat, assisted by the Centre for Research Evaluation and Social Assessment (CRESA), a Wellington-based social science research company. CRESA provided input on methodological design, frequency and cross-tabulation analysis of data, and quality assurance review of the IP report. The independent analysts undertook the summary and analysis of the submissions and wrote the IP report.

Methodological approach

The methodology used to analyse the 107 submissions involved both qualitative and quantitative data analysis methods. As the submitters were a "specially selected" group of interested persons, the data does not represent a statistically valid or random sample. Comments provided in the IP report are therefore not representative of the population at large.

The development of the methodology for the analysis began at the end of October 2000 and the first draft of the IP report was provided to the Commissioners on 22 December 2000.

Registration of submissions

All of the 107 submissions were given a specific identifier number when received by the Commission. The numbering system involved a code of one to three digits preceded by "IP" (standing for "Interested Person"). This system allowed differentiation between submissions received from Interested Persons and submissions received through the public submission process. Submissions are referred to throughout the IP report using the name of the submitter and the associated IP number. Details of the nomenclature for all Interested Persons are listed in Table 1 (see "Introduction to Appendix 2").

Copies of the submissions were distributed to the Commissioners and the analyst team. A master copy of the submissions was kept at the Commission's secretariat offices. Copies of the submissions were also placed on the Commission's website.

Data analysis methods

The first stage of analysis involved a qualitative approach whereby the analyst read through each submission and summarised the key points raised under each of the Warrant items and recorded the summary points on a form specially prepared for that exercise. Quotations that clearly illustrated points being made by submitters were also recorded. Other records noted included: if the submitter wanted the submission material to be kept confidential and not publicly released; which Warrant items the submission focused on; whether there was explicit Maori commentary; whether there was Maori witness input; whether the submission was in Maori (Te Reo); and what was the submitters' stance on genetic modification.

Once the qualitative review of the submissions was completed, the second phase was a quantitative analysis of the key issues raised. The quantitative analysis was designed so that the results could be analysed using the SPSS package (Statistical Package for the Social Sciences). This package performed frequency and cross-tabulation analysis of the data. Frequencies provided information on how many

submitters mentioned a particular issue; cross-tabulation analysis allowed relationships between different groups of data to be identified.

A coding system was developed to categorise the issues for quantitative analysis. Usually the coding of issues was relatively straightforward: a record of whether or not a submitter had mentioned a specific issue or had made "substantive comment" on an issue. In some instances, the analysts made an assessment across the whole submission to assign the code: for example, to determine the submitter's overall stance on genetic modification or orientation on strategic options. These issues are marked with an asterisk (*) in the list below.

The specific items for each submitter that were coded for quantitative analysis included:

- IP number
- primary sectoral focus (eg, economic/production, environment, health, cultural/ethical, or other)
- industry grouping (eg, industry networks/associations, research organisations, other advocacy networks/associations, private companies, religious/spiritual groups, Maori, organics groups, consumer networks/associations, government bodies, occupational/professional groups, or other groups)
- stance on genetic modification* (eg, whether submitters were 'strongly for' or 'tended to be or' genetic modification, 'neither for nor against', or whether they 'tended to be against' or were 'strongly against' genetic modification)
- strategic options orientation* (eg, where submitters might be located on a continuum of strategic options for genetic modification ranging from a position where submitters would embrace all aspects of genetic modification within a lightly controlled regulatory framework through to a position where a submitter wanted no genetic modification, genetically modified organisms or products permitted in New Zealand)
- view on adequacy of current statutory/regulatory process
- problems with current statutory/regulatory process
- improvements to legislation
- improvements to Environmental Risk Management Authority (ERMA)
- improvements to regulatory process
- opportunities for genetic modification use in New Zealand
- opportunities from avoidance of genetic modification use in New Zealand

- on the basis of current information, whether use of genetic modification might ever be acceptable*
- circumstances under which genetic modification use might be acceptable*
- circumstances under which genetic modification would not be acceptable*
- whether there is (or is no) evidence that genetic modification poses risks or whether it is predominantly safe
- international obligations affecting genetic modification practices
- adequacy of current liability laws for genetic modification
- main issues raised relating to liability
- adequacy of current treatment of intellectual property issues relating to genetic modification
- main issues raised relating to intellectual property
- uses of genetic modification that submitters identify (in New Zealand or overseas)
- issues that the submitter has concerns about in relation to genetic modification* (such things as public health safety risks, food safety risks, economic, cultural, religious, ethical and environmental implications, public education and uncertainties around risks and benefits)
- what potential benefits submitters might see from genetic modification use
- extent of commentary on Maori issues in the submission
- extent of commentary on Treaty of Waitangi issues in the submission
- whether there was a Maori witness input
- key Maori issues raised
- key issues on which the submitter made substantial comment*
- whether New Zealand can combine genetic modification, genetic modification-free uses and organic uses*
- on which Warrant items the submitter made substantial comment*.

Once the coding was completed the data was analysed by CRESA using the SPSS package and the results were provided to the Commission analysts for use in writing up the IP report.

IP report write-up

In writing up the report of the Interested Person submissions, the aim was to identify patterns of opinion on the specific matters set out in the Warrant and, in

particular, to identify:

- where common views were expressed
- where divergent views were expressed
- strength of opinion around issues expressed
- matters which submitters considered are unresolved
- profiles of who held what view
- quotations to help illustrate key points of view.

The IP report used material from the quantitative analysis of issues, from the qualitative data captured in the first template and, in some instances, from going back to the original submission. Some submitters presented highly detailed material: this was not reported in depth, and only key points were extracted. The full texts of the submissions from the Interested Persons are publicly available on the Commission's website (http://www.gmcommission.govt.nz) until at least June 2002.

The report makes extensive use of quotations from individual submissions by Interested Persons. It therefore differs from the type of report on public policy issues that emphasises common themes emerging from submissions received. Such reports tend to quote individual submitters only if theirs is the only submission making a particular point or taking a particular stance. They generally record direct quotes only if a submitter's view succinctly crystallises a position or if it provides a good summation of a position that is representative of that of several submitters.

In this instance, the IP report was prepared as a working document to assist the Commissioners in their deliberations on evidence presented. A decision was made to identify and isolate particular views expressed by individual submitters. Submitters' views were specifically referenced to Warrant items, the result of which was to clarify their positions on particular issues associated with those Warrant items but to make it less easy to compare and contrast submitters according to overall positions throughout their submissions.

The approach adopted for the summary and analysis of submissions by Interested Persons was therefore largely dictated by the format in which the evidence was presented (ie, the specific Warrant items) and by the perceived requirements of the Commissioners.

The report does not purport to record all the issues relevant to each of the matters raised by the Warrant items. Most submitters did not comment on all aspects of every issue. The report summaries and analyses the information that submitters placed before the Commission as being representative of their views.

Format and language in the IP report

An explanation of the format of quotations has been provided previously (see "Introduction to Appendix 2: Quotations, abbreviations and macrons"), together with the nomenclature of Interested Persons in Table 1. A key point is that differing formats for quotations do not imply differing values attached to those quotations.

Similarly, use of words such as "commented", "noted", "made the point", "expressed the view", "suggested" etc in reporting the opinions of submitters do not indicate any differences in acceptance.

The IP report summarises and analyses the views of submissions by Interested Persons. It reports the issues identified by submitters: it does not take a position on them.

Outline of the IP report

The IP report has been prepared in sections that correspond to the Warrant items. Warrant item (j), which dealt with four main areas of public interest, was dealt with as four separate sections preceded by an introduction to the topic. Where there was overlap between the Warrant items, the sections have been grouped together or combined. Thus, strategic matters were grouped:

- strategy: an introduction; strategic options (Warrant item (1)), strategic issues (Warrant item (k)) and strategic outcomes (Warrant item (m))

Two Warrant items on international matters in relation to genetic modification were combined and two on legislative matters, thus:

- statutory and regulatory processes: changes considered desirable to the current legislative, regulatory, policy or institutional arrangements (Warrant item (2)) and adequacy of the current statutory and regulatory processes (Warrant item (n))
- international obligations and implications: international legal obligations (Warrant item (d)) and international implications of measures that New Zealand might take (Warrant item (l))

Within the three sections listed above submitters tended to provide similar material across the related Warrant items. This was particularly so for strategic matters where submitters tended not to clearly distinguish between strategic options, issues and outcomes. In other instances, submitters addressed only one of the Warrant items and made cross-references under the other related Warrant item(s) to that material.

Most sections have an introduction explaining the Warrant item and then providing a profile of the submitters who responded to that Warrant item. Some overlap of material occurs across the sections because many of the issues are closely related and similar concerns or issues arise under the different Warrant items.

IP report content

The content of the IP report was largely dictated by the scope and depth of submissions presented by Interested Persons. The majority of the submissions were extensive and specifically focused on Warrant items. However, submitters clearly saw some Warrant items of more significance that others. In addition, many submitters took the opportunity to present wide-ranging views both within and outside specific Warrant items.

Assessments were made to provide an indication of where submitters' principal interests and major concerns were. Where submitters made "substantial comment" (ie, comments of some length or substance) on a particular issue or a particular Warrant item this was recorded and identified. The assessment covered 14 areas where submitters evinced a particular interest and focus (such as social, personal, economic and legal issues) and 16 separate Warrant items.

These assessments showed that the issues attracting most comment were economic, regulatory, health issues, risk assessment and environmental issues. The Warrant items attracting most substantial comments were: strategic options, statutory and regulatory issues, issues of public interest (including health, economic, environmental, cultural and ethical issues) and legislative changes. Assessment along these lines showed both the Warrant items that were the major thrust of each submitter's case and the major issues that the submitters saw as important. They showed, for example, that submitters' views on economic issues were not confined to Warrant item (j) on economic issues of public interest. Many economic arguments could be found throughout the Warrant items dealing with strategic options and legislative changes. They also showed that spiritual concerns were an area of public interest that was not specifically identified in the Warrant.

Statistics for assessment of substantial comment on issues were:

- economic issues (53 submitters)
- regulatory issues (45 submitters)
- health issues (41 submitters)
- risk, risk assessment and management (40 submitters)

- environmental issues (35 submitters)
- intellectual property issues (29 submitters)
- Treaty of Waitangi issues (22 submitters)
- liability issues (21 submitters)
- Maori cultural issues (21 submitters)
- ethical issues (20 submitters)
- social issues (six submitters)
- spiritual issues (four submitters)
- other cultural issues (four submitters)
- insurance and underwriting (one submitter).

Statistics for assessment of substantial comment on Warrant items were:

- Warrant item (1): strategic options (78 submitters)
- Warrant item (2): legislative changes (56 submitters)
- Warrant item (a): where, how and for what purpose (57 submitters)
- Warrant item (b): evidence and uncertainty (35 submitters)
- Warrant item (c): risks and benefits (48 submitters)
- Warrant item (d): international obligations (23 submitters)
- Warrant item (e): liability issues (33 submitters)
- Warrant item (f): intellectual property issues (38 submitters)
- Warrant item (g): Treaty of Waitangi issues (35 submitters)
- Warrant item (h): global developments (38 submitters)
- Warrant item (i): opportunities from use or avoidance (43 submitters)
- Warrant item (j): areas of public interest (58 submitters)
- Warrant item (k): strategic issues (39 submitters)
- Warrant item (l): international obligations (17 submitters)
- Warrant item (m): strategic outcomes (37 submitters)
- Warrant item (n): adequacy of statutory and regulatory processes (62 submitters).

IP report themes

Major themes became apparent for each of the Warrant items discussed and are usually summarised at the beginning of each section. In keeping with the many

aspects of genetic modification technology and the continuum of opinion about its use, these key themes were wide ranging. For example, they included:

- New Zealand's international reputation
- the role of the Treaty of Waitangi
- tikanga principles
- protection of Maori traditional knowledge
- differing philosophical approaches to liability.

Some themes crossed many individual Warrant items, for example:

- the public's right to choose and opportunity to exercise choice
- the need for reliable information and more education on genetic modification.

The total body of written submissions by 107 Interested Persons provides a notable source of information on the wide range of issues raised by the subject of genetic modification, genetically modified organisms and products. As stated previously, the total resource of submissions is publicly available on the Commission's website (http://www.gmcommission.govt.nz), at least until June 2002.

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Outcomes of Consultation: Submissions from Interested Persons

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2. Submitter profiles

A submitter profile was obtained by coding submitters according to the areas in which they were primarily engaged and the stances they took on various issues. This information identified the main sectoral focus (usually the production sector in which each submitter was principally engaged) and the submitter type (essentially the type of organisation where the submitter worked)

Main sector focus

The main sector focus of each submitter was coded according to the main activity or business focus of their organisation. Over 60 codes were identified. These codes covered the main production sectors in agriculture, forestry, fishing and manufacturing. Codes for submitters principally involved in industries focusing on biotechnology and research were also recorded, as well as environmental, religious, ethical, cultural and Maori groupings. For each broad sector a range of activities was identified. For example, in the health sector separate codes were identified for health advocacy, health research and health service providers.

Biotechnology was the main sector focus for the largest group of submitters. The prime sector focus for the major groups was:

- biotechnology (15 submitters)
- environmental advocacy (nine submitters)
- research sector other (ie, not health or social and economic) (six submitters)
- health research (five submitters)
- governance, including local government (five submitters).

Submitter type

Submitters were also coded according to the type or organisation they represented. The categories included Crown Research Institutes, private research companies, universities, consumer networks and associations, industry networks and associations, religious networks and associations, organic networks and associations, government departments, Maori networks and associations, Runanga and trust boards, national Maori organisations, state-owned enterprises and private companies.

The biggest grouping of submitters came from industry networks and associations.

A breakdown of the major grouping was:

- industry networks and associations (26 submitters)
- other advocacy networks (18 submitters)
- private companies (eight submitters)
- organic networks and association (six submitters)
- Crown Research Institutes (five submitters).

Attitude towards genetic modification

An assessment was made of each submitter's overall attitude towards genetic modification based on comments throughout each submitter's full submission. The majority of submitters with Interested Person status were assessed as being in support of the use of genetic modification technology. Opinion was distributed as follows:

- 'strongly for': 49 submitters
- 'tends to be for': 13 submitters
- 'neither for nor against': 10 submitters
- 'tends to be against': 12 submitters
- 'strongly against': 20 submitters
- missing/no position: one submitter.

This information is presented in Figure 1.

Stance of Interested Persons on differing uses of genetic modification

An assessment was also made from each submitter's full submission as to the circumstances where each submitter "approved" or "disapproved" of the use of genetic modification techniques. Eight broad categories of "support" and seven of "opposition" were recorded.

Uses of genetic modification on which submitters were most likely to feel positive were contained laboratory research and specified medical issues. Submitters were most concerned about uses that involved release of viable organisms into the environment, food production or the transfer of genetic material between "unlike" species (in particular, the transfer of human genetic material into plants or animals).

Submitters were likely to feel positive about using genetic modification if it was used for:

- contained laboratory research (29 submitters)

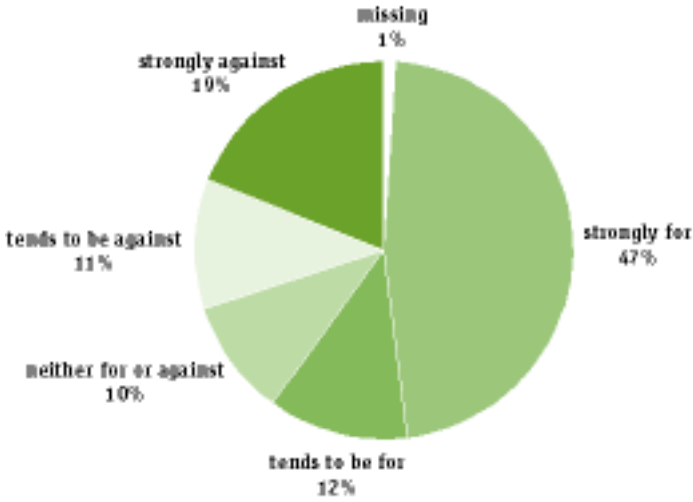

Fig 1 **Overall stance of Interested Persons on genetic modification**

- specified medical uses (19 submitters)
- non-specified medical uses (15 submitters)
- environmental protection (16 submitters)
- increased food production (nine submitters)
- increased food quality (eight submitters)
- non-viable genetically modified material only (one submitter)
- non-heritable genetic modification (one submitter).

Submitters were most concerned about the use of genetic modification techniques if it:

- involved transfer of genetic material between "unlike" species (12 submitters)
- involved the transfer of human genetic material into plants or animals (11 submitters)
- involved the production of genetically modified animals for "bio-factories" (four submitters)
- involved the release of viable organisms in the environment (21 submitters)
- was for food production (15 submitters)
- involved introducing inheritable genetic changes in humans (two submitters)
- privatised genetic material (12 submitters).

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3.1 Strategy: an introduction

The following three sections discuss three Warrant items concerning strategy. The Warrant items are:

(1) the strategic options available to enable New Zealand to address, now and in the future, genetic modification, genetically modified organisms and products

(k) the key strategic issues drawing on ethical, cultural, environmental, social, and economic risks and benefits arising form the use of genetic modification, genetically modified organisms, and products

(m) the range of strategic outcomes for the future application or avoidance of genetic modification, genetically modified organisms, and products in New Zealand

Strategic matters received considerable comment from submitters. Seventy-eight submitters commented on Warrant item (l) strategic 'options', 39 on Warrant item (k) strategic 'issues', and 37 on Warrant item (m) strategic 'outcomes'.

Strategic 'options', 'issues' and 'outcomes' have been addressed simultaneously to ensure the scope of submitters' comment is fully captured in relevant discussion. Where appropriate, comments across the three Warrant items have been grouped together. Submitters' comments suggest that there was no uniform and consistent understanding of the terms strategic 'options', strategic 'issues' and strategic 'outcomes'. Hence submitters have interpreted, defined and delineated these terms in different ways. For the purposes of this report, submitters' comments have been drawn together in the following manner.

Strategic options includes the broad-based, overall philosophy that might guide the direction of New Zealand policy for genetic modification. Strategic options include the various pathways, or courses of action, available to New Zealand. Strategic options available include, for example, an option for a totally 'genetic modification free' New Zealand, the option of a system which encompasses use of genetic modification technology in some areas but not in others, or the option of a widespread use of genetic modification in New Zealand.

Strategic issues discusses the general questions that arise when a particular course of action is followed. They can be seen as the linkage between the strategic options being pursued, and the resultant outcomes. The Warrant item mentions strategic issues that involve ethical, social, cultural, environmental, social and economic risks and benefits. In this report, submitter views on what are strategic issues includes discussion of these points with respect to considerations of 'acceptability', 'choice', 'risk management' and 'opportunities' to be gained or lost.

Strategic outcomes comprises the range of end results that might be specifically sought, or might result from, the application or avoidance of genetic modification, genetically modified organisms and products in New Zealand. Outcomes include, for example, the results from the use or the avoidance of genetic modification in the areas of health, environment, production, research, culture and ethics.

In brief, in selecting a particular course of action, or pathway (strategic option), certain questions and considerations are considered (strategic issues) in order to achieve the final goal or end result (strategic outcome).

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3.2 Strategic options

Introduction

Nearly three-quarters of the total number of submitters with Interested Person status (78) commented on strategic options as a component of the three Warrant items (items (1), (k) and (m)) dealing with strategy. The main sectoral focus of these submitters was the economic and productive sector (41 submitters).

The stance of most of these submitters was predominantly in support of genetic modification technology. Fifty submitters were assessed as being 'strongly for', or 'tending to be for', genetic modification, and 24 as being 'strongly against', or 'tending to be against', genetic moderation. Four submitters were assessed as being 'neither for nor against' genetic modification.

This Warrant item elicited two general types of responses:

- submitters who perceived strategic options available to New Zealand in terms of using biotechnology to achieve specific business or industry outcomes
- submitters who saw New Zealand's options in terms of measures to reduce risk from application of this technology.

Most supporters of industry-based use of genetic modification technology tended to advance strategic options in terms of favourable business outcomes. They highlighted the potential for improvement in competitiveness, innovation and research and development through use of this technology. Achievement of business objectives was promoted as the best strategic option for New Zealand. These submitters essentially equated best business practices with best outcome for New Zealand as a whole. This group of submitters tended to emanate from industry networks and associations (21 submitters), research organisations (14), other advocacy network and associations (14 submitters) and private companies (seven submitters).

The other main group of submitters on this Warrant item generally had concerns about (or strong opposition to) genetic modification. They tended to advance strategic options that would reduce the level of risk to New Zealand. Their preferred strategic options were to ban or delay the widespread use of such

technology in New Zealand. These submitters usually came from consumer networks and associations, Maori and religious groups.

Implicit in both types of response (ie, suggesting strategic options to achieve industry goals or options to reduce risk) was the underlying attitude toward the use of genetic modification technology. The 'stance' evident in submitters' comments was the common thread evident in all types of comments on strategic options. The continuum of attitudes to the technology, in effect, formed the basis of the range of strategic options that submitters saw as being available to New Zealand.

Continuum of attitude toward genetic modification

The continuum of attitude toward genetic modification spanned a wide range. At one end were those submitters who supported most, or all, aspects of genetic modification technology within a minimalist regulatory framework. At the other end were those submitters who were against any use of genetic modification technology in New Zealand. Middle-ground positions included submitters who supported case-by-case assessment of genetic modification, those who wanted a continuation of the current moratorium and those who wanted New Zealand to be free of genetic modification technology except for a limited and selected range of uses.

Taking into account the overall position apparent from the full text of submissions from all Interested Persons, an overall stance was apparent for 78 submitters. (For the remainder of submitters a clear and unequivocal position could not be determined.) The main groupings (and numbers) of these 78 submitters were identified as clustered around five positions:

- accepted most or all aspects of genetic modification (27 submitters)
- supported a system of case-by-case assessment of each application for use of this technology (10 submitters)
- wanted the current voluntary moratorium extended (15 submitters)
- wanted New Zealand to be "GM-free" except for limited and selected uses (17 submitters)
- wanted no genetic modification technology, no genetically modified organisms or products (nine submitters).

The following sections discuss the various specific strategic options advocated by submitters under the two broad headings:

- strategic options to achieve industry goals
- strategic options to reduce risk.

Strategic options to achieve industry goals

In response to identifying the strategic options available to New Zealand in addressing genetic modification technology, most submitters advanced options focusing on the achievement of various industry goals and objectives. Industry objectives included measures to sustain and improve New Zealand's productive capacity, to increase its competitiveness and to ensure its place in the international knowledge economy. Most submitters felt that New Zealand's interests would best be served by using genetic modification technology to meet these objectives. A minority felt that such objectives were best met by avoiding the use of such technology. In short, most submitters felt that New Zealand's best strategic options were the 'best' business options.

Genetic modification techniques were generally viewed as an essential and integral tool in achieving business outcomes. Although submitters advanced these goals as strategic 'options', many comments were more in line with discussion of 'outcomes'. Several comments dealt with strategic issues (ie, the questions that arise in pursuing certain outcomes). The comments provided therefore anticipated some of the discussion in the following sections on strategic 'outcomes' and strategic 'issues'. These views are referenced in both sections.

Most submitters saw New Zealand's overall wellbeing as being dependent on its ability to sustain a competitive and innovative knowledge-based economy drawing on current strengths in the productive sector. New Zealand's productive capacity, its research capability and global reputation were frequent themes in many comments.

The comments below are typical of the views advocating overall business goals such as competitiveness, innovation and the knowledge-based industries as key strategies for New Zealand.

Competitiveness and innovation

Meat New Zealand [IP31] argued that New Zealand should have a strategic option "consistent with the need to enhance sustainable competitiveness in the international economy". Biotenz [IP25] and Crop and Food Research [IP4] argued similarly, advocating that "New Zealand should choose an option that supports its strategic aims to be a globally competitive knowledge economy founded on the biological industries".

The role of New Zealand's Royal Commission on Genetic Modification in reporting to Government was seen to present a "unique" opportunity to deliver wide-ranging benefits. New Zealand Agritech [IP73] argued that the Commission

had "the opportunity to lead the world with the development of the first national strategy to manage and use GMOs to improve our international competitiveness, to protect our fragile fauna and flora and provide substantial benefits to humanity".

Several submitters stressed the close interlinking of innovation and competitiveness. Meat New Zealand [IP31] noted: "Innovation drives competition and is one of the very significant issues surrounding global development." It stressed the importance of being able to constantly adapt products to meet shifts in consumer preferences and lifestyle changes. New Zealand Grocery Marketers Association [IP54] made similar points arguing that:

> New Zealand cannot and should not quarantine itself from the use of gene technology. To do so would disadvantage the competitiveness and economic vitality of the industry.

New Zealand Dairy Board [IP67] maintained that New Zealand's current and future standard of living was "overwhelmingly dependent" on biological products that exceeded 60% of New Zealand's export earnings. It argued that there were "no other exports growing rapidly enough to reduce that dependence" and that this required New Zealand "maintaining and enhancing the competitiveness in biological industries [which are] our only major source of international competitive advantage". The Board saw New Zealand's only viable option with respect to genetic modification, if it were to maintain its competitiveness, would be "to ensure that the responsible use of GM is permitted".

Research and development and the knowledge-based economy

The importance of New Zealand retaining its research capability and place in the international knowledge economy was stressed by a number of submitters representing farming, biotechnology, medical research and university interests. They reinforced the importance of New Zealand's global credentials, seeing the option of avoiding genetic modification technology as compromising New Zealand's research and academic reputation.

Rural Women New Zealand [IP52] stressed the importance of New Zealand maintaining its position in the "international knowledge economy through supporting continued GM research" especially "in agricultural export markets through … leading edge science … and leading edge food safety and environmental risk management systems".

New Zealand Dairy Board [IP67] posed two questions:

> … does New Zealand choose … to abandon the strategy of pursuing the "knowledge economy" by ceasing to be involved in the GM revolution …?
>
> … does New Zealand choose to adopt a policy which will enable it to maintain and improve

> the competitiveness of its core industries, and to capture for all New Zealanders the benefits of the "knowledge economy"?

The Board concluded that New Zealand "must pursue the use of GM in agriculture" as a key aspect of its pursuit of the knowledge economy.

New Zealand universities gave particular emphasis to their role in New Zealand's pursuit of a successful knowledge-based economy. For example, Lincoln University [IP8] argued that "a University can only survive in a global market if it generates new knowledge, utilises new technologies and delivers outcomes in its field of expertise". The University said that it "must be involved in genetic modification in its educational and research programmes, to ensure it remains globally competitive". University of Otago [IP19] maintained that avoidance of genetic modification technology "would seriously compromise the university's ability to deliver teaching and research of an internationally satisfactory standard".

Submitters engaged in medical research advanced similar arguments. Researched Medicines Industry Association of New Zealand [IP55] viewed biotechnology industries as being critical to New Zealand's overall benefit. In an accompanying witness brief, it maintained:

> Biotechnology industries — with their emphasis on research and development, skills development, technological innovation, and activities that target the high value end of the market spectrum — are important to New Zealand's future economic and social wellbeing.

The option of limiting the use of genetic technology was seen to have deleterious effects. AgResearch [IP13] stated its belief that a strategy based on halting or restricting this technology "would have serious adverse implications for New Zealand science and consequently the nation's future economic, social and environmental wellbeing".

"GM-free" nation

Although most submitters who put forward specific industry goals as the best strategic options for New Zealand were generally in support of using genetic modification technology, several submitters argued the converse. The latter felt that nationwide industry goals would be best achieved by avoiding genetic modification. Most of these submitters saw benefits in New Zealand's potential as an organic 'haven'. These views are discussed below (see "Prohibiting the use of genetic modification technology").

Strategic options to reduce risk

Submitters who opposed, or expressed reluctance about New Zealand's adoption of genetic modification techniques often cited "risks" as a reason. Fears about the "safety" of genetic modification, particularly its impact on the environment, were the most commonly expressed concern. Strategic options available to New Zealand recommended by these submitters included:

- prohibiting the use of genetic modification technology
- extending the existing moratorium or delaying any decision until risks are better understood
- undertaking formal assessment of the risks involved.

Indicative of the level and type of concern for future strategic directions were the following stances. These stances generally give a clear indication of each submitter's position on the continuum of opinion on genetic modification.

Prohibiting the use of genetic modification technology

Several submitters advanced "GM-free" status for New Zealand. Submitters tended either to emphasise the benefits of a single-minded proactive policy for New Zealand to be "GM free", or to emphasise the risks involved in widespread use of this technology. Several submitters, however, stressed both the advantages of actively promoting "GM-free" status and the negative effects of allowing the use of genetic modification in New Zealand.

Submitters stressing the positive aspects of New Zealand identifying itself as "GM free" saw virtue in New Zealand promoting itself as the first country to be totally free of the use of genetic modification by choice.

For example, Green Party of Aotearoa/New Zealand [IP83] felt New Zealand should become "the first consciously GE Free nation". It argued that this "would be a major boost to our food exports" because such a policy would "profile New Zealand as a nation which had chosen to base its prosperity on sustainability, a sound understanding of ecological principles and respect for people and other life forms".

Also typical of this position were the views of the Canterbury Commercial Organics Group [IP65]. It argued that New Zealand's adoption of a "high-tech GE-free-agriculture, 'knowledge economy' future will ensure this country a much more secure, sustainable, successful and prosperous future than will … the GE version". It maintained that New Zealand's geographical isolation gave it "an opportunity to remain GM free and to develop the certified organic industry to take advantage of the expanding export opportunity".

Other comments from submitters stressed the risks involved with genetic modification technology. Representative of these views were the following comments:

- "New Zealand must maintain her GE-free status. This is because there are so many unknowns about the technology and our considered opinion is that it is inherently dangerous." (Physicians and Scientists for Responsible Genetics New Zealand [IP107])

Some submitters argued especially for the prohibition or restriction of genetically modified organisms because of the implications for the environment and agriculture. Comments included:

- Place "an immediate and indefinite ban on genetically engineered organisms in our food and our environment" (GE Free New Zealand (RAGE) in Food and Environment [IP63]).
- Sustain a "strategic vision" for "an ecologically sustainable Aotearoa New Zealand" which involved "a GE-Free environment, banning all releases of genetically engineered organisms into the environment" (Greenpeace New Zealand [IP82]).
- "Only … a complete and permanent ban of GM foods" and "a ban on genetic engineering" will protect "the future of our agricultural economy and the health and safety of the nation" (Soil and Health Association [IP97]).
- Apply "the precautionary principle to Genetic Engineering technology and ban all trials and releases of GE crops until it can be proven that they are safe" (Northland Conservation Board [IP68]).
- Have "no field release of GMOs in the New Zealand environment because this is an unproven technology with unknown long term potential irreversible side-effects" (Royal Forest and Bird Protection Society of New Zealand [IP79]).
- "The principal strategic option" should be that "New Zealand's natural and agricultural environment be kept free of genetically modified organisms" (Bio Dynamic Farming and Gardening Association in New Zealand [IP61]).

Extending existing moratorium/delaying decision on use of genetic modification

Several submitters supported extension of the current voluntary moratorium and other recommendations to delay any irrevocable decision on the use of genetic modification. This view came from a variety of quarters, especially environmental and Maori organisations and beekeepers. Views supporting an extension of the moratorium, or other delays in New Zealand's use of genetic modification

technology, focused on general concerns as well as particular issues for food and the environment.

Typical of general comments were the views of the following two submitters:

- Strategic options "should be defined by the kind of future that we want for New Zealand. … There are widely recognised risks in adopting GM technologies. … New Zealand has the opportunity to deliberately defer from the global trend and take a more measured response" (Sustainable Futures Trust [IP51]).
- "A fully legislated moratorium, would give New Zealand time to have a wide ranging and comprehensive discussion on our options before any irreversible steps are taken" (Environment and Conservation Organisations of New Zealand [IP102]).

Submitter views focusing on the environment included:

- Impose a "10 year moratorium on all field tests or general release of genetically modified organisms" so that New Zealand can "move away from conventional chemical agri-technology industry and fully adopt organic production by 2005" (Maori Congress [IP103]).
- Introduce 'a fully legislated moratorium, until there is definitive proof of its [genetic modification technology] safety" because a "GE Free New Zealand" is "the only option to allow the full protection of the biosphere and all organisms presently residing within it" (Nelson GE Free Awareness Group [IP100]).
- New Zealand should "legislate to create a permanent GM Commission … responsible for … the maintenance and review of a Moratorium on open-environment research and scientific and commercial activity with GM organisms" (National Beekeepers Association of New Zealand, Poverty Bay Branch [IP62]).

Submitters' views specifically addressing food included:

- To "delay commercial release of GM food until the extent of the negative consumer attitude can be seen and the producer benefits become more apparent" (New Zealand Council of Trade Unions [IP95]).

Undertaking formal assessment of risk

Several submitters with safety concerns proposed formal, independent testing and assessment of risks. For example, Comvita New Zealand [IP74] felt that New

Zealand policy needed to achieve the following:

a) Support fundamental research to develop precision and predictability in gene expression and gene transfer;

b) Develop a world-class independent testing regime, using evidence-based risk analysis and the precautionary principle, to ensure the safety of any GM organisms that may potentially be released into the New Zealand environment.

c) Prohibit the release of GM plants for commercial production in New Zealand for the foreseeable future, and at least until there is general public acceptance that policy objectives a) and b) have been met.

Specific research to assess impacts in various industries and sectors was also recommended as a strategic option. For example, New Zealand Worm Federation [IP94] recommended conduct of "appropriate research" on "the effects of genetically modified organisms on soil microbial and worm health" and "the effect of genetically engineered crops' residues on the microbial action of the soil" before endorsement of "genetic modification of agricultural products in New Zealand".

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3.3 Strategic issues

Introduction

Thirty-nine submitters made substantial comment on strategic issues as a component of the three Warrant items (items (1), (k) and (m)) dealing with strategy.

Comments under this Warrant item (k) identified strategic issues with wide-ranging theoretical and conceptual perspectives. Comments covered such issues as: the need for a framework based on principles; the importance of balanced solutions, justice and fairness in decision-making; clarity for future direction; and responsibility towards future generations. Implications for various populations such as future generations, Maori and sufferers of genetic-based diseases were also noted. Other matters raised included health and safety considerations and potential impacts on the environment and biodiversity.

Submitters' comments from the other Warrant items dealing with strategic matters also traversed strategic 'issues' and have been included in this section. For the purpose of this analysis, strategic 'issues' are broadly defined as the considerations raised in the course of selecting a particular pathway (strategic 'option') to achieve a certain result (strategic 'outcome').

Key themes

Throughout the comments on all three Warrant items dealing with strategic matters, strategic issues generally grouped around four themes:

- acceptability
- choice
- risk management
- opportunities.

The matters raised under these four general types of strategic issues are outlined below and a more detailed discussion follows.

Acceptability

The core issues grouped under this heading focused on whether particular policies, actions and other outcomes were acceptable to certain groups of people,

or to various industry sectors. Examples cited by submitters raised questions such as:

- Would this course of action be acceptable to the New Zealand public at large?
- Would it satisfy the demands and requirements of particular populations such as industry groupings, organic farmers, sufferers of genetic-based illnesses?
- Is it ethically acceptable?
- Would it affect the integrity or cultural values of any particular group?

Choice

The main issues raised affecting choice centred on whether certain pathways affected our choice to pursue other alternatives. The strategic perspective of choice was not so much what the choices were, but whether choice remained if a certain pathway were adopted. In effect, do certain pathways close off other choices?

For example, issues raised by submitters raised such questions as:

- How would a decision to disallow genetically modified products such as insulin affect diabetics? What other choices would they have?
- How would such a decision affect medical researchers actively engaged in pursuing diagnostic and palliative care solutions? What choices would it constrain?

Risk management

The strategic issues raised in this area were about how risks could best be managed. The strategic perspective on risk was therefore a question not so much of what risks there were, but of how any risks associated with a particular strategic pathway or option could be effectively managed. For example, strategic issues raised included:

- Could we effectively manage the risks of a 'mixed' production system allowing both genetically modified crops and organic produce?

Opportunities

Strategic issues raised in relation to opportunities centred around the extent to which particular pathways would allow maximisation of opportunities. The main strategic questions in this area concerned whether particular courses of action were maximising opportunities, or reducing and closing off certain other opportunities. Opportunities to be maximised included such business goals as

innovation and productive capacity. Questions raised in comments from submitters included:

- What export opportunities would be missed if New Zealand failed to allow genetically modified animals?
- What opportunities would be lost if New Zealand failed to use genetic modification technology for pest control?
- What opportunities would be lost to New Zealand from organic farming if commercial production of genetically modified organisms were allowed?
- What applications of genetic modification were irreversible?

The following sections identify and summarise specific submitters' comments in relation to acceptability, choice, risk management and opportunity.

Acceptability

The need for "acceptable" solutions with widespread public support was the most-mentioned strategic issue. Decision-making grounded in a predetermined framework and informed by public debate was a frequent call. Several submitters emphasised the need for a system that ensured widespread public acceptance with fair, just and participatory decisions. Submitters also mentioned acceptable "cultural" and acceptable "environmental" strategies.

Submitters who emphasised the need for just and equitable solutions that had widespread public support, included Interchurch Commission on Genetic Engineering [IP49], which spoke of the need for "justice and equity to ensure that all will benefit from any applications of GM technology".

The need for public education and informed debate was a frequently mentioned issue. For example, New Zealand Catholic Bishops' Conference [IP38] called for a public education and consultation process so that "an informed community can participate fully in discussion, confident in their knowledge of both the scientific facts and the ethical issues". Parliamentary Commissioner for the Environment [IP70] stressed the need for development of policy frameworks to "facilitate understanding about genetic science and engage in constructive debate". It saw a need for a "more coordinated approach" with a "purposeful framework" for dealing with genetic modification issues. Institute of Molecular Biosciences, Massey University [IP15] expressed similar views. Noting that knowledge and information' were the "key strategic issues", it maintained that in its experience the wider community appreciated the knowledge and benefits that had already accrued from the use of genetic modification technology but that the public wanted "authoritative assurance that the new GM products will be safe". Genesis

Research and Development [IP11] thought that "as a society, New Zealand needs to continue to have open and informed discussions about the issues and the concerns arising from using GMOs". It recommended that: "Appropriate forums must be created where information can be made available in a format that will allow the public to understand the basic technology, so that informed decisions can be made."

Reinforcing the need for public support in New Zealand's use of genetic modification technology, SAFE (Save Animals from Exploitation) [IP85] stressed that "the ethical position of the general public is vitally important" and "should be a major factor in the Commission's recommendations". This view was echoed in the position adopted by University of Canterbury [IP7], which argued for a "pragmatic approach" so that extreme positions were avoided. Noting that low-risk genetic modification work had "great potential to benefit society", the University said that some high-risk work was "beyond the bounds accepted by society".

Safeguards to enhance acceptability and reduce perceived risks were frequently advocated. For example, Greenpeace New Zealand [IP82] stressed the need for a "strategic vision" to provide the "necessary critical framework within which the appropriateness of new technologies … should be assessed". Environment and Conservation Organisations of New Zealand [IP102] argued for an approach to assessing the safety and possible use of genetic modification "to be explored in as wide a context as possible" that would include "ethical, cultural, social and economic risks and benefits as well as looking at the science involved …". New Zealand Wool Board [IP30] argued that "it may be necessary to put in place an interim management regime while values, ethics, risks and benefits are being dealt with". Bio Dynamic Farming and Gardening Association [IP61] emphasised that "genetic modifiers" had a "moral responsibility" to ensure that they also generated ways to reduce the uncertainty created by genetic modification technology to "acceptable levels".

Other submitters stressed the importance of clearly articulated public policy that provided certainty for the public. For example, Aventis CropScience [IP14] reinforced the importance of "clear policy directives from Government", noting that "public confidence results from sound regulatory policy". Anglican Church in Aotearoa New Zealand and Polynesia [IP42] commented that, in terms of "justice and equity", there was a need "to establish monitoring and regulatory mechanisms which will moderate the excesses of corporate enthusiasm and ensure the sovereignty of this Treaty nation".

Some submitters brought together the various strategic elements of acceptability, choice, risk management and opportunity. For example, Landcare Research [IP12] in its recommendation for a 'conceptual framework' for analysis of risks and benefits had 'four moral principles' at its core. The guiding principles for such a framework included such issues as "autonomy" (freedom of use and choice), "justice and fairness" (such as in the distribution of risks, benefits and costs), "beneficence" (good in matters such as health, environment and consumers), and "non-maleficence" (no harm in matters such as ecological impacts or food safety).

Submitters also addressed specific cultural and environmental strategic issues in terms of acceptability.

Cultural acceptability

Protection of the rights and the genetic heritage of indigenous peoples were among the culturally acceptable strategic issues noted. Physicians and Scientists for Responsible Genetic New Zealand (PSRG) [IP107] emphasised "protection of diversity of cultural perspective … especially that of indigenous peoples". Maori Congress [IP103] maintained that "protection of Maori concerns" was "paramount" and needed to be "actively promoted". WAI 262 claimants [IP89] stressed that Maori must "fully understand and appreciate the consequences of the modification of whakapapa" and that they must "say no to such modification until the consequences are proven to be of benefit".

Environmental acceptability

The uniqueness of New Zealand's biodiversity was a critical concern of several submitters who argued that this was a major strategic consideration. However, submitters were divided on whether this unique biodiversity was better ensured by the use or by the avoidance of genetic modification technology. Landcare Research [IP12] argued that "the protection of New Zealand's biodiversity is a national imperative and an international obligation" and suggested that such protection could be most readily achieved by giving conservation managers "a full management toolbox that includes GM technology".

Supporting the need to retain New Zealand's biodiversity through acceptable practices, PSRG [IP107] described the "protection of the biosphere against the adverse effects of genetic engineering" as a key strategic issue. Royal Forest and Bird Protection Society [IP79] argued similarly that "the key strategic issue is that of the New Zealand Biodiversity Strategy" and that "protection of New Zealand's unique wildlife is of international importance". Royal Forest and Bird Protection Society, Nelson/Tasman Branch [IP43] listed as a key concern the "consideration of effects over the whole ecosystem".

Friends of the Earth [IP78] sought to contribute "to the integrity of the ecosphere" by recommending "the institution of sound ecological principles as [a] basis for resource management and related national and international policy". Public Questions Committee (Methodist, Presbyterian, Churches of Christ, Quaker) [IP93] argued that "the integrity of the biosphere is a sacred heritage which we are ethically obliged not to harm" and that future generations "have a right to celebrate its … diversity intact".

Choice

The main strategic issues referenced by submitters as affecting choice centred on whether choice to follow certain strategic pathways affected our pursuit of other alternatives. In effect, did one person's choice concerning genetic modification affect someone else's range of choices? For example, New Zealand Life Sciences Network [IP24] queried whether New Zealand fulfilled its "fiduciary duty to future generations if we knowingly reduce our options to address the looming issues of the future at the very time when those issues are becoming increasingly better defined?"

Most considerations raised by submitters involving choice concerned the general right to exercise choice. Submitters offering specific comments on the exercise of choice most frequently provided examples of health issues (especially genetically modified foods) and organic farming.

Choice and food

Comments emphasising the right to choose in relation to food products included:

- the rights of individuals "to distance themselves from GM if conscience precludes the use of the technology or its products … particularly in relation to genetically modified foods" (New Zealand Catholic Bishops' Conference [IP38])
- the need for "respect for autonomy so that consumers will have a choice, particularly in the areas of GM foods" (Interchurch Commission on Genetic Engineering [IP49])

Choice and organics

Several submitters highlighted options for choice in relation to New Zealand's "clean green" image. Opinion was clearly demarcated between those who felt that

New Zealand could accommodate both organic agricultural systems and genetically modified plants and those who felt that the two production systems were incompatible.

Representative of comments that genetically modified production reduced choice to use organic production methods were the following:

- "The choice is stark" between "a knowledge-based, prosperous, safe and sustainable future paid for by producing and selling to the high value and exponentially expanding eco-tourism and certified organic, 'clean and green' IPM and GE-free markets of the world" or "a GE-contaminated, commodity producing economy" (Canterbury Commercial Organics Group [IP65]).
- "Genetic Engineering is no use to Organic agriculture and the environments that surround it. The introduction of GE … would effectively destroy decades of hard work … and the positive economic opportunity awaiting our country in developing sound sustainable Organic agriculture, produce, environments and related knowledge" (Organic Federation New Zealand [IP81]).
- "… genetic engineering and organic food production are incompatible" [Soil and Health Association of New Zealand [IP97]).
- "The introduction of GM crops and animals has the potential to compromise [organic] systems to the extent that produce will not meet the requirements [for certification] as organic thereby depriving New Zealand of a competitive advantage and individual farmers of their preferred choice of production method" (Commonsense Organics [IP66]).
- "Commercial production of GM food in New Zealand could impact negatively on the export of kiwifruit to Europe in particular, but also to Japan and Southern Asia. Adverse consumer opinion and retail trade action could lead to non tariff barriers to market access." This would jeopardise the kiwifruit export industry including "$400m of export earnings" (ZESPRI International [IP46]).

Submitters who felt that organics and genetically modified production systems could coexist included submitters with the following views:

- "Organic production is compatible with GMs as other nations have shown in a robust regulatory framework … General concerns about GMOs will become less over time and such concerns, unless based on scientific evidence, should not restrict genetic modification utilisation" (Association of Crown Research Institutes [IP22]).
- "New Zealand can maintain both organic production and the production of GM crops … competitive advantage lies in the rapid adoption of

biotechnology … Consumer resistance to GM foods will disappear …" (New Zealand Arable-Food Industry Council [IP56]).

Choice and medical care

Submitters representing patient groups of those who had genetically based conditions were unanimous in their call for the right to exercise choice as regards therapeutic care. Typical of these comments were the following:

- Say "yes" to genetic modification technology "because we can manage concerns and safety issues and at the same time gain great benefits in the health of our population, and take advantage of the technology for employment and economic growth" (Lysosomal Diseases New Zealand [IP99]).
- "… patients should have access to a choice of therapeutic products. Patient information and informed consent underpin real choice. If real choice and informed consent exist then ethical and cultural risks are minimised and environmental, social and economic benefits are maximised" (Diabetes Youth New Zealand [IP60]).
- "… people suffering haemophilia and other genetic bleeding disorders, should have access to choice in therapeutic products … limiting access to recombinant therapeutic products is unthinkable" (Haemophilia Foundation of New Zealand [IP48]).
- "Freedom of choice is important when making decisions in life or death situations — Cystic Fibrosis sufferers must be allowed to have access to genetically modified products if that is what they choose" (Cystic Fibrosis Association of New Zealand [IP39]).

Risk management

Several submitters saw the way in which New Zealand managed the risks associated with use of genetic modification technology as an important strategic issue. Submitters suggested a variety of ways in which risks could be most effectively managed. Most submitters advocated robust regulatory frameworks and assessment procedures.

Submitters who felt that risks of using genetic modification technology were manageable generally favoured the institution of robust regulatory frameworks and assessment procedures. Comment representative of this position included:

- … the risks are manageable, in particular through a regulatory framework that relies on comprehensive assessment and transparency in its functions" (Carter Holt Harvey /Fletcher Challenge Forests [IP17]).

- "The issues surrounding biotechnology are based around … potential risk and flow-on consequences of that risk becoming a reality. … Risk management and a robust regulatory framework … should minimise the negative consequences of biotechnological research and development" (Federation of Maori Authorities [IP69]).
- "A robust regulatory environment that promotes safe research and development is necessary" (Wrightson [IP3]).

Submitters with concerns about the risks associated with genetic modification technology also saw risk management as a key strategic issue. Several suggested adoption of the precautionary principle or argued for new approaches to managing risk. Comments representative of these viewpoints included:

- New Zealand should "apply the precautionary principle to Genetic Engineering technology and ban all trials and releases of GE crops until it can be proven that they are safe" (Northland Conservation Board [IP68]).
- "… consideration [of uncertainties] must include the widest possible survey of scientific and societal experience of new departures and new processes. … We do not manage the risks of any technology by relying on knowledge of the manufacturing process. … Empirical investigation is imperative. … New designs require new tests" (Bio Dynamic Farming and Gardening Association [IP61]).

Opportunities

A smaller number of submitters specifically noted opportunities from the use or from the avoidance of genetic modification technology as a key strategic issue when commenting on Warrant items in relation to strategic 'options', 'issues' and 'outcomes'. Most discussion of opportunities to be gained or lost was raised by submitters in discussion of other Warrant items, in particular Warrant item (i). Therefore much of the detailed comment on strategic issues as opportunities lost or gained is recorded in the section "Opportunities for use or avoidance". In commenting on strategy, submitters mostly saw opportunities in terms of benefits in productive capacity and development of a knowledge-based society.

appendix 2

Outcomes of Consultation: Submissions from Interested Persons

Section contents

3.4 Strategic outcomes

Introduction

Around one-third of the Interested Persons (37 submitters) provided substantive comment on strategic 'outcomes' as a component of the three Warrant items (items (1), (k) and (m)) dealing with strategy. With respect to the principal sector focus of these submitters, two-thirds (25 submitters) were from the economic/productive sector, three submitters were from the cultural/ethical sector, two were from the environmental sector, two were from the health sector and five were from other sectors. Looking at the industry groupings, the 37 submitters were primarily from industry networks or associations (just over one-third or 14 submitters), research organisations (eight submitters), and other advocacy networks or associations (five submitters).

In terms of stance on genetic modification which the submitters who made substantive comment on this issue took, most were assessed as 'strongly for' genetic modification (22 submitters) or 'tending to be for' (five submitters), with the remaining 10 submitters either 'tending to be against' (five submitters) or being 'strongly against' genetic modification (five submitters). The positions taken by submitters on genetic modification are reflected in the commentary on strategic outcomes below, where a greater proportion of comments reflect those of submitters who favoured genetic modification than those who were opposed to it.

The commentary provided below on the strategic outcomes for the promotion or avoidance of genetic modification has been categorised according to health, environmental, production, research, and cultural and ethical outcomes.

Health

Health outcomes from use

A range of mainly health research and patient groups provided commentary on strategic outcomes that might be derived from the use of genetic modification technology in the health arena, principally focusing on outcomes for patient groups and greater understanding of biological processes.

Submitters identified key strategic outcomes of the **use** of genetic modification in health areas as including:

- better understanding of diseases
- better understanding of fundamental cellular processes
- new applications for prevention, diagnosis and treatment of diseases
- opportunities for improved health in New Zealand
- continuation of biomedical research opportunities
- ability to develop a basic research and teaching capability in recombinant DNA and genetic modification technologies in New Zealand
- possibility for New Zealand to develop a biotechnology pharmaceutical industry
- labelled food which allows consumer choice.

Range of health outcomes

Lysosomal Diseases New Zealand [IP99] identified a range of beneficial strategic outcomes from the application of genetic modification in the areas of health, employment and economic growth and commented that "avoiding GM technology will maintain high levels of disability, and avoidable disease, suffering and death, [and] lead to third world health status". Malaghan Institute of Medical Research [IP10] also outlined a range of strategic health outcomes from genetic modification stating that:

> The strategic outcomes for future applications of GM, GMOs and products in the field of human health extend to every facet of the human condition from basic food requirements to understanding the nature of human disease and applying this knowledge to prevention, diagnosis and treatment.

Patient outcomes

Patient and medical research groups tended to identify outcomes from genetic modification that would directly benefit the sufferers of specific conditions. For example, Malaghan Institute [IP10] identified considerable potential for gene therapy to treat complex diseases such as cancer and heart disease. Similarly, Diabetes Youth New Zealand [IP60] identified that patient lives, now and in the future, "rely on genetically engineered medicines". Diabetes Youth commented further that their hopes for a cure, and a life free from the degenerative effects of their conditions, "lie in the latest techniques for manipulating biological material, including genetic modification and xenotransplantation".

Greater understanding of biological processes

Several submitters commented on the outcome that genetic modification would provide greater understanding of biological processes and human health

conditions. Sustainable Futures Trust [IP51] identified the potential for genetic modification research to contribute to the understanding and alleviation of genetic conditions. Researched Medicines Industry Association of New Zealand (RMI) [IP55] also observed that the most "critical" strategic outcome was ongoing research involving genetic modification in the health arena, permitting the creation and use of genetically modified organisms, and ongoing availability of genetically modified therapeutic products. Institute of Molecular BioSciences, Massey University [IP15] expressed a similar opinion that there was a requirement for New Zealand to develop a capability in basic research and teaching in recombinant DNA and genetic modification technologies. The Institute also noted the need for the Commission to understand the impact made by genetic modification on "our understanding of the fundamental cellular processes which govern the development and survival of plants, animals and microbes".

Other health outcomes from use

Federated Farmers of New Zealand [IP34] noted that food altered by genetic modification should be clearly labelled to allow consumer choice. Physicians and Scientists for Responsible Genetics New Zealand (PSRG) [IP107] expressed the opinion that all of the desirable outcomes of applying genetic modification technology in medicine can be achieved without compromising the "GE-free" status of the New Zealand environment, or prejudicing the quality and standing of biological research in New Zealand.

Health outcomes from avoidance

Comments from Interested Persons on the avoidance of genetic modification in the health arena focused on the negative effects that could result for medical research and patient care and on beneficial outcomes that might result from having time to establish more knowledge about the risks of genetic modification.

Submitters identified key strategic outcomes of the **avoidance** of genetic modification in health areas as including:

- reduction in medical research in New Zealand
- loss of tools to better understand medical conditions
- halt to advances in health research and treatment options in New Zealand
- reduced likelihood that New Zealand could be competitive in drug development
- greater assurance of food safety
- removal of unnecessary risks.

Effects on medical research and level of care

Human Genetics Society of Australasia, New Zealand Branch [IP59] identified that if genetic modification were to be avoided then serious repercussions would be experienced in terms of research, application of molecular technology and clinical care of patients. Council of Medical Colleges in New Zealand [IP37] expressed similar views, noting that without access to genetic modification technology advances in health research in New Zealand would be halted and some treatment options and many diagnostic tools would be removed. Genesis Research and Development [IP11] commented that without genetic modification technology it was unlikely that New Zealand could be competitive in drug development.

Knowledge of risks

ZESPRI International [IP46] commented that commercial food production should remain "GM free" until uncertainties were resolved and assurances of food safety could be given. In addition, Soil and Health Association of New Zealand [IP97] commented that there was no need to take unnecessary risks associated with genetic technology.

Environment

Environmental outcomes from use

Submitters, principally from research organisations, identified a range of outcomes from genetic modification that could provide environmental benefits. Submitters claimed that among these key strategic outcomes of the **use** of genetic modification in the environmental area were:

- better understanding of environmental systems
- greater control of pests and weeds
- protection of fragile flora and fauna
- bioremediation
- reduction in the use of herbicides and pesticides
- meeting international obligations.

Pest and weed control

Landcare Research [IP12] noted that research and development of genetic modification products should continue in order to achieve the outcome of control of environmental pests, including possums, stoats and wasps. New Zealand Plant Protection Society [IP36] agreed that New Zealand was facing a "very significant risk of adverse impacts from pests, diseases and weeds" and expressed the opinion that "GMOs need to be considered for difficult pest management problems" as

part of the overall solution. The Society commented further that there were examples of primary production systems faltering or failing because of a lack of sustainable solutions.

New Zealand Agritech [IP73] and Interchurch Commission on Genetic Engineering [IP49] also identified the outcome that genetic modification could help protect New Zealand's flora and fauna by controlling pests. Similarly, Association of Crown Research Institutes (ACRI) [IP22] identified that with genetic modification technology New Zealand would be better positioned to attack its environmental problems relating to introduced pests, remediation of polluted environments and the potential for reduced demand for agricultural land.

Understanding of environmental systems and effects

Royal Society of New Zealand [IP77] identified the knowledge gained from genetic modification as a strategic outcome that could be used to create wealth, wellbeing and provide "an informed understanding of the environment". Landcare Research [IP12] expressed the desire to see an outcome of increased funding for research into assessing risk of adverse environmental effects of genetically modified crops and products.

International obligations

Landcare Research [IP12] noted that it was important to permit the use of genetic modification tools for conservation genetics and related research so that New Zealand could fulfil its obligations under the Convention on Biological Diversity.

Other environmental outcomes from use

Genesis Research and Development [IP11] identified a range of beneficial environmental outcomes through implementation of biotechnology for the New Zealand forest industry. These outcomes included: maintaining a competitive edge and increasing land value to owners, as well as potentially improving the environment through maintenance of biodiversity, bioremediation, reduced pollution through less use of pesticides and herbicides, and recapturing of marginal soil. Landcare Research [IP12] also identified the outcome of minimising exposure to broad-scale pesticides as a desirable strategic outcome of genetic modification.

Environmental outcomes from avoidance

Submitters, principally from environmental and organics organisations, expressed views that the avoidance of genetic modification would allow a precautionary approach to be adopted until effects of genetic modification were known and that total avoidance of genetic modification was the only way to protect the environment.

Submitters identified key strategic outcomes of the **avoidance** of genetic modification in environmental areas as including:

- development of superior foods and crops
- avoidance of unknown, long-term, potentially irreversible side effects
- provision of time to develop testing programmes for potential health and environmental effects
- provision of time to make a considered response
- protection of the biosphere.

Precautionary approach until environmental effects are known

Royal Forest and Bird Protection Society [IP79] identified the outcome that unknown, long-term, potentially irreversible side effects could be avoided if genetically modified organisms were not released into the New Zealand environment. Similarly, Comvita New Zealand [IP74] made the point that genetically modified organisms should not be released into the New Zealand environment until consequences of recombinant DNA crop development could be assessed and objective testing programmes were in place to consider all potential health and environmental consequences. Environmental and Conservation Organisations of New Zealand [IP102] made a similar point; that a precautionary approach should be adopted and that time was needed to make a considered response to genetic modification in terms of environmental or health issues.

Avoidance of genetic modification as the only way to protect the environment

Royal Forest and Bird Protection Society, Nelson/Tasman Branch [IP43] viewed the release of genetically modified organisms into the environment as "untenable" and believed that sustaining New Zealand's unique flora and fauna and ecosystems was the paramount outcome to be achieved. On a similar note, Nelson GE Free Awareness Group [IP100] saw the avoidance of genetic modification as the only option that would allow "full protection" of the biosphere and all organisms residing in it.

Other environmental outcomes from avoidance

Landcare Research [IP12] noted that if genetic modification technology were avoided then it would be important that New Zealand not be left exposed to substantial health, environmental and trade risks through heavy dependence on large-scale use of 1080 and other broad-scale pesticides.

Production

Production outcomes from use

Submitters, principally from primary producer groups, universities and biotechnology organisations, identified a range of strategic outcomes from genetic modification that could provide productive or economic benefits. Organics groups identified strategic outcomes from the use of genetic modification that might have adverse effects for the future of the organics industry in New Zealand.

Among these key strategic outcomes of the **use** of genetic modification in production areas were:

- maintenance and enhancement of New Zealand's international agricultural competitiveness
- development and trade of intellectual property
- less reliance by New Zealand on overseas developments in genetic modification
- extraction of untapped value from food and fibre products
- development of superior foods and crops
- development of safe, sustainable internationally competitive products
- development of products that were better suited to specific purposes
- development of new cultivars in horticulture
- economic, social and environmental benefits for forestry
- loss of future earnings from organic products
- negative impacts on kiwifruit exports.

Global economic outcomes

ACRI [IP22] noted that genetic modification technology offered the potential outcome of high-value, niche-market products and better positioning of New Zealand in the global economy. Similarly, Biotenz [IP25] commented that New Zealand could use its agricultural science knowledge with the modern tools of genetic science (such as genomics, bio-informatics and proteomics) to remain a world leader in agriculture and create wealth. New Zealand Biotechnology Association (NZBA) [IP47] made the point that it was essential that New Zealand did not rely on overseas developments in biotechnology or it would lose its competitive advantages in agriculture and horticulture.

Several submitters from the production sector commented on the strategic outcome of New Zealand being able to achieve greater competitiveness

internationally if genetic modification technology were adopted, in particular for primary production industries. Wrightson [IP3] commented that the economy was heavily reliant on primary production, and that New Zealand needed to use biotechnology in agriculture to maintain and increase its international competitiveness. Carter Holt Harvey/Fletcher Challenge Forests [IP17] and New Zealand Forest Industries Council [IP9] also noted that genetic modification technology would enhance the competitiveness and sustainability of New Zealand's primary sector industries. Similarly, New Zealand Wool Board [IP30] commented that access to genetic modification technology was essential to New Zealand's long-term competitiveness. New Zealand Dairy Board [IP67] and Agritech [IP73] agreed that responsible use of genetic modification technology was needed to maintain New Zealand's international competitiveness in biological exports.

Biotechnology outcomes

Biotechnology groups identified a range of beneficial economic outcomes that might result from the use of genetic modification. RMI [IP55] noted that biotechnology industries were "crucial" to New Zealand's future economic and social wellbeing. Similarly, Monsanto New Zealand [IP6] identified that the development of biotechnology products could result in "safe, sustainable, internationally competitive products" that could sustain or further the standard of living of all New Zealanders. Hamilton City Council [IP20] also identified that genetic modification could be used to produce low-cost, high-value products and intellectual property for the international marketplace. Monsanto [IP6] commented that if biotechnology were embraced then this would be likely to lead to increased investment in biotechnology research.

Primary sector outcomes

Organisations from the primary sector made comment on a wide range of economic outcomes that the use of genetic modification might generate for primary industry sectors, including new products and services. New Zealand Arable-Food Industry Council [IP56] viewed strategic outcomes of genetic modification in terms of improved crop plants, development of superior foods, multiplication of seed for re-export and creation of intellectual property. New Zealand Forest Industries Council [IP9] identified economic, social and environmental benefits from the development of biotechnology applications in forestry.

Wrightson [IP3] commented that biotechnology would allow New Zealand to extract untapped value from food and fibre. Wool Board [IP30] identified a range of outcomes from genetic modification technology important in New Zealand's

biological economy including: allowing new goods and services to be produced, improving existing products, and producing products more efficiently.

Meat Industry Association of New Zealand (MIA) [IP32] identified that if New Zealand were to keep up with the latest technologies, including genetic modification, then it would be in the best position to adapt to changing attitudes within markets and the approaches taken by competitors. Wool Board [IP30] expressed caution, noting that unrestricted use of genetic modification could potentially compromise New Zealand's future markets. ZESPRI [IP46] expressed concern that commercial production of genetically modified food could impact negatively for New Zealand on the export of kiwifruit.

Organic industry outcomes

Organics groups, such as Organic Federation New Zealand [IP81] and Canterbury Commercial Organics Group [IP65], expressed the opinion that if genetic modification were promoted a strategic outcome would be a loss of present and projected future earnings from organic products. Golden Bay Organic Employment and Education Trust [IP104] was also of the opinion that the development of genetically engineered crop farming would destroy an entire market segment of organically grown crops and associated businesses. PSRG [IP107] agreed that field testing of genetically engineered foods would risk "irreparable damage" to the rapidly developing organics sector.

Producer groups, such as Dairy Board [IP67], commented on the possible conflict of interest between different production systems but noted that organic farming and farming using genetic modification technology were not mutually exclusive outcomes. Federated Farmers [IP34] agreed that adoption of genetic modification was compatible with a strong organic production industry. A2 Corporation [IP26] noted that New Zealand's clean green image was a valuable marketing tool that needed to be taken care of but stressed that that did not require banning genetic modification technology.

Production outcomes from avoidance

Submitters, principally from environmental and organics organisations, identified a range of positive strategic outcomes that the avoidance of genetic modification might generate, including the development of organics and genetically modified free products and markets. Research, biotechnology and primary producer groups adopted an opposing view on the avoidance of genetic modification and identified a range of negative strategic outcomes, including contraction of research and teaching in universities, reduced economic performance of biological industries and reduced quality of life.

Among these key strategic outcomes of the **avoidance** of genetic modification in productive areas were:

- development of New Zealand's clean, green, organic image and products
- diversion of energy and funding into "GM-free" alternatives
- opportunity for New Zealand to take advantage of high-value niche export markets for organic products
- opportunity for New Zealand to produce products for markets that demand "GM-free" food
- injection of capital from investors looking to exploit "GM-free" environments as a production base
- protection of the future of New Zealand's agricultural economy
- opportunity to clarify risks and benefits of commercial use of genetic modification
- serious implications for New Zealand science and wellbeing
- substantial reduction in market opportunities and choice
- reduction of options in sheep industry
- inability to preserve export income earned by dairy industry
- detrimental consequences for economic performance of biological industries
- disadvantage for competitiveness of industry
- contraction of economy
- detrimental effects on quality of life in New Zealand.

Outcomes from being "GM free"

The main economic outcomes of avoiding genetic modification presented by submitters related to the economic benefits that might be gained from marketing of New Zealand's clean, green, organic image and products. Green Party of Aotearoa/New Zealand [IP83] considered that an outcome of a "GE-free" status would result in a "major boost to our food exports" and similarly, GE Free New Zealand (RAGE) in Food and Environment [IP63] identified the expansion of organic agriculture as a strategic outcome of the avoidance of genetic modification. Friends of the Earth (New Zealand) [IP78] expressed the opinion that avoidance of genetically modified products would lead to energy and funding being diverted into the development of "non-GM" alternatives in medicines, agriculture and other fields.

Several submitters identified positive strategic outcomes of a "GM-free" stance. New Zealand Council of Trade Unions [IP95] noted that if New Zealand delayed

the commercial release of genetically modified food then it could position itself as "GM free" and obtain price premiums and preferential market access for its exports. Similarly, Hamilton City Council [IP20] identified that the strategic non-use of genetic modification would allow New Zealand to sell products to markets that demand "GM-free food". National Beekeepers Association of New Zealand, Poverty Bay Branch [IP62] also identified that high-value, niche-market export opportunities might arise if a "GM-free" position were adopted, but noted that the market promotional opportunities of being "GM free" would have to be desired by international markets. The Association also noted that limitation of genetic modification would lead to injection of capital and skill resources by overseas investors looking to exploit a "GM-free" environment as a production base.

Royal Forest and Bird Protection Society, Marlborough Branch [IP40] identified that New Zealand could have a global economic advantage from maintaining "GE-free" agricultural and horticultural crops. Canterbury Commercial Organics Group [IP65] also supported the view that New Zealand would have a more secure, sustainable and successful future as a "GM-free" nation and could take advantage of expanding export opportunities in the organic sector. Te Runanga o Ngai Tahu [IP41] commented that New Zealand's future as an organic producer cannot coexist with genetically modified products.

Soil and Health Association [IP97] expressed the opinion that a ban on genetic engineering would protect the health and safety and the future of New Zealand's agricultural economy. Similarly, Organic Product Exporters Group [IP53] commented that a moratorium on genetic modification would allow the opportunity to clarify risks and possible benefits that might arise from the commercial use of genetic modification.

Primary sector outcomes

MIA [IP32] expressed the view that if restrictions were placed on genetic modification technology then New Zealand's meat sector of the economy would contract. Crop and Food Research [IP4] also identified that a "substantial" reduction in market opportunities would result from avoidance of genetic modification technology. Wool Board [IP30] commented that a prohibition on genetic modification would reduce options for the sheep industry. Similarly, Dairy Board [IP67] commented that a totally organic strategy would not preserve the export income earned by the New Zealand dairy industry.

New Zealand Grocery Marketers Association [IP54] commented that restrictions on genetic modification would result in denial of consumer choice, breaching of international obligations and loss of economic benefits including competitiveness and economic vitality of industry. Similarly, New Zealand Vice Chancellors

Committee [IP18] and Lincoln University [IP8] noted that there would be detrimental consequences for the economic performance of biological industries and for the quality of life in New Zealand if genetic modification technology were avoided.

Research

Research outcomes from use

Submitters identified key strategic outcomes of the **use** of genetic modification in research areas as including:

- maintenance of the global competitiveness of New Zealand universities
- increased investment in biotechnology research
- participation of New Zealand in the knowledge economy

Knowledge-based outcomes

Submissions from the universities expressed a clear view that if genetic modification were not adopted they would not be able to remain competitive in a global research and teaching market. Lincoln University [IP8] noted that genetic modification was a global research tool and modern universities could only survive in global markets if they generated and utilised new knowledge. Lincoln University commented further that it must be involved in genetic modification research and teaching "to ensure it remains globally competitive". Auckland University [IP16] agreed that if it did not adopt genetic modification technology there would be a "significant adverse effect" on the University's overall research effort and questioned whether it would be able to comply with the requirements of the Education Act 1989. Auckland University expressed the opinion that the option of allowing genetic modification within "an appropriate regulatory regime" was the only option that would be consistent with New Zealand participating in the "knowledge economy".

Rural Women New Zealand [IP52] supported the views expressed by universities that through supporting genetic modification research New Zealand could maintain its position in the international knowledge economy. Institute of Molecular BioSciences [IP15] also noted that New Zealand must ensure that it was not left behind in the new "knowledge revolution". NZBA [IP47] identified the need for a clear policy on genetic modification so that research funding authorities could create clear and open opportunities for research investment.

Research outcomes from avoidance

Submitters identified key strategic outcomes of the **avoidance** of genetic modification in research areas as including:

- genetic modification research and teaching at New Zealand universities becoming outdated
- New Zealand's medical research capability being crippled.

Knowledge-based outcomes

AgResearch [IP13] commented that if genetic modification technology were to be halted or restricted there would be serious implications for New Zealand science and wellbeing. University of Canterbury [IP7] provided the example that potential losses would be incurred by avoiding genetic modification as universities would cease to be current in their genetic modification research and teaching. Similarly, University of Otago [IP19] noted that its ability to deliver teaching and research of an internationally accepted standard would be seriously compromised if genetically modified organisms and their products were avoided. In an accompanying witness brief, the University commented further that avoidance of genetic modification was entirely incompatible with the development of a knowledge-based economy.

Biotechnology outcomes

New Zealand Transgenic Animal Users [IP45] commented that New Zealand could not afford to avoid genetic modification animal research in the future. To do so would:

> … cripple our medical research capability, negatively impact on our fledgling biotechnology industry, downgrade the quality of education in postgraduate biomedical and biotechnology programmes, and undermine our global credibility as a developed and technologically capable nation.

Culture and ethics

Cultural and ethical outcomes from use

Submitters, principally from religious, ethical and Maori organisations, identified a range of strategic outcomes from the use of genetic modification that focused around the need for establishing an ethical framework for decision-making on genetic modification and issues relating to genetic modification that were contrary to ethical or cultural beliefs or integrity.

Among these key strategic outcomes of the **use** of genetic modification in cultural and ethical areas were:

- transfer of human genes causing insult to Maori whakapapa

- impacts for Maori on whakapapa, kaitiakitanga and rangatiratanga
- licences for rights to genetics capable of being on-sold as leases
- world leadership in setting high ethical standards
- a culture fostering high-quality science and rigorous evaluation of issues
- scientific freedom within a culture of social and cultural responsibility.

Need for an ethical framework

Public Questions Committee (Methodist, Presbyterian, Churches of Christ, Quaker) [IP93] commented that New Zealand could lead the world in setting high ethical standards in genetic modification research and development. New Zealand Catholic Bishops' Conference [IP38] also identified the need for regulation of the use of genetic modification to be based on principles of ethical decision-making and noted that if regulation were too onerous in areas of low-risk application, the benefits of genetic modification might be lost to New Zealanders. Environmental Risk Management Authority [IP76] also commented on the need for a robust regulatory process that involved a reflection of community views in decision-making on genetic modification and that allowed decisions capable of the prevention of unreasonable risks. Eubios Ethics Institute [IP96] noted that genetic modification technology would eventually be used in every country and that New Zealand would have to become "bioethically mature enough to deal with the future".

HortResearch [IP5] noted that if New Zealand supported biotechnology, a culture that fostered high-quality science and rigorous evaluation of all issues, including safety, could be established. Meat New Zealand [IP31] and New Zealand Game Industry Board [IP33] commented that scientific freedom within a framework of social and cultural responsibility was a key factor for an environment in which technologies such as genetic modification could develop.

Maori issues

Te Runanga o Ngai Tahu [IP41] expressed the view that the release of genetically modified organisms into the environment was not acceptable. Ngai Tahu also noted consequences for Maori in that the development of genetically modified organisms would have an impact on whakapapa, kaitiakitanga and rangatiratanga. However, New Zealand Maori Council [IP105] identified beneficial outcomes from genetic modification; for example, the possibility of creating licences for genetic rights which can be on-sold as leases (using a similar approach as the Crown Forest Rental Trust model) and with ownership of such rights determined by the Waitangi Tribunal.

Cultural and ethical outcomes from avoidance

Submitters, principally from Maori, environmental, religious and other advocacy groups, identified a range of strategic outcomes from the avoidance of genetic modification that focused around the need to take time to establish an ethical framework for decision-making on genetic modification and issues relating to genetic modification that were contrary to ethical or cultural beliefs.

Among these key strategic outcomes of the **avoidance** of genetic modification in cultural and ethical areas were:

- avoidance of mixing of genes which is contrary to some religious beliefs
- compatibility with the Treaty of Waitangi
- right of Maori to an unmodified genetic endowment
- time for discussion of the options on genetic modification
- time for developing an agreed paradigm within which genetic modification would operate
- time for establishing ethical considerations for research applications
- avoidance of imposing the cultural and ethical views of some groups on to everyone.

Maori issues

Nga Wahine Tiaki o te Ao [IP64] commented that "positive strategic outcomes" could be derived only from the establishment of a nation that was "GM free" and considered genetic modification to be "an act of violence against tangata whenua". Maori Congress [IP103] proposed development of a "Tikanga Maori Framework of Protection" that had as a basic premise that Maori had a collective right to an undisturbed inheritance of the genetic cell line: ie, the right to an "unmodified genetic endowment". Friends of the Earth [IP78] added that avoidance of genetic modification was the only option that would be compatible with the Treaty of Waitangi.

Need time to develop an ethical framework

Environment and Conservation Organisations of New Zealand [IP101] made the point that a fully legislated moratorium on genetic modification would provide time for New Zealand to have wide-ranging discussions on genetic modification options before irreversible decisions were taken. Koanga Gardens Trust [IP72] agreed that genetic modification should not be permitted until all parties had agreed on a "paradigm" within which genetic modification should operate. Maori Congress [IP103] made a similar point, that genetic modification should be banned until a regulatory framework is in place that recognises Maori as

tangata whenua and provides them with a decisive role in the decision-making process. Similarly, SAFE (Save Animals From Exploitation) [IP85] suggested that any approvals sought for "laboratory-based research involving the genetic engineering of animals" should be subject to a system of ethical considerations such as those developed in the Netherlands. Dairy Board [IP67] made the point that the cultural and ethical views of some should not be imposed on everyone in terms of banning genetic modification.

Religious beliefs

Quaker Spiritual Ecology Group, Religious Society of Friends [IP50] expressed its concern about genetic modification on "the spiritual and ecological understanding that all life is sacred". The Group commented that New Zealand should not proceed with growing genetically modified crops because "GM mixes genes across species and kingdoms in ways that do not occur naturally".

section 3.5 |

3.

appendix 2

Outcomes of Consultation: Submissions from Interested Persons

Section contents

3.5 Statutory and regulatory processes

Introduction

The issues raised by submitters on statutory and regulatory processes for genetic modification in New Zealand were provided in responses to two similar Warrant items, Warrant item (2) and Warrant item (n). As a result, the responses to these two Warrant items have been combined into one section of this report.

The Warrant under item (2) called for information on:

> 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

and Warrant item (n) called for information on:

> 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

Submitters were invited to respond to Warrant item (n) by providing information on whether the current statutory and regulatory processes in New Zealand were adequate to address the outcomes for genetic modification that the submitter desired to see. Submitters also responded to the Warrant item by commenting on whether any legislative, regulatory, policy or other changes were needed to achieve the strategic outcomes for genetic modification that the submitter considered desirable.

Context

The information below provides a context for the reader on the legislative, policy, regulatory and institutional arrangements for genetic modification in New Zealand. This commentary provides a brief summary of the current arrangements: the complexity of the statutory and regulatory processes is too detailed to be fully set out within this analysis of submissions, but is discussed in greater detail in Appendix 1.

Legislative context

New Zealand's statutory and regulatory legislative context for genetic modification and environmental protection from risks associated with genetically modified organisms currently comprises two key pieces of legislation: the Hazardous Substances and New Organisms (HSNO) Act 1996 and the Biosecurity Act 1993. The HSNO Act is the main tool for management of potential adverse effects of genetically modified organisms and has as its purpose 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". The Biosecurity Act provides legislation for the exclusion, eradication and effective management of pests and unwanted organisms.

There are also other enactments and associated regulations that deal with aspects of genetically modified organisms or genetically modified products, such as the Medicines Act 1981, Food Act 1981, Resource Management Act 1991, Environment Act 1986, Health Act 1956, New Zealand Public Health and Disability Act 2000, Animal Remedies Act 1967 and Stock Foods Act 1946 (soon to be replaced by the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997), Consumer Guarantees Act 1993, Fair Trading Act 1986, and other laws relating to conservation, environmental protection and intellectual property.

Policy context

The Ministry for the Environment is responsible for policy in relation to the HSNO Act. The Ministry of Agriculture and Forestry has policy responsibilities in the area of development and approval of health standards for organisms imported into New Zealand, including new organisms requiring containment. The Parliamentary Commissioner for the Environment has policy responsibility in reviewing and providing advice on the allocation, use and protection of natural and physical resources. In addition, the Ministry of Health provides policy relating to food and health matters relating to genetic modification.

Regulatory context

The key regulatory mechanisms that relate to genetic modification in New Zealand include:

- **Food regulation**; administered under the Food Act and regulations, Australia New Zealand Joint Food Standards Treaty, Consumer Guarantees and Fair Trading Acts and the HSNO Act.
- **Human therapies regulation**; administered under the Medicines Act and the HSNO Act.

- **Environmental protection regulation**; administered under the HSNO Act, the Biosecurity Act, the Resource Management Act and conservation legislation.
- **Veterinary, medicines and animal feed regulation**; administered under the HSNO Act, Animal Remedies Act and Stock Foods Act (ACVM Act).
- **Intellectual and cultural property issue regulation**; administered under the Patents Act 1953 and the Plant Variety Rights Act 1987.

International relations regulations and agreements are administered under the Foreign Affairs Act 1988, Convention on Biological Diversity, World Trade Organization (WTO) agreements, Codex Alimentarius Commission, Food and Agriculture Organization of the United Nations (FAO), World Health Organization (WHO) and Closer Economic Relations ((CER), an umbrella term for bilateral trade and economic relationships with Australia, including the Australia New Zealand Closer Economic Relations Trade Agreement (ANZCERTA) and other agreements).

Institutional arrangements

The key agencies that are responsible for approvals, administration and compliance relating to genetic modification in New Zealand include:

- **Ministry for the Environment** is responsible for policy advice to the Minister for the Environment on all aspects of environmental administration. Ministry for the Environment administers the HSNO Act and monitors the Environmental Risk Management Authority.
- **Environmental Risk Management Authority** (ERMA) derives its powers from the HSNO Act and has as its main functions: to make decisions on applications for new organisms to be developed or field-tested in containment, imported into containment, or released into New Zealand, monitor compliance with the HSNO Act, promote public awareness of adverse effects of hazardous substances or new organisms, advise on the effectiveness of the HSNO Act and inquire into accidents and emergencies.
- **Institutional Biological Safety Committees** (IBSCs) are located within scientific institutions and can be delegated powers by ERMA in relation to low-risk, genetically modified organisms.
- **Ministry of Agriculture and Forestry** (MAF) has inspectors appointed under the Biosecurity Act who audit the operation of field tests and containment facilities approved under HSNO legislation. MAF's Biosecurity Authority is also responsible for coordinating the New Zealand Government's biosecurity programme.

- **Ministry of Health** is responsible under the Biosecurity Act and the HSNO Act for the protection of human health from the adverse effects of certain organisms, and under the Health Act and New Zealand Public Health and Disability Act for public health.
- Other enforcement agencies that have obligations under the HSNO Act include the Occupational Safety and Health Service (OSH) and local government bodies.

How submitters responded to the Warrant items

Many submitters provided similar comments across the two Warrant items, with some making cross-references to material contained in either one Warrant item or the other.

Submitters often did not differentiate clearly between changes sought to legislation, regulation, policy or institutional arrangements. As a result, and given that similar issues were raised across the categories, a 'key issues' approach has been adopted for discussion of the main themes arising from these two Warrant items. A large proportion of submitters' comments on statutory and regulatory processes focused on the HSNO Act rather than on other legislation relating to genetic modification.

Many submitters did not make the connection between "strategic outcomes" for genetic modification (Warrant item (m)) and their response to Warrant item (n). Although submitters provided in-depth commentary on the adequacy of existing statutory and regulatory processes and suggested changes to improve their operation, those changes, in most instances, were not linked to the strategic outcomes that they had identified as their wish for future application or avoidance of genetic modification in New Zealand. As a result, much of the commentary under Warrant item (n) related directly to how the existing statutory and regulatory system was operating and how it might be improved.

Profile of submitters

Fifty-six submitters provided substantial comment on changes to the existing legislative and regulatory system (Warrant item (2)). Of this group of submitters, just over half (31 submitters) were from the economic/productive sector; the remaining submitters were from the environment (seven submitters), cultural and ethics (four submitters), health (two submitters) and other (12 submitters) sectors. Of the 56 submitters, a breakdown of industry groupings showed submitters were principally from industry networks/associations (18 submitters), followed by research organisations (14 submitters), advocacy networks/associations (six submitters), and private companies (six submitters).

In terms of the stance taken on genetic modification, this group of 56 submitters was particularly polarised in favour of genetic modification, with 41 of the 56 submitters supporting genetic modification (either being 'strongly for' or 'tending to be for' genetic modification) and only 13 against genetic modification (either 'tending to be against' or 'strongly against' genetic modification). As a result, the commentary in this section of the report is particularly representative of supporters of genetic modification.

Slightly more submitters provided substantial comment on Warrant item (n), with 62 submitters commenting on the adequacy of existing statutory and regulatory issues and what changes might be required to address strategic outcomes. The breakdown in terms of principal sector focus and stance of submitter for this Warrant item was similar to Warrant item (2) above. Just over half of the submitters (33 out of 62) were from the economic/productive sector; the remaining submitters were from the environment (seven submitters), health (five submitters), cultural and ethics (five submitters) and other (12 submitters) sectors. The breakdown of industry sector for Warrant item (n) was also similar to Warrant item (2) above, with submitters principally coming from industry networks/associations (17 submitters), research organisations (12 submitters), advocacy networks/associations (11 submitters), private companies (six submitters) and Maori organisations (four submitters).

With respect to stance on genetic modification, this group of 62 submitters was also particularly polarised in favour of genetic modification, with 43 of the 62 submitters supporting genetic modification (either being 'strongly for' or 'tending to be for' genetic modification) and only 16 against genetic modification (either 'tending to be against' or 'strongly against' genetic modification).

Key themes

The key themes identified in this section of the report include:

- adequacy of the current statutory and regulatory processes
- changes sought by submitters to the current statutory and regulatory system
- key issues raised by submitters in relation to statutory and regulatory changes, including:
    - international consistency
    - features of a good regulatory framework
    - interrelationship between the HSNO Act and other legislation
    - HSNO Act principles, concepts and definitions
    - costs
    - decision-making

compliance and monitoring
risk assessment
discretionary powers
regulation of low-risk, contained experiments
regulation of genetically modified food
Maori views
role of ERMA
policy framework
new organisational/institutional mechanisms.

Adequacy of statutory and regulatory processes

Comments on the adequacy of the existing statutory and regulatory processes controlling genetic modification technology in New Zealand were categorised according to submitters' overall views on adequacy of the framework, profiles of the submitters holding contrasting views on adequacy or inadequacy, and their evaluation of the strengths and weaknesses of the existing statutory and regulatory system.

Views on the current framework

Submitters' views on the adequacy of the current statutory and regulatory system for genetic modification were coded where this was possible. The table below provides a breakdown of the views of submitters on adequacy of the statutory and regulatory processes.

Table 3.1 shows that the submitters who commented on this issue were evenly split between considering the current system to be adequate (39 submitters or 46%) and considering that the current system was not adequate (39 submitters or 46%). Only one submitter considered the system to be inadequate and require complete renewal. The category termed "no position" was used where submitters specifically stated that they did not have a position on whether or not the current statutory and regulatory system was adequate or required change.

Of the submitters who believed that the current system was adequate, the vast majority of submitters (35 submitters or 41%) considered that there could be some improvement made to the statutory and regulatory system, with only four submitters considering that no improvement was needed.

Of those who believed the current system was not adequate, 10 submitters (12%) considered that only minor change was needed to the current system, with one-

third of the submitters (28 submitters) arguing for major change to the system, and only one submitter seeking a complete renewal of the current statutory and regulatory system. In summary, 49 submitters (58%) considered that the current system was adequate or required only minor improvement to achieve adequacy.

Profiling the views on adequacy

Profile of those who thought the system was "adequate"

Submitters who considered the existing statutory and regulatory system to be adequate tended to be supporters of genetic modification, principally from the economic/productive sector and from industry networks/associations, research, advocacy or private organisations.

Looking at the stance on genetic modification taken by the 39 submitters who considered the system to be adequate, 35 were in favour of genetic modification and only four were against. In terms of sector groupings, submitters were primarily from the economic/productive sector (22 submitters) and the health sector (six submitters). In terms of industry groupings, submitters tended to be from industry networks/associations (13 submitters), research organisations (seven submitters), advocacy groups (six submitters) and private organisations (four submitters).

Table 3.1 Submitters' positions on adequacy of current statutory and regulatory processes

Position	Number of submitters	(%)
Adequate — no improvement required	4	5
Adequate — but could be improved	35	41
Needs minor improvement to be made adequate	10	12
Needs major improvement to be made adequate	28	33
Inadequate — complete renewal required	1	1
No position	7	8
Total number of submitters who commented on the issue	85	100

Profile of those who thought the system was "inadequate"

Alternatively, submitters who did not consider the existing statutory and regulatory system to be adequate included an almost even balance of submitters who supported genetic modification and those who opposed it. This group of 39 submitters was principally from the economic sector and was more widespread in terms of industry type.

With respect to stance on genetic modification, 20 of the 39 submitters were supporters of genetic modification, 17 were opposed to genetic modification and two submitters were neither 'for' nor 'against'. In terms of the principal sector focus of these submitters, the main groupings came from the economic sector (19 submitters), environment sector (six submitters) and cultural and ethics sector (four submitters). Industry groupings were concentrated around industry networks/ associations (nine submitters), research organisations (eight submitters), advocacy groups (eight submitters) and private companies (two submitters). Of the submitters who considered that the system was inadequate, more submitters (28) considered that it needed major improvement than those who considered only minor improvements were required (10 submitters).

Strengths and weaknesses of the statutory and regulatory system

General support for the current system

A range of submitters expressed comments reflecting general support for the current statutory and regulatory system. Meat Industry Association of New Zealand [IP32] commented, "the system provided by the HSNO and ERMA is entirely adequate to deal with the issues surrounding the release of GM plants and animals for use within New Zealand". New Zealand Life Sciences Network [IP24] identified that there was "no fundamental problems with existing legislation" and Carter Holt Harvey/Fletcher Challenge Forests [IP17] considered it to be "a logical approach to regulating biotechnology in New Zealand". Similarly, Federated Farmers of New Zealand [IP34] registered its support for "the status quo" and New Zealand Forest Industries Council [IP9] and Landcare Research [IP12] also noted their support for the current system. However, relatively few submitters considered the existing statutory and regulatory framework to be totally adequate and not require any change.

Strengths of the current system

Several submitters identified specific attributes of the current statutory and regulatory system that they considered should be retained. National Testing Centre [IP44] commented that the current statutory and regulatory processes

involving genetic modification "in treatment for inherited metabolic diseases are well controlled under legislation" and Genesis Research and Development [IP11] noted that the regulations in place for drugs and vaccines "have been effective". Specific strengths of the current system identified by Landcare Research [IP12] included:

- a comprehensive risk-based framework
- a case-by-case approach to decision-making which balances risks and benefits
- a transparent framework for public consultation and decision-making.

New Zealand Wool Board [IP30] identified that the HSNO Act was relatively new and was of the opinion that "fundamental change is not yet appropriate".

Limitations of the current system

Other submitters considered the current system to be adequate but were conditional in their support, or recognised some limitations within the system. Lincoln University [IP8], for example, commented that existing legislation and regulatory provisions for "the containment of modified programmes are generally acceptable, but, unfortunately, apply to all genetically modified organisms whether they impose a risk or not". Similarly, Crop and Food Research [IP4] noted its conditional support for the existing regulatory system, stating that no major changes to the current regulatory system were necessary, provided they were implemented in a way "in which all parties have confidence and where compliance costs are not excessive compared to the risks involved".

Limitations of the current statutory and regulatory system most commonly cited by submitters included:

- Transaction costs associated with ERMA approvals are too high (33 submitters).
- The current system over-regulates genetic modification (31 submitters): or, the system under-regulates genetic modification (14 submitters).
- New Zealand's system of regulation is not consistent with its international trading partners (16 submitters) or with international agreements (nine submitters).
- The current system acts as a barrier to investment in genetic modification research in New Zealand (12 submitters).
- The current system fails to protect intellectual property (five submitters).
- The system provides too little recognition for those opposed to genetic modification (four submitters).

- The system should not permit genetic modification for ethical, spiritual and cultural reasons (three submitters).

Other limitations of the current statutory and regulatory system mentioned by one or two submitters included systems, implementation and process issues, including the need for:

- clarification of legislative responsibilities, particularly where genetically modified products fall under several jurisdictions
- stronger regulation of genetically modified food
- less restriction on low-risk experimentation
- better treatment of ethical issues within the system and the development of an ethical framework
- recognition and better treatment of Maori concerns in decision-making
- improvement in approval processes
- more research on genetic modification
- more monitoring.

The matters identified above are discussed in more detail in the key issues section.

Changes sought by submitters to the current statutory and regulatory system

The following section provides examples of the nature of changes submitters put forward and summarises some of the key changes sought by submitters to the statutory and regulatory system. Most comments related to the principal legislation that affects genetic modification in New Zealand, the HSNO Act.

Nature of changes sought

Submitters proposed a broad range of changes to the HSNO Act. The quotes below indicate the types of changes sought by submitters. University of Otago [IP19] and New Zealand Biotechnology Association (NZBA) [IP47] recommended a wide range of changes to the HSNO Act, which were similar in nature. The nature of these changes tended to focus on reducing the level of regulation for low-risk, contained experiments. University of Otago recommended the following revisions:

- applications to develop genetically modified organisms in containment to be assessed on a project rather than an organism basis

- projects involving the development of demonstrably low-risk organisms requiring PC1 containment to be exempted from needing prior approval for appropriately certified laboratories; retrospective notification to ERMA
- assessment of projects involving development of genetically modified organisms under laboratory containment to be delegated to institutions with appropriate IBSCs
- ERMA to establish a panel of experts to advise IBSCs on the assessment of projects involving the development of higher-risk organisms in containment
- genetically modified organisms to be imported into approved containment facilities to be treated in the same way as equivalent organisms that are developed in containment

ERMA [IP76] recommended a raft of changes to the HSNO Act, many of which were also put forward by other submitters. These changes also focused on setting the level of regulation to more closely match the level of risk involved. ERMA suggested the need for:

- ability to set policies/determinations that provide guidance on applications on types of genetically modified organisms
- risk-based differentiation between containment types
- more discretion over public notification
- controls on releases, but notification only of low-risk genetically modified organisms
- changing definition of a new organism from species to type
- clarifying the assessment of risks for containment applications
- making MAF a HSNO enforcement agency
- clarifying coverage of human cell use
- providing a clear interface with companion legislation.

Changes sought to HSNO legislation and regulatory processes

The main problems with the HSNO Act identified by submitters included:

- Clearer definition is needed for the terms "new organism", "hazardous" and "precautionary approach".
- The Act is overly rigorous and restrictive for low-risk experimentation.
- The Act and regulations are overly prescriptive in nature.
- Compliance costs are high.
- ERMA, under the HSNO Act, lacks discretionary powers.

- The Act differs from most modern legislation as it does not specify outcomes.
- The HSNO Act and ERMA create a regulatory environment that has a negative impact on research.
- The level of information disclosure is too high.
- The Act is not consistent with the legislative systems of countries with which New Zealand trades.
- The Act needs a more balanced approach to decision-making.
- Treaty issues need to be better provided for in the Act.

In addition to identifying problems, submitters also provided suggestions for improving the legislation. Some of the most common improvements are listed in Table 3.2.

Table 3.2 Improvements to legislation suggested by submitters

Improvement	Number of submitters
Allow greater procedural discretion	18
Increase consistency with trading partners	17
Provide more stringent labelling of genetically modified food and genetically modified organisms	13
New organisational/institutional mechanisms	13
Expand legislation to include social, economic and ethical issues	12
Ban all genetically modified food and crops	10
Increase compatibility with international obligations	7
Clarify principles, concepts and definitions	7
Increase prescription of procedures	5

Submitters also provided suggestions for improvements to regulatory processes. The most common improvements are detailed in Table 3.3.

The proposed improvements to legislative and regulatory processes, as well as the problems identified above, are discussed in context according to the key issues framework set out below.

Key issues raised by submitters in relation to statutory and regulatory changes

The following section adopts a 'key issues' approach to identify where submitters considered problems existed within the current statutory and regulatory system and where they thought change was required. In most instances, the discussion

Table 3.3 Improvements to regulatory processes suggested by submitters

Improvement	Number of submitters
Establish controls commensurate with risk	30
Delegate oversight of low-risk, laboratory-contained experiments	23
Delegate oversight of contained laboratory experiments	16
Increase public consultation and participation	13
New organisational/institutional mechanisms	12
Allow industry to undertake regulation	9
Allow self-regulation through peer review process	8
Case-by-case assessment	7
Decrease public consultation and participation	6
Improve protection of information and intellectual property	5
Increase consultation and participation of Maori	4

relates to the operation of the HSNO Act, as this was the legislative framework on which submitters tended to focus.

International consistency

Submitters raised a range of key issues in relation to international consistency associated with the statutory and regulatory process, including:

- the need for greater consistency with trading partners
- the need for greater consistency with international obligations and reciprocal rights
- lessons New Zealand could learn from other regulatory systems.

Consistency with trading partners

Seventeen submitters noted the need for increased consistency of New Zealand's legislation with that of its key trading partners.

University of Canterbury [IP7] remarked that "regulation of low risk work in New Zealand is out of line with other countries". The University commented further that it "is possible to identify low-risk organisms … and regulate [them] simply by containment". The main difference identified with the New Zealand approval process was that it was more stringent for low-risk, contained genetic modification experiments. University of Auckland [IP16] suggested:

> HSNO should be amended to manage and monitor low risk GMOs that are not intended for release into the environment in a manner which is comparable to regulatory controls in Australia, North America and the European Union. This could be achieved by minor modifications to the HSNO Act.

Aventis CropScience [IP14] also identified that New Zealand's field-trial process was not in line with approaches in the United States, Canada and Australia in terms of costs and process. Similarly, New Zealand Vice Chancellors Committee [IP18], Institute of Molecular BioSciences, Massey University [IP15] and University of Auckland [IP16] all identified that New Zealand's approval process was not consistent with the regulatory controls in Australia, United States and Europe. AgResearch [IP13] commented that if the current framework was not changed "there is a serious risk that New Zealand will be at a competitive disadvantage compared with the other major countries engaged in genetic research and development".

Consistency with international obligations and reciprocal rights

Seven submitters commented on the need for consistency with existing international obligations. Haemophilia Foundation of New Zealand [IP48] and

Diabetes Youth New Zealand [IP60] said that New Zealand's legal framework should be compatible with international obligations. These two organisations specifically referred to the need for genetic modification legislation to be "compatible with the Ottawa Charter", which requires that countries do their best to ensure people have access to appropriate health care.

New Zealand Institute of Patent Attorneys [IP71] expressed concern that disclosure of "confidential data about genetic modification and/or genetically modified organisms" supplied as part of the approval process "may negate future patentability of the genetically modified invention for which regulatory approval is sought". The Institute commented further that, because adequate protection was not provided for confidential information, the HSNO Act was not in line with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). Te Runanga o Ngai Tahu [IP41] also raised concerns relating to international agreements in respect to patenting of life forms. Te Runanga recommended a review of the provisions of international agreements such TRIPS and General Agreement on Tariffs and Trade (GATT).

New Zealand Arable-Food Industry Council [IP56] commented that there was no recognition for genetic modification testing in other countries and noted "reciprocal agreements do not exist".

Lessons from other regulatory systems

Several submitters, including Meat New Zealand (MNZ) [IP31], Malaghan Institute of Medical Research [IP10], Institute of Patent Attorneys [IP71], Aventis CropScience [IP14], NZBA [IP47] and University of Canterbury [IP7] made the point that the HSNO Act needed to be revised to take into account current "international best practice".

Submitters described how systems were operating in other countries and suggested how these models could be useful in the New Zealand situation. Such models included:

- Australia's Gene Technology Bill 2000
- Swiss regulatory model
- United Kingdom's GMO Regulations 2000.

Institute of Molecular BioSciences [IP15] identified that "all PC1 experiments in Australia no longer require approval by GMAC, the Australian Genetic Modifications Approval Committee" and these types of experiments "are retrospectively notified on an annual basis". Hamilton City Council [IP20] and DuPont New Zealand [IP1] both noted support for the regulatory approach put forward in Australia's Gene Technology Bill 2000.

University of Canterbury [IP7] advocated the adoption of the Swiss regulatory model, noting that the Swiss Government adopted "sensible and workable containment standards and dismissed the approach legislated by HSNO to evaluate low risk work in containment, or the import or organisms into containment". Malaghan Institute [IP10] favoured changes to the HSNO Act and regulations "based on the recently released UK GMO Regulations 2000".

Submitters compared New Zealand's regulatory system with overseas systems and identified differences. Crop and Food Research [IP4] noted that "the timeline for different types of release in this country has lagged behind that in other countries and the moratorium is causing it to lag further". AgResearch [IP13] noted that New Zealand's legal framework provided for a high level of public input compared with other regulatory systems. AgResearch stated:

> It is notable that few, if any, countries who are active in gene technology provide such wide and open opportunities for public hearings in relation to research and development activities not involving release to the environment.

Royal Society of New Zealand [IP77a (biological sciences)] expressed the view that the existing legislation compromised the competitiveness of New Zealand scientists, noting:

> The legislation in its present form makes unreasonable demands on research workers, in terms of both time and cost, and seriously compromises the ability of New Zealand scientists to work in this internationally competitive field. The introduction of the HSNO legislation has resulted in a regulatory regime in New Zealand that, largely unwittingly, threatens both the international competitiveness of New Zealand science and the ability of New Zealand scientists to undertake international collaborative research.

Features of a good regulatory framework

Submitters identified key components that they considered would help make a good regulatory framework for genetic modification based on the operation of the current regime.

Aventis CropScience [IP14] wished to see a regulatory framework and a decision-making process which was "science driven, transparent, less complicated, working efficiently to a predictable time schedule, with clear responsibilities to deliver decisions, and which is internationally compatible". Aventis CropScience also noted the need for "flexibility within the regulatory framework" so that it could "adapt to rapid technological developments". DuPont [IP1] wished to see a process that was "scientifically impeccable", provided a "strong and effective" regime, and was "robustly administered".

Federation of Maori Authorities (FoMA) [IP69] suggested that a comprehensive regulatory framework was required because of the uncertainty surrounding the implications and consequences arising from biotechnology. The Federation noted that harmonisation of New Zealand's regulatory framework with its international equivalents in regards to the introduction of new organisms would prevent New Zealand from being identified "as an easy target among the international community for high-risk and potentially disastrous biotechnological research, development and practice" or "too stringent an environment to undertake biotechnological research, development and practice".

Diabetes Youth [IP60] desired a regulatory environment that "that does not pose unnecessary burdens of cost or proof that could stifle medical research, or reduce access to new medicines".

Lysosomal Diseases New Zealand [IP99] requested that regulations should be "sufficiently light-touch to maximise the potential benefits but robust enough to protect the public". Lincoln University [IP8] considered that the regulations were "too restrictive for low risk non-field release bacterial genetic modification research".

Monsanto New Zealand [IP6] noted that if New Zealand proceeded to embrace genetic modification it might find that the current regulatory process would be "a significant barrier to investment". Monsanto advocated "the need for a credible regulatory process that controls the development and release of genetically modified organisms" and for Government to provide a stable and secure operating environment for commercial investors.

New Zealand Feed Manufacturers Association/Poultry Industry Association of New Zealand/Egg Producers Federation of New Zealand [IP35] made the point that "potential applications go through too many regulatory bodies".

Interrelationship between the HSNO Act and other legislation

Submitters commented on the interrelationship between the HSNO Act and other legislation. They raised:

- issues around duplication of legislative control
- issues involving related legislation

Duplication of legislative control

Researched Medicines Industry Association of New Zealand (RMI) [IP55] identified duplication of legislative control where the Medicines Act and the HSNO Act both apply to medicines that contain live genetically modified

organisms. The Researched Medicines Industry Association stated:

> … medicines that contain live GMOs — for example, vaccines — are subject to control under the HSNO Act and must receive approval from ERMA to be developed or imported, in addition to control under the medicines legislation and Ministry of Health approval.

RMI considered this to be unnecessary and a duplication of effort in terms of information, application and compliance costs and monitoring by two different agencies. On behalf of the pharmaceutical industry in New Zealand, the Association stated that it "seeks consistency such that no medicinal product that is the outcome of biotechnology and contains a GMO is required to be subject to the HSNO regulatory framework". Lysosomal Diseases [IP99] agreed that there was a duplication of approvals required for medicines under the Medicines Act and the HSNO Act, and sought "a separation of risk assessment for medicines and other products" so that such duplication did not occur.

Related legislation

Submitters identified legislation, other than the HSNO Act, that affected the control of genetic modification in New Zealand. MNZ [IP31] and New Zealand Game Industry Board (NZGIB) [IP33] commented that existing regulations "such as the Medicines Act, Animal Products Act, Biosecurity Act, Animal Remedies [Act] and [Agricultural Compounds and] Veterinary Medicines [Act] provide for assessing and monitoring a range of products" that had the potential to be genetically modified.

Federated Farmers [IP34] pointed out that it was "essential to recognise that the HSNO Act and the decision-making responsibilities of ERMA form one pillar of the set of risk management legislation in place in New Zealand". It noted that New Zealand had in place "a comprehensive set of legislation for managing risks to human health, food safety, the environment, primary production, and animal welfare". Furthermore, Federated Farmers expressed the opinion that "many of the future risks associated with new organisms developed by genetic modification are manageable through existing legislation", namely the HSNO Act, Biosecurity Act, Animal Products Act 1999, ACVM Act, Food Act, Resource Management Act and Animal Welfare Act.

Institute of Patent Attorneys [IP71] identified the need for an "upgrade of the Plant Variety Rights Act". Friends of the Earth (New Zealand) [IP78] expressed the opinion that the New Zealand Bill of Rights 1990 "would need to be amended" in the area of provisions relating to the right not to be "subjected to medical or scientific experimentation without consent".

HSNO principles, concepts and definitions

Submitters raised a range of key issues in relation to principles, concepts and definitions in the HSNO Act, including:

- the need to define and adopt a precautionary approach
- the need to define the term "organism"
- the need to define the terms "field test" and "development".

Precautionary approach

Most commentary on definitions focused on the need to clarify and define the precautionary approach in the HSNO Act.

Several submitters wished to see the "precautionary principle" adopted into the HSNO Act. Organics sector groups also sought a precautionary approach. Bio Dynamic Farming and Gardening Association in New Zealand [IP61] commented in an accompanying witness brief that "the precautionary principle … must be adhered to" and Canterbury Commonsense Organics Group [IP65] noted that "adoption of the precautionary principle is the only logical approach in a scenario where so much is at stake". Golden Bay Organic Employment and Education Trust [IP104] commented that the "precautionary principle must become the law regarding all testing, trials, and releases of any genetically engineered substances and organisms". Other submitters, such as Safe Food Campaign [IP86] also supported New Zealand adopting a precautionary or "no regrets" approach.

Landcare Research [IP12] expressed the desire to "include clarification, in statute and regulations of when and how to use the Precautionary Principle of the Rio Declaration vis-a-vis using the precautionary approach of s 7 [(Part II) section 7] of the HSNO Act". New Zealand Dairy Board [IP67] also identified that "the operation of the precautionary approach mandated by Section 7 should be clarified". Similarly, Forest Industries Council [IP9] supported clarification of the precautionary approach to genetic modification, noting:

> We advocate clarification of current regulations with respect to the interpretation of the precautionary principle. Specifically, we request that the regulatory framework not be allowed to adopt the extreme and unrealistic position that interprets this principle to mean only activities with a complete absence of risk are acceptable.

Greenpeace New Zealand [IP82] sought "implementation of the Precautionary Principle according to the United Nations Cartagena Protocol on Biosafety", under which New Zealand would "ban the deliberate release into the environment of genetically modified organisms … for the purposes of both field trials and commercial release [and] the importation for food processing, human or animal

consumption of living modified organisms … that if released … could germinate and replicate".

Definition of the term "organism"

Several submitters, including New Zealand Transgenic Animal Users [IP45] and Royal Society [IP77a (biological sciences)], noted the need for clarification in the use of the term "organism" in the HSNO Act. Royal Society was concerned with the term "new organism" applying to all classes of genetically modified organisms, regardless of the risks posed to the environment, and including the products of "standard recombination experiments". Transgenic Animal Users [IP45] identified a particular concern that "the cells of higher animals are considered to be organisms" under the HSNO Act.

Definition of the terms "field test" and "development"

AgResearch [IP13] commented on the need to clarify the terms "field test" and "development" within the HSNO Act, stating:

> HSNO sets out different criteria for the assessment of applications for the development of a new organism and applications for the field testing of a new organism" … AgResearch considers it very important that the definitions of field test and development should be clarified to ensure the proper intent of the legislation is applied.

Other proposed changes to HSNO Act

Thirty-three submitters suggested a range of other key changes to the HSNO Act (many of which are discussed in other sections), including:

- the need to prohibit certain genetic modification activities
- the need to include Treaty issues in the HSNO Act

Prohibition of certain genetic modification activities

Submitters from environmental organisations wanted legislation that would prohibit certain genetic modification activities. Royal Forest and Bird Protection Society of New Zealand [IP79] and Green Party of Aotearoa/New Zealand [IP83] wanted legislation that would prohibit release into the environment and field testing of genetically modified organisms. Friends of the Earth [IP78] sought "the immediate and total ban by legislation … of all genetically modified food or food derived from genetic modification".

Transgenic Animal Users [IP45] considered that the legislation had a negative impact on genetically modified animal research, and commented:

> … the HSNO Act, and its interpretation by ERMA, has created a regulatory environment that has a strongly negative impact on GM animal research in this country. This is particularly apparent when applications to import or develop a GM mouse in laboratory

> containment conditions are required to fulfil similar regulatory demands as a large animal or GM crop trials.

Inclusion of Treaty issues in the HSNO Act

AgResearch [IP13] also noted problems relating to incorporation of Treaty issues in the HSNO Act. AgResearch commented that "the implementation of section 6(d) and section 8" relating to the Treaty "has proven difficult" and considered it to be the responsibility for the Crown and Maori "to provide authoritative guidance on the resolution of Treaty related issues".

Costs

Submitters raised a range of key issues in relation to costs associated with the statutory and regulatory process, including:

- the need to reduce HSNO Act approval costs
- the need to reduce HSNO Act compliance costs
- effects of costs on research
- effects of costs on investment
- who should pay the costs associated with risk assessment.

HSNO Act approval costs

A common theme identified by submitters was the need to reduce the costs associated with applications for genetic modification activities under the HSNO Act. Thirty-three submitters commented that transaction costs were too high for applicants within the current statutory and regulatory system. These submitters were principally from industry networks/associations and research organisations in the economic/productive sector. They were also strongly in favour of genetic modification, with 30 of the 33 submitters taking a 'strongly for' stance on genetic modification. Twenty-five submitters specifically referred to the need to reduce the costs of the ERMA regulatory approval process. An opposing view was expressed by Maori Congress [IP103], which wished to see the costs of applications increased and a deposit provided for a security bond to cover future liability.

Monsanto [IP6] commented that the legislation needed to be modified to reduce the cost of approvals. Monsanto provided an example of the cost of an approval application in New Zealand, stating:

> Monsanto's first attempt to evaluate a GMO in New Zealand concerned a Roundup-Ready wheat cultivar. The application reached the stage where it was ready for public consultation. To that point we paid ERMA $47,944.86 plus GST. The government contributed a further $50,000. … This was for permission to conduct one trial measuring

> 32 metres by 22 metres. Colleagues in the USA indicate that a similar approval for a GMO trial in their country would incur fees of around $US15.

Vice Chancellors Committee [IP18] expressed the opinion that approval costs needed to reflect the degree of risk involved with the activity and considered that costs were too high where the application was for a low-risk genetic modification activity. The Committee noted:

> Compliance, entry and approval costs must be appropriate for the degree of risk involved. Low risk GM organisms which are contained and not intended for release currently attract excessive compliance costs and delays in approval.

HSNO Act compliance costs

Federated Farmers [IP34] commented that the HSNO Act "should be amended to make it more cost effective and user friendly". Similarly, Lincoln University [IP8] expressed the opinion that consideration should be given "to a reduction in compliance costs for low risk non-field release research". Wool Board [IP30] also noted "it is important that costs are minimised and that New Zealand is not disadvantaged compared with our competitors".

Malaghan Institute [IP10] agreed that costs associated with HSNO were too high, and commented:

> The statutory and regulatory processes controlling GM, GMOs and products in New Zealand are imposing unnecessary costs, time delays and restrictions on scientific laboratory-based research and so are restricting desirable strategic outcomes. Legislative and regulatory changes are essential if we are to achieve the full benefits of a knowledge-based economy that embraces GM technologies.

University of Otago [IP19] remarked that "compliance costs … associated with current statutory and regulatory processes are excessive compared to what is necessary to assure safety" and were "inhibiting research". Biotenz [IP25] also made the comment that "there can be diminishing returns for safety as compliance costs increase".

Effects of costs on research

Twelve submitters, including several universities, considered that high transaction costs were acting as a barrier to research investment. University of Otago [IP19] commented that compliance costs are "inhibiting research involving the use of genetic modification in containment" and noted that this was interfering with the University's ability to carry out internationally competitive research, training and development of intellectual property.

Another university, University of Auckland [IP16], expressed concern about compliance costs and the impact on research. It stated: "The approval process has

substantially increased the compliance costs to investigators and the University of Auckland and led to delays in research programmes." NZBA [IP47] agreed that failure to change the current "substantial" compliance costs would, over time, "seriously erode the international competitiveness of New Zealand science".

Effects of costs on investment

Arable-Food Industry Council [IP56] considered that "compliance costs … are too high" and, as a result, "do not encourage investment in GM in New Zealand". Monsanto [IP6] was of a similar opinion, commenting that "the costs relating to the introduction of GMOs to New Zealand are likely to act as a barrier to the trialling of GM crops, and accordingly as a barrier to investment in agricultural biotechnology".

Biotenz [IP25] expressed the view that "the cost of complying with current regulations discourages small enterprises from innovating in this field" and believed that biotechnology development was becoming "concentrated in the hands of those who can afford it". Monsanto [IP6] made the point that "for any commercial or research-based organisation, cost considerations are of prime importance".

Costs associated with risk assessment

University of Canterbury [IP7] commented that it was "inappropriate that regulatory agencies, eg ERMA, should have the financial incentive of charging for risk assessments". Federated Farmers [IP34] advocated that Government should cover a "substantial share of assessment costs where there is an element of public good" involved. The issue of high costs incurred with the re-testing of products "which have already been declared safe by other overseas regulatory bodies" was raised by Feed Manufacturers Association/Poultry Industry Association/Egg Producers Federation [IP35].

Decision-making

Submitters raised a range of key issues in relation to decision-making associated with the statutory and regulatory process, including:

- levels of public consultation and participation in the process, with some parties wanting higher levels of participation and others wanting less
- timing of public input into decision-making
- the need for protection of confidential information and intellectual property
- inclusion of social, economic and ethical issues in decision-making
- inclusion of Maori concerns in decision-making

- the need for an ethical framework for decision-making
- the need for balanced decision-making.

Levels of public consultation and participation

Thirteen submitters made the point that there should be greater public consultation and/or participation opportunities in the regulatory approval process. Nelson GE Free Awareness Group [IP100] commented that "public consultation processes should be made fair and accessible" and believed that a public referendum was required on genetic modification. Anglican Church in Aotearoa New Zealand and Polynesia [IP42] stated that it urged "the Commission to recommend strategic interventions which will ensure the rights of the people and encourage a high level of communal participation in the process".

However, not all submitters considered that there should be increased consultation and participation in the regulatory approval process. Six submitters commented on the need to limit public involvement in the approval process or adjust the timing of when public input takes place. AgResearch [IP13] noted that "public participation can be a significant cost to an applicant and there is a need for a reasonable balance". AgResearch considered that public participation "may be appropriate for release applications" but submitted that the nature of public involvement "should primarily involve written submissions to ERMA".

Aventis CropScience [IP14] questioned the added value of public hearings, commenting that they had been used "as a sounding board for non-scientific, generalist objections to the technology which are unrelated to the field trials under assessment".

Timing of public input into decision-making

Monsanto [IP6] questioned "the appropriateness of public input" at the early evaluative stage of an application where there was no commitment that the project would proceed. It suggested that a more appropriate time for public scrutiny would be "when the applicant has determined to proceed with commercialisation of the project". Monsanto commented further that ERMA needed to make it clear that the role of the public "is not to adjudicate on the issue of GMOs" but "to consider trial applications objectively".

AgResearch [IP13] expressed the opinion that "unwarranted delays can compromise the commercialisation of research". Federated Farmers [IP34] made the point that "iwi consultation should be made subject to statutory timeframes" to reduce delays in the approval process.

Protection of confidential information and intellectual property

Five submitters expressed views on the need for improved protection of information and intellectual property in the regulatory approval process. Submitters noted concern that having to provide information in the regulatory approval process under the HSNO Act can cause difficulties in establishing intellectual property rights. Monsanto [IP6] was of the view that "its intellectual property may not be secure in the current regulatory environment". Similarly, HortResearch [IP5] identified some "serious" intellectual property problems relating to information disclosure and intellectual property. HortResearch exemplified some of these issues in the comment:

> The obligation to prepare and maintain a public register of GMOs results in a number of serious intellectual property problems. The problems with this approach include 1) revealing the strategy of the research long before protection can be achieved, 2) the way in which a public register compromises the ability to protect information, 3) in light of 1) and 2) the conflict between the prescriptive nature of the application process as interpreted by the regulatory body and the ability to subsequently patent.

Similarly, AgResearch [IP13] remarked that although the HSNO system was trying to balance the need for public participation and confidentiality, at present confidentiality was not being achieved. AgResearch stated:

> The HSNO process attempts to balance public participation and access to information with the need for applicants to protect commercially sensitive information. In the experience of AgResearch the current balance makes it impossible to preserve confidentiality of research direction.

AgCarm [IP29] suggested that a "data protection provision in the HSNO Act, similar to that for hazardous substances or as similar as possible to section 45 of the Australian Gene Technology Bill 2000" would assist in the protection of approval information. AgCarm also commented on the need for a protocol to be developed for handling releases of information from HSNO Act approvals under the Official Information Act 1982, so that guidelines could set out "the type of information that may be kept confidential as of right".

Inclusion of social, economic and ethical issues in decision-making

Twelve submitters commented on the need to expand HSNO legislation to take explicit account of social, economic and ethical considerations. Seven submitters, including three church organisations, commented on the need to expand the

matters that ERMA considers to include social, economic and/or ethical issues.

ERMA [IP76] admitted that the current regulatory framework was unable to address "the 'big picture' ethical issues relating to such matters as unnatural creation, human cloning, genetic screening, and scientists 'playing God'" and noted that there needed to be a broader approach to "balancing up of spiritual beliefs and scientific endeavour". Sustainable Futures Trust [IP51] and Interchurch Commission on Genetic Engineering [IP49] agreed that ERMA needed to give more consideration to ethical issues. Interchurch Commission also wished to see "very clear guidelines available to researchers as to what matters must be considered". New Zealand National Commission for UNESCO [IP90] recognised there was a need for "public and specialist education in … ethical considerations of situations created by genetic technology".

Wrightson [IP3] commented that "ERMA's terms of reference should be widened to take into account social and economic issues" as it considered ERMA's core role of determining applications "should be to weigh benefit against risk".

Inclusion of Maori concerns in decision-making

Te Runanga o Ngai Tahu [IP41] criticised the HSNO Act for the lack of provision for Maori concerns. An example of this concern was provided in section 8 of the HSNO Act, which requires persons exercising functions only to "take into account the principles of the Treaty of Waitangi". This standard "has allowed iwi concerns to be virtually ignored", despite the fact that "among those principles are 'consultation' and 'active protection'". As a result, Te Runanga considered ERMA's decision-making process did not "adequately reflect the concerns of iwi".

Te Runanga o Ngai Tahu noted that the Resource Management Act set a higher standard as it specified the need to "recognise and provide for" iwi concerns. Te Runanga therefore recommended a review of tangata whenua provisions under HSNO and, as a minimum standard, to "recognise and provide for" tangata whenua concerns.

Ethical framework for decision-making

New Zealand Catholic Bishops' Conference [IP38] identified the need for "a framework of ethical principles … in relation to the use of genetic modification" and considered that "all regulation and decision-making processes should be based on these principles". The Conference also noted that any ethical framework must fully integrate the principles of the Treaty of Waitangi. WAI 262 claimants, Ngati Wai, Ngati Kuri, Te Rarawa [IP89] referred the Commission to principles and the Code of Ethics developed by an international non-governmental organisation, International Society of Ethnobiologists (ISE), for accessing plant, genetic resources and benefit-sharing.

On a similar note, both Anglican Church [IP42] and Interchurch Commission [IP49] advocated that an "Ethics Council" be established for genetic modification. Anglican Church submitted that, in addition to an Ethics Council, "Principles for Corporate Responsibility" should be defined "in the field of genetic engineering and modification", and provided an example of such principles known as "the Bench Mark Project". The Church suggested that any "Ethics Council would be bound to utilise guidelines or principles which may be adopted from the recommendations of the Royal Commission". Interchurch Commission [IP49] suggested setting up a "GM Ethics Council" that "would produce guidelines, have a regulatory role in reviewing proposals … and would provide an advisory role". National Commission for UNESCO [IP90] made the point that the Ministry of Health was currently reviewing the National Standards for Ethics Committees.

Catholic Bishops' Conference [IP38] also gave some examples of genetic modification technology that it found ethically unacceptable, noting that "the use of germ-line therapy should be prohibited for a defined period of time [and] the use of genetic modification for purposes of "enhancement" should be specifically prohibited".

Balanced decision-making

Wool Board [IP30] advocated a "balanced approach" to risks and benefits in the regulatory process and made comparisons with the provisions of the Commerce Act 1986 and the Resource Management Act. The Board also noted that it would be useful for the regulatory regime to identify "what can be done 'as of right' … without prior approval".

Compliance and monitoring

Submitters raised the key issue of the need for increased monitoring in relation to compliance and monitoring regulatory issues.

Level of monitoring

Submitters commented on the need for improved monitoring within the regulatory process. Arable-Food Industry Council [IP56] noted that "approval, monitoring and subsequent control" were "not always transparent". Greenpeace [IP82] also identified the need for "strict monitoring and liability measures to protect our GE free environment". Public Questions Committee (Methodist, Presbyterian, Churches of Christ, Quaker) [IP93] remarked that there was also a need for Government to "rigorously monitor the monitors" and "not delegate sweeping decision-making powers to committees of experts".

Organic Products Exporters Group (OPEG) [IP53] commented on the need for monitoring what happened elsewhere to allow informed decision-making in New Zealand. It recommended "a greater level of resource to be targeted towards the monitoring, analysis and reporting of international trends and issues in this area by independent agencies".

Risk assessment

Submitters raised a range of key statutory and regulatory issues in relation to risk assessment, including:

- the need to establish controls commensurate with risk
- problems with the current risk management regime
- the need to balance risks and benefits
- the basis for risk assessment and management models.

Establish controls commensurate with risk

Thirty submitters commented on the need for controls to reflect the level of risk involved. Wool Board [IP30] submitted that there "should be a relationship between the level of risk … and the level of regulatory control". New Zealand Forest Research Institute [IP2] also put forward the idea that "New Zealand should define risk classes based on scientific evidence, and adopt such an approach for field trials of low risk modifications". AgResearch [IP13] noted its support for "a legislative and policy regime which ensures any risks … are managed in a scientifically responsible and credible manner".

HortResearch [IP5] also considered that "the current regulations for getting approval to work on genetically engineered organisms are prescriptive and do not correlate particularly well with the degree of risk posed by the research". ERMA [IP76] commented that there "is merit in grouping GMO types and/or types of applications on the basis of common risk characteristics".

Association of Crown Research Institutes (ACRI) [IP22] remarked that current practices waste resources and intellectual capacity as researchers "go through repetitive cycles of applications for GMO development work, basically for the same risk class of organism". ACRI suggested a "release under controls" category should be available where extra requirements on genetically modified releases would lower risks.

AgResearch [IP13] suggested re-evaluating the HSNO risk management regime "to ensure approval processes are focused on identifying and managing actual risk with potentially serious harm to human health or the environment". It also recommended "greater emphasis on responsible self regulation and internal risk management protocols and systems subject to independent review and audit" and

that "risk assessment obligations and processes are scientifically based and are not intermingled with broader policy issues".

Current risk management regime

University of Auckland [IP16] commented that the "HSNO legislation is unduly prescriptive leading to containment requirements that are inconsistent with the real environmental risk of those organisms". The University also noted: "Research has been delayed while facilities have been upgraded to containment levels which do not match the environmental risk associated with the organism." AgResearch [IP13] agreed that some HSNO Act regulations were "overly prescriptive".

AgResearch also expressed the view that "ERMA's risk assessment process is not clear" with respect to what information was required from applicants, how that information linked to the decision-making criteria in the HSNO Act and how non-scientific risk was to be assessed. Dairy Board [IP67] noted that "a clear distinction should be drawn, in the risk assessment processes, between: (i) scientific risks … and (ii) cultural, social, or ethical concerns".

NZBA [IP47] identified that risk procedures were already in place in New Zealand laboratories and that the Australia/NZ Standard 2243.3 "Safety in Laboratories" was adopted. The Association noted that this standard had four risk categories and that the system was "used worldwide … for determining containment standards for GMOs". However, the Association remarked that, in New Zealand, ERMA's rules were stricter because applications for organisms in the "PC1" category required approval, which was not the case in the United Kingdom, Australia or United States.

University of Canterbury [IP7] commented that "sound evidence" already existed "that the regulations do not increase safety in New Zealand" and noted that "ERMA uncovered over 150 contained GE experiments that escaped risk assessment but, in review, they were found to be safe". Nelson GE Free Awareness Group [IP100] expressed the opinion that there was a need to strengthen ERMA's risk management process. Friends of the Earth [IP78] sought "an immediate review of all GM medicines currently in use" and a "halt to the further development of GM medicines without proper research and controls".

HortResearch [IP5] expressed concern that the current system did not allow controls to be placed on the release of a new organism; thus "any application to release a genetically modified organism … from containment (or to import a genetically modified organism for release) must therefore cover the full range of risks caused by all potential uses of the organism". University of Canterbury [IP7] also provided commentary on the differing levels of risk between the introduction of an organism into a contained facility and introducing an organism

into the environment, and stated:

> The introduction of an organism into a contained facility in New Zealand (or the generation of a new organism in such a facility) is **not** the same as introducing the organism into New Zealand, since the very purpose of containment is to ensure that it is **not** so introduced.

Balancing risks and benefits

Federated Farmers [IP34] noted the need to balance risk to consumers and producers with the ability of scientists and producers to produce new technology without cost constraints. Federated Farmers stated:

> The legislative and regulatory framework for assessing genetically modified organisms needs to balance assurances to consumers and producers that scientific development is being undertaken with appropriate caution about possible consequences, with the need for scientists and producers to be able to develop and adopt safe, effective new technology without unnecessary and costly constraints.

Lysosomal Diseases [IP99] commented: "An approach based on excessive caution will cost investment, opportunities, careers, health status, and lives". AgResearch [IP13] also made the point that the current legislation "creates compliance costs and levels of uncertainty in interpretation and practice which result in the benefits being diminished".

Basis for risk assessment and management models

Canterbury Commercial Organics Group [IP65] questioned the overall approach to risk assessment and expressed the opinion that risk assessment models "must evolve from principles and concepts of biological and ecological systematics" rather than being based on "mechanistic, input-output, dose-response toxicological models".

Federated Farmers [IP34] suggested that the "optimal regulatory model", known as the "Swedavia model", which had been adopted for "management of risks, including biosecurity, agricultural compounds and veterinary medicines, and food safety risks" should be used in risk assessment for genetic modification. Federated Farmers pointed out that, under this model, organisations undertaking no-risk or low-risk genetic modification research would be approved "if they met standards set by the policy ministry". Life Sciences Network [IP24] agreed that the Swedavia-McGregor model of risk management, which it noted was also used by Civil Aviation Authority, "is appropriate for consideration of the scientific, environmental and agricultural risk management issues".

Forest Research Institute [IP2] made the point that risk analysis should be focused "on the product rather than the process used to make a product" and that

future legislation should ensure that risk assessment is conducted independently of process. Arable-Food Industry Council [IP56] noted also that genetic modification risk assessment should be scientific and that political considerations should not become involved in the process.

Discretionary powers

Eighteen submitters raised a range of key regulatory issues in relation to allowing greater discretion under the HSNO Act, including:

- the need for greater discretion under the HSNO Act
- the need for responsible self-regulation.

HSNO Act restriction versus discretion

Transgenic Animal Users Group [IP45], NZGIB [IP33] and NZBA [IP47] were all of the opinion that current HSNO legislation was unnecessarily restrictive, particularly for genetically modified organisms in containment. NZBA noted that this "puts New Zealand biotechnology at a competitive disadvantage".

Institute of Molecular BioSciences [IP15] also noted that the HSNO Act was particularly restrictive in relation to low-risk, contained genetic modification experiments. The Institute stated:

> The HSNO Act does not allow ERMA the discretion of delegating to IBSCs the authority to import into containment low risk GMOs. IBSCs however are able to approve, on behalf of ERMA, the development of the same GMOs in containment. This is a major inconsistency in the Act that should be amended.

Self-regulation

NZGIB [IP33] expressed the opinion that there should be "greater emphasis on responsible self regulation and internal risk management protocols and systems subject to independent review and audit". Federated Farmers [IP34] also commented that the "control of field trials and commercial release can be done through risk management programmes". New Zealand Agritech [IP73] sought a lower level of regulation, recommending that the HSNO Act and ERMA be changed so that scientific institutions could carry out work in specific areas of research with appropriate codes or guidelines.

Regulation of low-risk, contained experiments

Submitters raised a range of key issues in relation to regulation of low-risk, contained experiments associated with the statutory and regulatory process including:

- the need for regulatory change for low-risk, contained experiments

- the need for delegation of low-risk, contained experiments
- the strictness of New Zealand's system for low-risk, contained experiments compared with overseas systems
- the need to remove low-risk, contained experiments from requiring ERMA approval
- use of the physical containment risk categorisation system.

Regulatory change for low-risk contained experiments

A cross-section of submitters identified the need for change in legislation in the area of low-risk containment, including submitters not from the research sector or particularly in favour of genetic modification. ZESPRI International [IP46], for example, commented that "low risk GM experimentation in controlled laboratories should be facilitated by appropriate changes". Rural Women New Zealand [IP52] noted that there was a need to "streamline approvals for low risk research [and] provide for post release monitoring and control". University of Canterbury [IP7] made the point that current regulations for low-risk work "introduce high compliance costs".

Wool Board [IP30] concurred that regulations for low-risk laboratory research needed change and commented:

> There is presently too great a level of inflexibility and control in relation to low-risk laboratory research and, at the other end of the scale, little capacity to control organisms once they are approved for general release.

Malaghan Institute [IP10] identified some of the key problems submitters raised in relation to low-risk, contained experiments, namely the need for international consistency and regulation at the physical-containment level rather than at organism level. The Institute stated:

> Changes to the HSNO Act 1996 and its Regulations of 1998 are required in the area of low risk GM to bring New Zealand into line with international best practice and to ensure that the detail of the regulatory requirements are commensurate with the risk involved. We recommend that low risk developments be regulated by the level of physical containment and not by the description of the organism. A single regulatory body and process for the importation and development of low risk organisms is urgently required to minimise duplication, avoid unnecessary costs and reduce prolonged delays without altering risk.

Institute of Molecular BioSciences [IP15] also put forward a range of recommendations for the regulation of low-risk, laboratory-based, genetic modification research. (A number of these recommendations have been raised by other submitters and are discussed in the following sections.) The Institute's

recommendations included:

> Oversight of all low-risk laboratory-based GM research … [should] continue to be delegated to [Institutional] Biological Safety Committees (IBSCs).
>
> Approvals should be project-based.
>
> Approvals for low risk GMO developments should be retrospective by an annual notification process.
>
> A national expert group should be formed to advise IBSCs on higher risk … applications.
>
> The HSNO Act and Regulations should be modified to give ERMA the discretion to modify application forms, schedules and assessment processes to more efficiently manage risks associated with GM research in New Zealand.

Delegation of authority for low-risk, contained experiments

Twenty-three submitters expressed the need for some form of delegation by ERMA of responsibility for regulation of low-risk, laboratory-contained experiments involving genetic modification. Sixteen submitters commented that regulatory authority over experiments in contained laboratories should be delegated. Most of these submitters considered that the current regulatory process was overly restrictive for "low-risk", genetic modification experiments that were conducted in contained laboratories and suggested that this regulation should be delegated to IBSCs or similar bodies. Maori Congress [IP103] put forward an opposing view, noting that ERMA's discretion to delegate authority to internal IBSCs should be removed.

New Zealand Organisation for Rare Diseases [IP98] commented that "low risk genetic research should be delegated to institutions to manage via institutional biological safety committees". Similarly, Lysosomal Diseases [IP99] noted that "risk management should be the responsibility of those engaged in the work, under local control … [including] delegation to bio-safety committees". New Zealand Association of Scientists (NZAS) [IP92] suggested that "all laboratory-based GM research conducted under physical containment be delegated to approved institutional authorities". Dairy Board [IP67] also agreed that "direct responsibility for observance of the prescribed conditions" for low-risk experiments should be delegated to IBSCs and suggested ERMA should be given "an overall supervisory function".

Genesis [IP11] submitted that "experiments with low-risk GMOs performed in authorised containment facilities are safe and do not pose a risk to the environment" and sought "amendment of ERMA regulations for development of low risk GMOs in a laboratory". Genesis suggested a more workable approach would be to "focus on research programmes and the appropriate use, accreditation and maintenance

of containment facilities where GMOs are used". University of Otago [IP19] agreed that low-risk, contained experiments were safe and commented:

> The experience of … 25 years of [international] laboratory-based research has shown no evidence of risk to human health or the environment from contained research using GMOs — indeed, we are not aware of even a single documented incident of an adverse effect of such a GMO on human health or the environment.

New Zealand's system for low-risk, contained experiments

Several submitters, including Genesis [IP11] and University of Canterbury [IP7], commented that New Zealand had a very strict regulatory system for low-risk, contained experiments compared with those operating in other countries. University of Canterbury expressed the opinion that New Zealand's stringent regime was resulting in "serious disincentives to essential biological research with no evidence of improved safety". Genesis commented that "New Zealand has one of the strictest regulation processes for the development of low-risk GMOs in containment" and suggested that regulations for low-risk experiments involving genetically modified organisms in contained laboratories be reviewed because they had "proven to be cumbersome and an undue burden to scientists".

University of Canterbury [IP7] remarked that New Zealand's approach to regulation of low-risk genetic modification differed from that of other countries, as New Zealand focused on regulation at an organism level rather than at a containment level. The University stated:

> The regulation of low risk work in New Zealand on an organism-by-organism basis is out of line with other countries (where regulation at the generic level of containment is the norm). If containment facilities are adequate, the risks to the environment and health of low-risk GE are negligible. … To our knowledge, no ecological hazard has ever been reported to emerge from experiments conducted in containment anywhere in the world.

Low-risk, contained experiments and ERMA approval

Submitters commented that low-risk, genetic modification experiments carried out under physical containment should not require an approval from ERMA. NZAS [IP92] suggested that "all low risk category GM developments carried out under physical containment be exempt from formal application" and instead should be "monitored by an annual registration process".

University of Auckland [IP16] also proposed that "all low risk Category A experiments be exempt from the current approval process". The University suggested that the "importation of low risk GMOs into approved facilities should require a single import permit issued by the Ministry of Agriculture and Forestry, and no longer require application to ERMA".

Similarly, Life Sciences Network [IP24] identified that "low or no risk experiments are subjected to a highly complicated approval process" and suggested that organisations should be "free to undertake no or low risk GM research within an ERMA approved risk management plan". Forest Research Institute [IP2] noted "many developed countries have adopted a notification system for low risk contained field trials of transgenic organisms". Life Sciences Network [IP24] referred to "the inability of ERMA to exercise an appropriate level of discretion on whether or not to notify applications thereby creating a perception the proposed activity is risky".

Use of the physical containment risk categorisation system

Submitters, including Royal Society [IP77a (biological sciences)] and the University of Otago [IP19] commented that the existing system was overly restrictive for low-risk, genetic modification research. Royal Society noted four different types of risk associated with distinct aspects to regulation of genetic modification research — "contained laboratory experiments, contained field testing, partially controlled field testing, full-scale environmental release" — and recommended that these distinctions should be taken into account in the regulatory process. University of Otago [IP19] and NZBA [IP47] also noted that the physical containment risk categorisation system is used internationally and that in some countries activities meeting PC1 criteria do not require approvals. The University stated:

> This Risk Group categorisation system is used world-wide … for determining containment standards for GMOs. However in the United Kingdom, Australia and the USA, developments of GMOs that clearly meet PC1 criteria are exempted from requiring approval for development …

Forest Research Institute [IP2] also identified that the practice in most developed countries "concentrates on specific containment classes attributed to a laboratory" that enabled "any development work related to all organisms belonging to that risk class to occur in that laboratory". The Institute suggested that "New Zealand should adopt such an approach". Similarly, University of Canterbury [IP7] submitted that it was "unnecessary and highly damaging to regulate the importation and manipulation of low-risk organisms in containment by regulation at the level of the individual organism, rather than by controlling at the generic level of containment". ACRI [IP22] agreed that there was a need to focus on the safety of the facility in which the research was conducted.

University of Auckland [IP16] noted that "there has been no review of the approved host/vector systems, categorisation of Category A and Category B experiments and levels of containment" within the HSNO regulatory framework.

The University was also of the opinion that "all low risk Category A experiments" should be exempt from the current approval process.

Regulation of genetically modified food

Submitters identified a range of statutory and regulatory key issues in relation to genetically modified food. They raised:

- the need for greater labelling of genetically modified products
- issues of food labelling
- the need to remove exemptions to ANZFA food labelling
- the need for greater testing of genetically modified foods
- issues of liability and patenting associated with genetically modified foods
- the need for regulatory changes for food safety.

Labelling of genetically modified products

Thirteen submitters expressed comments around the need for more stringent labelling of genetically modified foods and genetically modified products. Submitters who expressed views on this issue tended to be from organic or environmental groups.

New Zealand Veterinary Association [IP28] 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". New Zealand Vegetable and Potato Growers' Federation/New Zealand Fruitgrowers' Federation/New Zealand Berryfruit Growers' Federation [IP75], in reference to genetically modified plants, noted the need for "labelling of seeds, nursery stock and other propagative material with their GM status".

The need for mandatory labelling of goods having genetically modified contents was a view expressed by National Beekeepers Association of New Zealand, Poverty Bay Branch [IP62], New Zealand Jewish Community [IP80], Canterbury Commercial Organics Group [IP65] and Bio Dynamic Farming and Gardening Association [IP61]. Maori Congress [IP103] also sought mandatory labelling on all products, medicines and foods containing genetically modified materials.

Quaker Spiritual Ecology Group, Religious Society of Friends [IP50] recommended legislation that kept New Zealand free from genetically modified crops and supported a complete ban on genetically modified food and food products. However, the Group noted that if genetically modified food and food products were not banned there "must be legislation to require complete labelling of all such products" and "infringements must carry penalties".

Food labelling issues

Green Party [IP83] commented that genetically modified foods "should not be accepted for sale in New Zealand" or, if that proved impossible, such foods "must go through a safety testing programme similar to that for pharmaceuticals and be fully labelled". Bio Dynamic Farming and Gardening Association [IP61] also noted the need "to prove safety beyond reasonable doubt for the release of products such as food". Interchurch Commission [IP49] expressed the need for ANZFA regulations on release of genetically modified foods "to ensure respect is shown to cultural diversity" and noted that labelling needed to reflect that.

Pesticide Action Network New Zealand [IP87] suggested the labelling of genetically modified food should be more stringent. Nelson GE Free Awareness Group [IP100] voiced a stronger opinion on food labelling, stating that the "refusal to allow credible labelling … [indicated] overt manipulation of the regulatory processes".

Exemptions to ANZFA food labelling

Green Party [IP83] commented: "All exemptions in the current ANZFA labelling system should be phased out over the next two years so that the labelling system is comprehensive." Canterbury Commercial Organics Group [IP65] detailed the nature of its food labelling concerns, stating that it wanted "mandatory labelling, without exception, of all foods that contain any material derived from GE sources, without a 'May Contain' option and without a '1% accidental content" allowance'".

Testing of genetically modified foods

Pesticide Action Network [IP87] expressed the need for "much more stringent testing for GE food and crops". Safe Food Campaign [IP86] noted that it wanted "production, importation and development of 'safe foods'", and defined such foods as not containing pesticides, not irradiated, not from animals fed antibiotics or hormones, not factory farmed, not containing additives and not the result of genetic modification. At the extreme, Nelson GE Free Awareness Group [IP100] wished to see "a complete ban on all imported foods".

Environment and Conservation Organisations of New Zealand (ECO) [IP102] requested that ANZFA "investigate more fully the actual testing that has been done on the foods approved" and noted that United States Food and Drug Administration (FDA) testing should not be relied upon because past behaviour "calls into question the impartiality of the FDA's decisions".

New Zealand Grocery Marketers Association [IP54] noted that the management of food safety aspects of genetically modified foods should "be the responsibility of one Food Administration Agency" and "not the multiplicity of agencies that currently exists".

Liability and patenting associated with genetically modified foods

Green Party [IP83] commented that "the issue of liability for GMOs and GM food products should be addressed in legislation". Maori Congress [IP103] expressed the view that biotechnology companies should be denied the right to self-insure.

Pacific Institute of Resource Management [IP84] called on Government "to introduce a 5-year freeze on patenting in food and farming until the socio-economic and environmental impacts can be evaluated".

Regulatory changes for food safety

Nelson GE Free Awareness Group [IP100] advocated that "the New Zealand government withdraw from ANZFA policies and instigate their own regulations regarding foodstuffs" in order to protect public health, food supply and the environment. Quaker Spiritual Ecology Group [IP50] highlighted concerns with ANZFA, and believed there was a need to address ANZFA's "potentially conflicting objectives" of public health and safety versus the promotion of trade and commerce.

Dairy Board [IP67] held an opposing view, stating: "The ANZFA process for food product regulation is appropriate." New Zealand Cooperative Dairy Company [IP88] commented "there should be no change in the regulatory framework for food products". Life Sciences Network [IP24] agreed that the ANZFA process was "suitable for consideration of risks associated with food products derived from GMOs".

Royal Society [IP77b (social sciences)] also identified the need "to establish regulations to deal with the development and distribution of nutriceuticals".

Maori views

Maori submitters raised a range of statutory and regulatory key issues in relation to genetically modification, including:

- Maori views on changes to the HSNO Act
- the need for international protection of genetic rights.

Maori perspective on changes to the HSNO Act

Maori Congress [IP103] proposed a range of amendments to the HSNO Act, some of which have been discussed under other key issues. Further points made by Maori Congress included:

- Nga Kaihautu Tikanga Taiao [ERMA's Maori advisory group] should have binding recommendatory powers.

- Conducting unauthorised genetic modification work without approval should become a criminal offence carrying higher penalties.
- Unauthorised experiments should be assessed by a Hearing Committee.
- All applicants must provide risk analysis of all applications, rather than emphasis of considered benefits.
- Prescribe rigorous scientific testing on genetically modified products similar to that for medicines.
- Increase requirements to undertake risk analysis of horizontal gene transfer technology on all applications.
- Amend the principal Act should New Zealand adopt a moratorium on accepting further applications.
- Legislate for all research applications.
- Strengthen the conditions for destruction of genetically modified experiments and penalise research institutes for retaining embryos longer than a specific period.
- Cancel and then prohibit all transgenic laboratory experiments and field tests, as consistent with international declarations.

Nga Wahine Tiaki o te Ao [IP64] did not submit any recommendations for change to the HSNO Act. Rather, this submitter was of the view that the Crown and, in turn, the Commission were in breach of the Treaty of Waitangi and that all genetic modification must be stopped. Constitutional change to honour the Treaty was recommended.

International protection of genetic rights

New Zealand Maori Council [IP105] stressed the need for New Zealand to "cement solid relationships with Maori on the way development of Genetics takes place" and, in turn, such a relationship would become "part of the basis for international relationships with conditions such as that of the Singapore Treaty which keeps Treaty of Waitangi issues unaffected by the relationship". The Council recommended the Crown Forest Rental Trust model as a "blueprint". In this model, the Crown addressed "how to sell the trees, establishing a Trust to receive licence fees for the trees" while the Treaty of Waitangi addressed "the claims of ownership".

Maori Council suggested that licences for rights to genetics could be created and sold as leases to Government, Maori, corporate or private bodies. The Waitangi Tribunal would be responsible for making binding recommendations as to ownership of genetic rights. The Council saw the creation of such genetic rights as

a way that whakapapa, taiao, tikanga Maori, intellectual capacity, and flora and fauna would be protected.

Role of ERMA

Submitters raised a range of key issues in relation to the role of ERMA, including:

- the need for changes to the operation of ERMA
- the need for ERMA to be more independent
- the need for wider representation on ERMA
- the need for wider discretionary powers for ERMA
- Maori views on changes to ERMA.

Changes to the operation of the ERMA

Submitters identified a range of changes to ERMA's current operation that they thought would provide improvements to the existing system of operation, as detailed in Table 3.4.

ERMA [IP76] made the point that a significant proportion of the funding needed to support the HSNO regulatory regime without discouraging research and innovation should be borne by Government. Human Genetics Society of

Table 3.4 Changes to the operation of the Environmental Risk Management Authority (ERMA) suggested by submitters

Nature of change suggested	Number of submitters
Reduce costs	25
Increase discretion over procedures	13
Expand capacity on social, economic and ethical considerations	7
Increase independence of ERMA	5
Clarify assessment criteria and/or methods	5

Australasia, New Zealand Branch [IP59] in an accompanying witness brief commented on the need to clarify the role of ERMA, as well as that of the Standing Committee on Therapeutic Trials (SCOTT), Genetic Technology Advisory Committee (GTAC) and the National Ethics Committee. AgResearch [IP13] commented that ERMA's decision-making procedure, criteria and obligations should be consolidated in a unified statutory form. Several submitters, including Genesis [IP11], expressed their support for the operation of the ERMA field-trial regulations prior to the voluntary moratorium.

Discretionary powers

Thirteen submitters raised issues in relation to increased discretion of procedures for ERMA. Institute of Molecular BioSciences [IP15] expressed the opinion that ERMA had a "lack of discretionary powers" and consequently that the process for managing genetic modification experimentation was "inefficient and costly".

New Zealand Vice Chancellors Committee [IP18] recommended that ERMA should "have the authority to impose conditions on the release of GM organisms into the environment". NZGIB [IP33] also accepted the need for "post release conditions". Life Sciences Network [IP24] commented that ERMA should be empowered "to set post-release monitoring requirements". In addition, Vegetable and Potato Growers' Federation/Fruitgrowers' Federation/Berryfruit Growers' Federation [IP75] made the point that there was a need to extend the ERMA process "to include provision for post approval monitoring and control". Aventis CropScience [IP14] suggested "conditional approvals" could be given by ERMA, and noted that this was not done at present. Federated Farmers [IP34] also suggested that the HSNO Act could be amended to "allow ERMA to set appropriate conditions for GMOs released in to the environment". Maori Congress [IP103] expressed the view that there was a need to provide legally binding conditions on the release of genetically modified organisms.

Independence of ERMA

Five submitters commented on the need for ERMA to have increased independence. Submitters noted that ERMA needed to be independent from Government and from political changes. Forest Industries Council [IP9] and Carter Holt Harvey/Fletcher Challenge Forests [IP17] commented:

> We support the independence of ERMA from other branches of Government, as a means of maintaining both its objectivity and independence. We suggest that stronger controls be put in place to prevent political interference with ERMA, as happened with the government's recent imposition of a moratorium on field trials and field tests of biotechnology.

Monsanto [IP6] and Aventis CropScience [IP14] agreed that ERMA should be kept free of political changes. Monsanto commented that "commercial organisations cannot operate in a continuously shifting regulatory environment" and Aventis CropScience noted "the evaluation process must be reliable and not be subjected to unexpected political shifts".

Representation on ERMA

Royal Forest and Bird Protection Society, Nelson/Tasman Branch [IP43] advocated that ERMA should be "a more democratic and balanced body". ECO [IP102] was also of the opinion that ERMA and ANZFA needed a more representative membership and noted "consumers without industry or governmental affiliations need to be appointed to these boards". Comvita New Zealand [IP74] expressed the wish for ERMA to have "a recognised honey bee scientist in the panel that assesses the likely potential of visitation of GM trials by honey bees". Interchurch Commission [IP49] advocated a review of ERMA's terms of reference to ensure adequate Maori representation and adequate respect for Maori views.

Maori views on changes to ERMA

Maori Congress [IP103] commented that presently ERMA is obliged to receive and consider all applications. The Congress sought provision to enable ERMA to decline an application instantly.

Federation of Maori Authorities (FoMA) [IP69] noted its support for the current ERMA process in principle. However, it recommended the establishment of an independent non-governmental regulatory body. The Federation suggested that such a body must include:

- funding from government
- independent appointments
- participation of Maori within the independent body and of Maori in the region where the application applied
- risk/benefit analysis functions
- case-by-case determination
- full disclosure to and informed input from the public on all applications
- terms of reference to include social/cultural and economic issues
- non-prohibitive costs for application process.

FoMA also suggested a classification system for applications that included the level of genetic modification sought, distinction of inter- or intra-species genetic modification, and how the application related to plants, animals and humans.

Policy framework

Submitters mentioned a range of key changes to policy, including:

- the need for a generic policy framework
- the need for sound regulatory policy
- the need for border control policies
- the need for public information and education
- Maori views on changes to policy.

Generic policy framework

Biotenz [IP25] expressed the opinion that "New Zealand needs a policy framework that directs ERMA's applications of HSNO and ensures that issues are not continually re-litigated". AgResearch [IP13] also expressed the need for national policy direction, commenting that the HSNO Act should be amended "to provide for national policy direction on generic policy issues and/or questions that cannot be resolved by scientific risk assessment and management". ACRI [IP22] expressed the opinion that, in future, "Government should publish high level policy directives defining the risk boundaries and social acceptability" of different categories of genetic modification.

MNZ [IP31] and NZGIB [IP33] commented that "cultural, ethical and other issues involving values" should be encompassed "in the overall regulatory framework at a generic or policy level, rather than being incorporated into the specific approval process".

Regulatory policy

Aventis CropScience [IP14] commented that "public confidence results from sound regulatory policy". It considered the principles for sound regulatory policy to include "harmonisation, transparency, review, consultation".

Border control policy

Green Party [IP83] identified the need for a policy to be developed for border control of genetically modified seed, stating that currently "there is no testing for GM contamination of imported seed at the border" and that "this policy issue urgently needs to be addressed".

Public information and education

Organisation for Rare Diseases [IP98] expressed the desire for Government to "fund new initiatives of public communication". Royal Society [IP77b (social sciences)] advocated the need for an increase in "Public Good Science Funding for the evaluation of the socioeconomic impact of commercial production of

GMOs and the facilitation of consultation with key stakeholders". National Commission for UNESCO [IP90] also suggested there was a "need for public and specialist education in genetic technology".

ECO [IP102] commented: "New Zealand should adopt a policy on gene technology based on a much fuller and wider conversation with the public than has happened to date." ERMA [IP76] agreed that "an effective programme of public education" was needed, and noted that funding was required for this, as well as for investigation of issues and monitoring of effects to support regulation under the HSNO Act. Feed Manufacturers Association/Poultry Industry Association/Egg Producers Federation [IP35] identified the need "to start with regular communication with the public, using language that is understandable and simple".

Other groups commented on the need for greater information on genetic modification to be made available to the public, but for different reasons. DuPont [IP1] expressed the opinion that "as much information as possible should be made available publicly" and believed that public concerns about gene technology arose "from misinformation or alarmist exaggeration". Wrightson [IP3] considered that applications to ERMA "should be the subject of greater publicity" so that "the general public is informed about the value and safety of work involving genetic modification or GMOs in New Zealand".

Maori perspective on changes to policy

In regards to policy changes, Maori Congress [IP103] recommended a raft of changes, including "an immediate and substantive increase in research", with research areas including:

- establishment of an independent Tikanga Maori Framework of Protection
- application of the Treaty of Waitangi in all future research (in particular, using WAI 262's statement of claim)
- the ethical, moral and spiritual dimensions of tangata whenua, including the beliefs and values of all communities within New Zealand
- establishment and expansion of education and communications about genetically modified foods and products by industry and communities of interest in association with tangata whenua
- development, funding and facilitation of mechanisms for ongoing forums for information exchange between tangata whenua and communities of interest, research institutes and funding agencies.

New organisational or institutional mechanisms

Thirteen submitters raised a range of key issues in relation to new organisational structures or institutional mechanisms required, including:

- the need to separate HSNO into two separate Acts
- the need for a tiered system of consents
- the need for a mechanism for similar applications
- the need for an expert panel for high-risk applications
- issues around medical applications
- the need to retain or remove the moratorium
- the need for a Tikanga Framework of Maori Protection
- other mechanisms.

Separating HSNO into two separate Acts

Royal Society [IP77a (biological sciences)] commented that the HSNO Act "is flawed both in science and in logic". In the longer term, the Society suggested that the HSNO Act should be split into two Acts, "of which one could be specifically directed towards the problem of the control of various approaches to the genetic modification of living organisms in New Zealand and the use of the products of such modification". The split was recommended because it was "unrealistic to expect that a single, broad regulatory approach could be found to problems as diverse as laboratory-contained experiments, field testing, release of new organisms into the environment, and the safe use of hazardous chemicals on the farm and in the workplace".

Tiered system of consents

A2 Corporation [IP26] made the point that "a good consent process is important", and favoured adopting a tiered system of consents loosely modelled on the Resource Management Act, where "less contentious applications can be dealt with quickly" and the regulatory system freed up for more contentious applications.

ACRI [IP22] commented that there should be a "release under controls" category of release. Crop and Food Research [IP4] also suggested that "an intermediate step between the current field trials under containment and general release" would be beneficial.

Mechanism for similar applications

ERMA [IP76] identified a deficiency in the legislation in that there was no provision "as to how issues which are common to many applications should be dealt with" and, instead, a case-by-case approach was used.

University of Otago [IP19] also commented on problems arising from the HSNO Act where the precise nature of the genetically modified organism being developed must be described in the development application, and the reality was that "laboratory-based research usually involves the development of groups of organisms of the same general nature and risk category, but the precise nature of the genetic modification may change in light of continuing experimentation".

Expert panel for high-risk applications

NZAS [IP92] suggested that "an expert panel be established to advise on all applications to import into containment and develop GM organisms where significant risk is involved". University of Canterbury [IP7] also supported "specially established panels of informed representatives of society including ethicists, scientists, risk-assessment experts and lay-people" to undertake consultation on issues of high-risk work relating to genetic modification.

Medical applications

Human Genetics Society [IP59] noted the HSNO Act needed changing so that "medical applications of molecular cytogenetics can continue to be introduced into appropriately contained New Zealand hospital and medical diagnostic laboratories".

Moratorium

Genesis [IP11] recommended that "the voluntary moratorium on field trials be removed" and that "the controlled process in place for field trials and release into the environment, as implemented through ERMA" should remain unchanged. Federated Farmers [IP34] and New Zealand Cooperative Dairy Company [IP88] agreed that there should be no extension of the voluntary moratorium. Cooperative Dairy Company noted further that certain genetically modified plants and animals that had been developed overseas should be trialled under New Zealand conditions and that local research of pasture plants requiring field testing should be pursued. Dairy Board [IP67] specified a date for the ending of the voluntary moratorium: namely, 31 August 2001.

Several other submitters, from environmental and organics organisations, recommended that the moratorium should continue in various forms. Nelson GE Free Awareness Group [IP100] sought "an indefinite and fully legislated moratorium" on "trial crops, GE experimentation and libraries of genetic material", and also expressed concern that the current moratorium allowed exemptions. Pesticide Action Network [IP87] wished to see a "five-year moratorium on all outside GE applications" if the Commission decided "not to recommend a GE-free policy for New Zealand". Similarly, Canterbury Commercial Organics Group [IP65] requested that if the release of "GE material into the New Zealand

agricultural environment" was not banned they wished to see "a mandatory moratorium of no less than 10–15 years imposed on genetically modified plant/animal production and field trials". Pacific Institute of Resource Management [IP84] was also in support of a "moratorium on release of GMOs in New Zealand".

Tikanga Framework of Maori Protection

At the institutional level, Maori Congress [IP103] proposed a Tikanga Maori Framework of Protection based on a Maori cultural perspective that ensured:

- Tangata whenua have automatic access to all applications for assessment.
- Maori have the right to an unmodified genetic endowment; however, individuals have the right to have their genes manipulated provided they first discharge their obligations to the group and its control over whakapapa.
- The rights over the Maori genome are held collectively by Maori; this includes the right to receive benefits from its use and advance.
- Scientific and ethical considerations of Maori must prevail; Maori genome, human tissue and DNA remain in the ownership and collective control of Maori; no Maori DNA or blood samples can be used for research without full and informed knowledge of the donor.

WAI 262 claimants [IP89] also proposed a framework of protection for Maori customary and intellectual heritage rights. The claimants proposed that any framework or mechanism to protect cultural heritage rights must be flexible so that "differences and shared interests between tribes can be reflected and accommodated". WAI 262 claimants made the point that "measures are needed to protect the knowledge and resources of Maori until such legislation is in place" and that the claimants would be seeking interim recommendations from the Waitangi Tribunal. Accordingly, WAI 262 claimants urged the Commission to await the Waitangi Tribunal's findings on how such a system would work in practice.

Other mechanisms suggested by submitters

Submitters put forward suggestions for a range of other mechanisms, including:

- A referendum on genetic modification should be held (Pesticide Action Network [IP87]).
- New Zealand should legislate to create a permanent Genetic Modification Commission (National Beekeepers Association, Poverty Bay [IP62]).
- Setting up a Ministry of Biosecurity that had no "commercial interests" and dealt with policy and border control (Forest and Bird, Nelson/Tasman [IP43]).

- Three industry groups should be established to provide advice and information to ERMA and Government in relation to plants, animals and human/medical uses of genetic modification (Wrightson [IP3]).
- Quarantine facilities under the Biosecurity Act should be recognised as suitable locations to conduct research and field trials (Wrightson [IP3]).

section 3.6 |

appendix 2

Outcomes of Consultation: Submissions from Interested Persons

Section contents

3.6 Where, how, and for what purpose ...

Introduction

Warrant item (a) asked for investigation into and representation on:

> where, how, and for what purpose genetic modification, genetically modified organisms, and products are being used in New Zealand at present

Fifty-seven submitters made substantial comment on this Warrant item. Within this group, 28 submitters had economic and productive issues as their main sectoral focus. Seven had environmental issues as a principal focus and six had health issues. Most submitters were from industry associations or networks (14 submitters), research organisations (13 submitters), other advocacy networks (nine submitters) and private companies (seven submitters).

Of the 57 submitters, 41 were identified as being 'strongly for' or 'tending to be for' genetic modification; 12 were considered to be 'strongly against' or 'tending to be against'. Four were assessed as 'neither for nor against' the use of genetic modification technology.

Many submitters expressed concern about the public availability of the information specified in this Warrant item. This issue is discussed more fully in other sections (eg, sections "Statutory and regulatory processes" and "Areas of public interest: an introduction").

Submitter responses to the Warrant item provided a wide range in the level of detail. Responses indicated the following:

- The terms "where", "how" and "for what purpose" were interpreted in various ways. Submitters who were not actively involved in research or in the use or application of any genetically modified products or processes usually did not provide specific details of what was currently happening in New Zealand.
- Submitters clearly had differing levels of access to information about genetic modification activities and products.
- It was unclear whether all the examples provided by submitters related specifically to activities and uses "in New Zealand at present" (the wording

of the Warrant item). Several witnesses noted activities that had been undertaken in New Zealand in the past; they noted research or use that was based on overseas experience; or they mentioned work that was planned for the future.

- Although individual submitters cited the research that they believed was being conducted in their own organisations, no one submitter purported to provide a complete picture of all the research being undertaken in a particular industry or sector.

Responses to Warrant item (a) are described according to:

- Types of response to "where", "how", and "for what purpose"
- Uses of genetic modification technology in New Zealand
- Specific examples of use of genetic modification technology
- Extent of information on the use of genetic modification.

Types of response to 'where', 'how', and 'for what purpose'

Most submitters gave a general outline of current undertakings in their own organisations with respect to research or product development using genetic modification techniques or their perception of what was happening in their industry sector. Some submitters noted their support for other organisations' research activities. The remainder tended to express reservations about the use of genetic modification techniques.

The more detailed information about the process and overall purpose for using genetic modification was usually supplied by those organisations that were actively involved in using genetic modification processes and products. This group included several research facilities (research institutes, universities and Crown Research Institutes) and private companies. Several references to specific projects were provided.

Where genetic modification is used

Submitters variously interpreted "where" genetic modification technology was used, usually as a broad geographical location or a general industry or sector. Most submitters indicated the general industry or range or type of activity in which genetic modification, genetically modified organisms and products were employed. Relatively few submitters gave specific geographic locations where genetic modification techniques were used. Typical references included: "medical research",

in the "biological industries", in the "environment sector", "in the apple industry", "in New Zealand research institutions", "in contained field trials", "in containment laboratories and containment greenhouses" and "throughout New Zealand at various organisations".

Some submitters noted specific locations. For example, AgResearch [IP13] mentioned its main research and development sites at Ruakura, Grasslands (Palmerston North), Wallaceville, Lincoln and Invermay (Mosgiel).

How genetic modification is used

In response to "how" genetic modification technology was used, most comments came from submitters whose organisations were actively involved in using or investing in genetic modification technology. They usually gave detailed information and examples of the processes and products involved. These activities embraced basic or fundamental research and, to a lesser extent, the product from use of this technology. Many of the comments were incorporated into their comments on the purpose of use.

Typical of more detailed categorisation were the comments in a witness brief from Foundation for Research, Science and Technology (FRST) [IP21], which identified three broad areas of research: "proof of concept" studies (see below), research targeted at producing genetically modified products, and research aimed at understanding and addressing the key effects associated with genetic modification.

Purpose of genetic modification

Submitters also treated variously the notion of "for what purpose" genetic modification techniques were being used. The majority interpreted the Warrant item to mean current uses in New Zealand. Most of those submitters who had direct involvement in a particular research activity (or used products or processes using genetic modification technology) interpreted purpose to mean the sector in which the genetic modification activity occurred. They usually gave information that scoped the nature of activities undertaken.

Several provided details of a representative selection of the activities being undertaken. For example, Landcare Research [IP12] noted the use of genetic modification in possum fertility control for the purpose of solving a major environmental pest problem. Landcare Research detailed the project in an accompanying witness brief.

Submitters noting examples of specific projects in specific industry sectors gave details of work in four main areas: land-based production (including animal and plant production), environment, human health, food for human consumption. To a

lesser extent, application of this technology in veterinarian medicine and animal feed was mentioned, as well as its industrial uses.

Most organisations focused on one particular activity (for example, medical applications or horticulture). However, some organisations' research activities spanned several sectors (for example, Crown Research Institutes were involved in the agricultural production sector and also the environment sector).

Uses of genetic modification technology in New Zealand

Most submitters responded to the Warrant item's "where, how, and for what purpose" in terms of the current use of genetic modification. From information provided by submitters, the overall impression about the extent and range of activity involving genetic modification technology in New Zealand in 2000 may be summarised as follows:

- Genetic modification technology was widely used in university and other research institutions in New Zealand as an integral part of ongoing research activities.
- Genetic modification-related research had been conducted for many years.
- Many organisations (including those in the productive sector, private companies and patient advocacy groups), which did not themselves use genetic modification techniques, acknowledged that they either actively supported and/or directly benefited from research using this technology.
- "Use" included basic or fundamental research (for example, where genetic modification was used as a tool in a research process) and applied research (for example, development of a particular genetically modified product).
- Continuing use of genetic modification technology was clearly anticipated by most submitters.
- Genetic modification technology was applied in a wide range of New Zealand's productive base. Its use spanned land-based production (including horticulture, agriculture, forestry), human health applications (for research and specific products, especially vaccines), in animal welfare and animal feed, in the environment (including bioremediation, maintenance of biodiversity and pest control), as well as industrial applications.
- There was no commercial production of genetically modified food, although some food products or food ingredients imported from overseas could contain genetically modified material.

- Research being undertaken using this technology was with the express approval of Environmental Risk Management Authority (ERMA).
- Despite ERMA's requirements, unauthorised experiments had been conducted. Green Party of Aotearoa/New Zealand [IP83] identified that 15% of experiments under way in August 2000 were unauthorised.
- Submitters identified specific projects that were known to involve use of genetic modification technology. A complete list of all current projects was generally perceived to be not readily available.

Specific examples of use of genetic modification technology

Specific examples of what submitters stated was currently happening in New Zealand in the use of genetic modification technology are outlined below. Comments from 13 submitters were selected to illustrate the responses. Information from two government agencies involved in the funding and approvals for genetic modification research (FRST [IP21] and ERMA [IP78]) is outlined first. Then comments of 11 submitters from the major industry groupings (universities, Crown Research Institutes, private companies and sector organisations) illustrate a range of genetic modification uses: Carter Holt Harvey/ Fletcher Challenge Forests [IP17], Institute of Molecular BioSciences, Massey University [IP15], Crop and Food Research [IP4], AgResearch [IP13], Monsanto New Zealand [IP6], Landcare Research [IP12], University of Auckland [IP16], Malaghan Institute of Medical Research [IP10], Auckland Healthcare Services [IP91], New Zealand Grocery Marketers Association [IP54] and New Zealand Vegetable and Potato Growers' Federation/New Zealand Fruitgrowers' Federation/New Zealand Berryfruit Growers' Federation [IP75].

Examples cover four broad sectoral areas:

- land-based production (including animal and plant production)
- environment
- human health
- food for human consumption.

Some of the activities identified span more than one sector. For example, "proof of concept" research (FRST [IP21) had implications for both agriculture and the environment. Some activities involving food were in both plant research and production of food for human consumption.

Government funding and approval agencies

The activities of two government agencies involved in the funding and approvals for genetic modification research span the broad sectors identified.

Foundation for Research, Science and Technology

FRST [IP21] said that it was the primary investor in research, science and technology in New Zealand investing around $383 million on behalf of the New Zealand Government. It estimated that approximately $130–135 million (or 33–35% of the Foundation's total investment) was invested in research programmes that used or were associated with gene technology. In an accompanying witness brief, three types of research were identified:

- "Proof of concept" research. Approximately $27 million was invested in research where genetic modification and other gene technology techniques were being used as "proof of concept". Such research was aimed at extending scientific understanding and might or might not lead to genetically modified products or solutions. Examples included: the recent discovery of a gene in Inverdale sheep that causes increased fertility; use of genetic modification in research to understand the effect that a plant growth regulator or hormone has on the storage and shelf-life of vegetables.
- Research involving development of genetically modified products or solutions. Approximately $6.4 million was invested in research targeted at producing a particular genetically modified product or solution. Examples included: producing a genetically modified crop plant with increased pest resistance to improve plant performance; generating genetically modified cows with improved casein content in their milk; developing vaccines against bovine tuberculosis; and producing novel, high-value, ornamental species.
- Research aimed at understanding the issues and addressing the effects associated with genetically modified organisms. Approximately $1.4 million was invested in research in this area. Specific examples provided included: research to better understand characteristics of the target organism (eg, pollen release and movement); and research to better understand how genetic modification tools work and to develop new tools to help minimise risks (eg, vectors that do not include antibiotic resistance markers).

Environmental Risk Management Authority

ERMA [IP76] noted:

> No approvals by the Authority or by any other agency to the Authority's knowledge have been given for the release of a viable GMO. This includes current applications put before

> the Authority and approvals carried over from the previous regime. Current use of GMOs has therefore been restricted to teaching, research and developmental work carried out in containment in the main by Universities and the Crown Research Institutes.
>
> Much of the GMO development work has been in understanding the function of specific genes. Such research has been for the purposes of modelling diseases and possible treatments and for understanding the fundamental mechanisms controlling plant growth. Once the gene function has been understood attempts have been made to shift genes firstly within and then between species. This work has included the development of agronomically important characteristics in plants and the development of biopharmaceuticals.

ERMA further noted that its comments on current usage of genetic modification technologies in New Zealand were derived primarily from the applications put before it for importation or development of genetically modified organisms. However, the Authority was aware that pharmaceuticals derived from genetically modified organisms (such as insulin and hepatitis vaccine) were already in use in New Zealand.

Seven approvals by ERMA for field tests with controls are listed below, namely approvals to:

- PPL Therapeutics for the establishment of a manufacturing flock of sheep genetically modified to contain a copy of a human gene, so as to produce a biopharmaceutical in the milk of the sheep
- Crop and Food Research for genetically modified petunia for altered plant form or pigmentation, to assess field performance of the vegetative plant
- Kimihia Research Centre to evaluate agronomically important characteristics of genetically modified sugarbeets for herbicide resistance
- Pioneer New Zealand for genetically modified, herbicide-tolerant and insect-resistant maize for breeding purposes
- Crop and Food Research to evaluate resistance and yield performance of individual lines, over a five-year period, of potato cultivars genetically modified for increased resistance to bacterial soft rots and tuber moth
- AgResearch to perform large-scale fermentation of genetically modified *Escherichia coli* to obtain registration of the hydatids vaccine by the Animal Remedies Board and maintain hydatids vaccine supplies for trial and future commercial overseas markets
- Carter Holt Harvey to study factors influencing gene expression and to assess the influence of genetic modification involving the insertion of marker genes on growth and morphology of pine trees.

Land-based production uses of genetic modification

Submitters provided examples of the use of genetic modification in research directed toward land-based production. A wide range of scientific investigations included studies in forestry, symbiosis, apomixis and resistance to pests, diseases or herbicides.

Carter Holt Harvey/Fletcher Challenge Forests

Carter Holt Harvey/Fletcher Challenge Forests [IP17] noted that it did "not have commercialised applications of biotechnology in use in forestry in New Zealand at the present time". It confirmed that Carter Holt Harvey had obtained approval from ERMA in 1999 "to field test a strain of genetically modified radiata pine incorporating genetic markers". It had subsequently produced 120 such seedlings. It also noted examples of possible applications in projects to increase wood yields, improve wood quality, reduce tree damage from the exotic fungus *Dothistroma* and reduce the survival of pests.

Institute of Molecular Biosciences, Massey University

Institute of Molecular BioSciences [IP15] noted that its staff members were "engaged predominantly in basic research using recombinant DNA techniques to address a wide range of questions in biological processes". It noted eight examples of general types of research being undertaken and itemised some of the individual projects. For example, under the broad category of research into "host-microbe interactions including pathogens and symbionts", it listed project "GMO99/MU/10" as "Evaluation of dothistromin production by the pine pathogen *Dothistroma pini*".

Crop and Food Research

Crop and Food Research [IP4] noted seven areas of its research that currently used genetic modification. They were:

- modification of the biochemical pathways for carotenoids and flavonoids to introduce new colour combinations into ornamentals and improve food properties such as nutritional quality and colour
- modification of the biochemical processes of senescence to improve the shelf-life of perishable products such as vegetables and ornamentals
- introduction of new pest- and disease-resistance characters
- investigation of "apomixis", a form of asexual seed production in plants with potentially worldwide benefits for plant improvement

- production of potential pharmaceuticals in plant tissue
- improvement of genetic modification techniques through the development of new vector systems and transformation methods for crops that cannot currently be transformed.
- gene discovery within crop plant species

AgResearch

AgResearch [IP13] advised that it used three major methods of research: traditional breeding, genetic marker-assisted selection for traits and genome manipulation (which results in genetically modified animals, plants or micro-organisms that either have new gene sequences inserted or the functions of particular genes modified). It provided examples of 14 projects involving a range of organisms, genetic modification techniques and applications. The organisms used included bacteria, parasitic worms, cattle, sheep, mice, and pasture plants (ryegrass and white clover). Among the techniques identified were: gene libraries, gene isolation and functional analysis, gene deletion and gene insertion techniques in bovine cells, transgenic mouse models (micro-injection and gene targeting techniques), bacterial cloning, and gene disruption by transposon mutagenesis.

Monsanto New Zealand

Monsanto [IP6] stated that it had evaluated several projects in New Zealand and, "owing to uncertainty of future direction", put them on hold. These projects included: commercial release of 'Roundup-Ready' canola (canola that will tolerate applications of Roundup herbicide), a trial of herbicide-tolerant wheat and herbicide-tolerant radiata pine. It also noted "Monsanto-developed genetic material ... and processes (eg, promoters) are freely available to the scientific community and are in use in a number of scientific programmes."

Environment-focused use of genetic modification

Landcare Research

Landcare Research [IP12] said that it was directly undertaking or subcontracting genetic modification work to the value of $2.8 million in 2000-2001. About $2 million was for research on development of potential products derived from genetic modification for improving environmental management. It gave details of research into 12 areas: conservation genetics, DNA typing for identification and monitoring of mammal pests, whakapapa of harakeke (New Zealand flax, *Phormium tenax*), horizontal gene transfer in bacteria, origins of nitrogen-fixing rhizobia, rapid assessment of plant pathogenic bacteria, possum fertility control, stoat biocontrol, new pest control toxins, wasp control, biosensors and bioremediation. It expected its genetic modification-related work "to rise slowly as we increase our

focus on describing, understanding and protecting genetic diversity of New Zealand's flora and fauna".

Human health-related use of genetic modification

University of Auckland

University of Auckland [IP16] said "genetic modification, genetically modified organisms and products are widely used in New Zealand at present. In the University's Schools of Biological Sciences and Medicine, GM, GMOs and products derived from GMOs are being widely used for medical research." It noted that the technology is used extensively in fields such as biochemistry, clinical biochemistry, molecular biology and medicine, as well as in some areas of engineering. Some specific therapies based on genetically modified products were detailed, including erythropoietin, growth hormone, granulocyte-colony stimulating factor (G-CSF) and plasminogen activator.

Malaghan Institute of Medical Research

Malaghan Institute [IP10] also confirmed it made "extensive use of GM, GMOs and GM products to achieve the objectives of its biomedical research programmes". It recounted developmental work over the 1970s and 1980s into protein hormones, growth factors, cytokines and immuno-modulatory agents, and noted: "Today, many hundreds of recombinant proteins are available for research purposes." Various research projects at the Institute made "wide use of interleukins, ... interferons, colony-stimulating factors, peptide hormones and other recombinant immuno-modulatory proteins". In addition, the Institute said that it employed extensive use of cell lines genetically modified to produce specific cytokines and frequently imported such genetically modified organisms into containment. Over the past five years, transgenic and gene knockout mouse models had been "increasingly used ... to facilitate research into cancer, asthma, tuberculosis and multiple sclerosis".

Auckland Healthcare Services

Auckland Healthcare Services [IP91] noted that genetic modification technology was currently being used for investigation and diagnosis of genetic disorders and congenital metabolic diseases in areas such as prenatal diagnosis, diagnosis confirmation, carrier detection, predictive testing, predisposition testing, diagnosis and treatment of congenital metabolic disorders in newborn babies. Predictive testing included DNA testing of individuals who are at risk of developing a late-onset genetic disorder such as Huntingtons disease before the onset of symptoms. Congenital metabolic diseases, for which Auckland Healthcare's National Testing

Centre screened newborn babies, included the conditions of phenylketonuria (PKU), maple syrup urine disease, congenital hypothyroidism and cystic fibrosis.

Food-related use of genetic modification

New Zealand Grocery Marketers Association

Grocery Marketers Association [IP54] summarised the situation for the food processing as follows:

- Derivatives from GM crops were being used as ingredients in food processing.
- Genetic modification was also useful to food processing in the production of enzymes and additives, potentially enabling more efficient production of such micro-ingredients.
- The extent to which genetic modification was used by the industry and its different uses was not recognised or appreciated by many consumers.
- The application of genetic modification in the food processing industry extended beyond products. The technology could be used to detect pathogens, toxins and chemical contaminants, as well as degradation of quality.

The Association also gave some examples of the processed foods in which genetically modified ingredients "may be used in New Zealand". Its list included six genetically modified organisms such as forms of soybean, canola, potato and sugarbeet. Details were supplied of the ingredients, additives and processing aids that could be derived from these genetically modified crop plants. A list of the foods in which these products and processes were used was also provided. For example, information for soybean, cotton and potato is shown in Table 3.5.

Vegetable and Fruitgrowers Federations

New Zealand Vegetable and Potato Growers' Federation/New Zealand Fruitgrowers' Federation/New Zealand Berryfruit Growers' Federation [IP75] confirmed that in New Zealand "there are no genetically modified fruit or vegetables grown commercially". The Federations also stated that several trials were under way. These included: a trial to produce potato plants with genetically modified resistance to potato tuber moth; a trial to produce genetically modified resistance to alfalfa mosaic virus in peas; and a project breeding tamarillo plants with resistance to tamarillo mosaic virus. In addition, the Federations referenced HortResearch's genomics programme involving sequencing genes from apples, kiwifruit and berryfruit, including the possibility "to introduce crop improvements via smart breeding and marker assisted selection".

Table 3.5 Ingredients derived from genetically modified crops and their use in foodstuffs

GMO	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 flour carriers/diluents	cooking oils, salad dressings
	tocopherols – vitamin E	margarines and spreads, peanut butter
		confectionery, savoury snacks, infant food
Cotton	cotton seed oil	baked goods
		cooking oils
		salad dressings
		margarines
Potato	potato	soups
	potato starch	sauces, pickles and chutneys
	modified starch	confectionery
		savoury snacks

Source: Submission of New Zealand Grocery Marketers Association [IP54]

Extent of information on use of genetic modification

A few submitters noted that their organisations did not directly undertake genetic modification-related research but that they supported and benefited from such activities, or that their members were actively engaged in such activities. These submitters included Meat Industry Association of New Zealand [IP32], New Zealand Game Industry Board [IP33], Diabetes Youth New Zealand [IP60], Royal Society of New Zealand [IP77a (biological sciences)] and Lysosomal Diseases New Zealand [IP99].

A greater number of submitters expressed their concern at a lack of information on who was using this technology and for what purpose. Others were uncertain about, or against, the use of this technology. Several queried the reliability of the information on current use. This group comprised approximately a dozen submitters on this Warrant item. Specific comments included:

- "We ... are concerned that such information is not easily available" (Public Questions Committee (Methodist, Presbyterian, Churches of Christ, Quaker) [IP93]).
- "... at present GM experimentation is going on in New Zealand without public knowledge or consent" (Friends of the Earth (New Zealand) [IP78]).
- "Genetically modified food infiltrated the food supply in New Zealand with no agreement of the government or people of this country" (Pacific Institute of Resource Management [IP84]).
- "Trial crops are being grown regardless of risks, products are being imported and incorporated into unlabelled food" (Nelson GE Free Awareness Group [IP100]).
- "Maori Congress from reading the submissions to the Royal Commission has discovered that genetic modification has taken place [in a number of areas] ... The list is relentless and continues to be added to without the knowledge of Maori. ... [Biotechnology] companies have failed spectacularly in their efforts to advise us of their work. And it begs the question as to why?" (National Maori Congress [IP103]).
- "A survey of 433 members of the Association of Anglican Women has indicated a high level of uncertainty and lack of information upon which to make considered opinions." (Anglican Church in Aotearoa New Zealand and Polynesia [IP42]).

- Green Party [IP83] expressed its concerns about research being undertaken without Environmental Risk Management Authority (ERMA) approval. It noted:

> As at 16 August 2000 ERMA had approved:
>
> 39 applications to allow a genetically modified organism to be either developed in containment or imported into a contained facility. Such approvals include genetically engineered mice for medical research;
>
> 10 field trials of genetically modified organisms in containment (including three approvals for animals — goats, PPL Sheep and AgResearch cattle), several plant approvals — including sugarbeet, potatoes, petunias and maize, and one fermentation approval.
>
> Of the genetically engineered field trials granted approval before the formation of ERMA, seven are still current although several are in the post harvest monitoring stage which was a condition of their approval. These trials were for sheep, pine trees and crops.
>
> Earlier this year [2000] ERMA completed a nationwide check of 27 research facilities around New Zealand to find out what GM work was being conducted. ERMA found that of the 1065 GM experiments, 152 current experiments had not been approved and a further 39 were old work without approval where the material had since been destroyed.
>
> In short, of the current experiments then under way in New Zealand labs and research facilities, around 15% were found to be unauthorised, or illegal. The absence of monitoring or approval for these experiments raises issues around the ethics of the projects, their safety, the containment of the organisms and the intent of the scientists conducting them.

section 3.7 |

appendix 2

Outcomes of Consultation: Submissions from Interested Persons

Section contents

3.7 Evidence and uncertainty

Introduction

Warrant item (b), called for information on:

> 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

Submitter profile

Thirty-five submissions made substantial comment on this item of the Warrant. Of these, 20 submissions came from the economic/production sector. Five submissions were received from organisations in the environment sector; three from organisations in the health sector and six submissions were received from other sectors, such as governance organisations. One submission was received from an organisation with a cultural or ethical focus.

The majority of the submissions supported the use of genetic modification, genetically modified organisms and products in New Zealand. Twenty-one of the submissions making substantial comment on the Warrant item had taken an overall stance that was 'strongly for' genetic modification, with another two submissions 'tending to be for' the use of genetic modification. Only five were 'strongly against', with a further four submissions taking a stance that 'tended to be against' genetic modification. The remaining three submissions took a stance that was 'neither for nor against' genetic modification.

The majority of the submissions came from organisations with an interest in either researching genetic modification or the development or promotion of genetic techniques or genetically modified products. Five of the submissions came from private companies, some of which dealt with genetically modified products and some of which dealt with natural and organic products. Nine submissions came from industry networks or associations and six from research organisations. Seven advocacy networks and associations also made substantial comment and the remaining eight submissions came from a variety of organisations, including two from Maori organisations and two from consumer networks and associations. One organics organisation and one occupational or professional organisation each made submissions.

Content of the submissions

Some submissions discussed briefly the future uses of genetic modification. Several submissions from patient representative organisations and from other agencies working in the health sector stressed the increasing importance of the technology, particularly since completion of the human genome project. Submissions from primary sector organisations outlined the likely future uses of the technology in pastoral agriculture and cropping. Aventis CropScience [IP14] listed the genetically modified plant varieties that it intended to make available in New Zealand. The forestry industry submissions also referred to the future use of genetic technology in the production of timber and timber products.

None of the submissions, however, dealt in any length with the future uses of genetic modification. Instead, this Warrant item was used as an opportunity to express views on the level and scope of uncertainty relating to genetic modification, and, in particular, to deal with issues relating to the risks and safety of the technology. This focus on uncertainty, rather than evidence of use, may have been the result of an apparent overlap between this Warrant item and the previous Warrant item (a), which had sought information on the present use of genetic modification in New Zealand.

Key themes

Three key themes relating to uncertainty emerged from the submissions making substantial comment on this Warrant item. These were:

- the public's perception of the technology
- uncertainty about the ability to manage the risks of genetic modification
- the possible impacts of the use of genetic modification.

Public perception

Several submissions discussed the public's perception of genetic modification, genetically modified organisms and products. Irrespective of whether the submissions supported or opposed the use of genetic modification, there was agreement that the public had, in general, a negative perception of genetic modification and was uncertain whether it should be used.

Causes of public uncertainty

There was no shared common view of the cause of public uncertainty about genetic modification. Some submissions, particularly those from opponents of genetic modification, considered that the public's reluctance to accept genetic

modification was because of the risks associated with the technology. They suggested that an awareness of the inherently unpredictable nature of gene technology and the potential for widespread and irreversible adverse effects provided a justified basis for public uncertainty about the acceptability of genetic modification.

Proponents of genetic modification, and some submissions that took a more neutral stance, suggested that the public's concern about the safety of genetic modification was no different from the doubts that had been expressed in the past when a new technology was introduced. They suggested that public uncertainty would diminish with time and familiarity. Submissions from the opponents of genetic modification, however, saw no similarity between past new technologies and the development of genetic technology, which was seen as moving into areas beyond current scientific knowledge. These submissions did not, therefore, accept that public uncertainty would lessen with time: they suggested that public uncertainty could be removed only when there was adequate proof that the use of the technology would be without risk.

Several submissions suggested that public uncertainty arose from insufficient knowledge and understanding of the technology. Monsanto New Zealand [IP6], for example, suggested, "Much of public uncertainty in New Zealand arises from poor communication to the public of the science behind genetic modification and of the real and potential value of its products." Other submissions suggested that uncertainty about the technology resulted not simply from a lack of understanding of the technology but also from the difficulty the public experienced in accessing "reliable" information. In the absence of easy access to information, even people who had an understanding of the technology had insufficient information on which to make judgments about its use.

Submissions from various organisations involved in the research and development of genetic modification suggested that increasing the public's understanding and knowledge of the technology would help allay some of the public uncertainty about the use of genetic modification. The view that access to information would increase the acceptability of the technology was not shared by all the submissions. Interchurch Commission on Genetic Engineering [IP49] agreed that there was a need for more information to be made available to the public but did not agree that increased information would necessarily result in a greater public acceptance of genetic modification. Interchurch Commission suggested that uncertainty was

caused by "fear of the unknown" and by "feelings of powerlessness" and commented that there were "deep-seated and fundamental ethical concerns to be addressed with the general public" which would not necessarily be dispelled by providing additional information about the technology. Other submissions, particularly from religious and spiritual groups, confirmed this view, and some submissions from Maori groups indicated that there was considerable uncertainty about the appropriateness of using genetic modification within the Maori cultural and spiritual framework, the precepts of which amounted to a rejection of the technology.

Some submissions claimed that the public's negative perception of genetic modification and uncertainty about its safety was the result of an international political campaign against "free trade and the global marketplace", which the submission from New Zealand Life Sciences Network [IP24] suggested was based on the "calamity theory". The submission explained that this theory "postulates [the] worst-case scenario as though it were an inevitability" and therefore encouraged the public to be uncertain about the safety or appropriateness of the use of genetic modification..

Acceptable and unacceptable uses

Submissions tended to agree that, because of the current level of uncertainty, it would be difficult to determine what future uses of the technology would be acceptable to the public. Notwithstanding the general concern and uncertainty about genetic modification, some submissions suggested that the public already accepted certain uses of genetic modification. Submissions also suggested that other uses of genetic modification were unlikely ever to be acceptable.

Some uses of genetic modification that were identified as likely to be unacceptable to the public for a long period of time, such as cloning and xenotransplantations, fell outside the Warrant's ambit. Of the uses that came within the scope of the Warrant, the creation of transgenic organisms using human genes was one use that many submitters were certain would not gain public acceptability.

Several submissions also stated the belief that genetic modification in food was a use that would never be acceptable because of the long-term risk to human health. Other submissions did not go as far as to suggest that genetically modified food would never be acceptable, but did suggest that there was a general discomfort with the idea of eating modified foods knowingly. Submissions from organisations involved in the production of food, while strongly disagreeing that there was a risk to human health, acknowledged that genetically modified food was not widely acceptable to the public and that there was strong consumer resistance to its use.

Because of this, the submitters suggested New Zealand producers would be unlikely to use genetic modification in the production of foodstuffs such as meat, fruit and vegetables until there was a change in public attitudes.

Submissions also suggested that, despite public uncertainty, some uses of genetic modification were already accepted by the public. Submissions from organisations involved in pure research stated that low-risk, scientific research projects involving genetic modification that were carried out in containment in the laboratory were generally accepted. These submissions, particularly those from universities, emphasised that any policy with regard to genetic modification should not result in the prohibition of genetic modification for research and teaching purposes.

Medical research organisations also emphasised that the use of genetic modification as a diagnostic and therapeutic tool was already widely accepted by the public. The submissions suggested that this public acceptance arose either because the use was seen as being carried out in containment or because the use of the technology was considered to be a matter of individual choice. Only a handful of submissions suggested that medicines and treatments involving genetic modification were not acceptable. The reasons given were concerns either about safety or about the reduction of research into alternative, non-genetically modified methods of treatment if the focus shifted to development of treatments using gene technology.

Research into public attitudes

Several submissions considered that it was not easy to determine which future uses of genetic technology would be acceptable to the public because of the different factors that influenced individual perception. Nevertheless, because the acceptability and consequent use of genetic modification would be determined by the public's perception of genetic modification, the submissions suggested there was a need to research public attitudes towards the technology.

Some submissions indicated that research into public attitudes had already been undertaken or were under way. Landcare Research [IP12] discussed the research it had undertaken into public attitudes as part of its research into possum control. AgResearch [IP13] advised that it had been asked by University of Waikato to contribute to a Foundation for Research, Science and Technology (FRST) tender proposal to determine key potential effects and acceptability of genetically modified organisms. Church groups, such as Interchurch Commission [IP49] and Anglican Church in Aotearoa New Zealand and Polynesia [IP42], had also carried out research and consultation among church members to determine attitudes towards genetic modification.

Research organisations, however, indicated a need for increased social, as well as scientific, research as part of the development of genetic modification, genetically modified organisms and products. The submission from Landcare Research [IP12] commented:

> Our experience is that 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 and, increasingly, at least as important as biotechnological research.

Changing public perception

Several of the submissions made suggestions on how the public's uncertainty about genetic modification could be changed to increase acceptance of the technology. Submissions suggested that the provision of reliable information would develop greater public understanding and acceptance of the technology, and that uncertainty about its safety would be resolved by increasing public confidence in the ability of science to manage any risks resulting from its use. Submissions from the proponents of genetic modification believed that uncertainty would lessen if the public felt confidence in a regulatory framework that assessed the risks and the benefits resulting from the technology and ensured that the technology was applied within the bounds of public acceptability. Submissions from opponents of genetic modification, however, suggested that public confidence in the present regulatory framework and, in particular, in the regulatory agencies was very low.

Risks and safety

Most of the submissions identified safety concerns as the major source of uncertainty about future use of genetic modification in New Zealand. There was, however, general acceptance that the use of genetic modification for research purposes in laboratory containment should continue because of the low level of risk from such use. The discussion in most of the submissions focused on the environmental risks associated with the use of genetic technology for agricultural purposes, and the risks to human health from genetically modified food.

Opinions diverged sharply about the use of genetic modification outside laboratory containment for agricultural research purposes. Whereas agricultural research in laboratories was accepted in most of the submissions, the opponents of genetic modification made no differentiation between field trials of genetically modified plants or animals and the release of genetically modified organisms into the wider environment. Research organisations, however, considered field trials to be a

necessary extension of laboratory research. The submissions pointed out that field trials were subject to strict controls that minimised the likelihood of risk and were, therefore, different from the general release of genetically modified organisms and products.

In considering whether or not there were risks associated with the use of genetic modification, many submissions focused on environmental risks. Such risks included: the development of "super-weeds" from herbicide-resistant, genetically modified plants; the risk of cross-pollination of non-genetically modified crops by pollen from genetically modified plants; and the risk of contamination of honey products if bees collected pollen and other materials from genetically modified plants. The horizontal transfer of genes from genetically modified organisms to non-target organisms was also identified as a risk.

Several submissions were concerned about the risks to human health posed by the consumption of genetically modified foods. Submissions identified a risk that consumption of the food from plants into which genes had been inserted could allow transfer of those novel genes to humans. Some submissions suggested that there was a risk that genetically modified foods could contain unknown allergens or toxins or could produce unanticipated toxic and allergenic reactions as a result of genetic modification. The use of antibiotic resistance as marker genes was also identified as a risk to both human and animal health and to the environment.

There was considerable disagreement in the submissions as to whether there was any evidence to show that the risks associated with the use of the technology were actual rather than theoretical. Opponents of genetic modification quoted overseas studies that found that some of the possible adverse effects identified, particularly the contamination of non-genetically modified crops by pollen from genetically modified crops, had already occurred. They suggested that science lacked sufficient knowledge to predict the risks and ensure the safety of the technology. Supporters of genetic modification, however, pointed to the 20 years over which genetically modified organisms had been safely used and stressed the considerable body of knowledge of the technology that had been built up over that time. Submissions also cited a number of international regulatory agencies that had approved the release of genetically modified products. The findings of overseas inquiries, such as the April 2000 report of the United States Congress Committee on Science, were also cited in submissions as evidence of the safety of genetic modification.

Risk management

It was clear from the submissions that the debate between those who supported the use of genetic modification and those who opposed its use outside laboratory

containment focused on whether the risks associated with the use of genetic technology could first be ascertained and then managed within an acceptable level of risk.

Submissions from those who opposed the use of genetic modification expressed concern about the technology's inherent unpredictability and the difficulty of reversing or containing any harm to human health or to the environment caused by the release and use of genetically modified organisms. Green Party of Aotearoa/New Zealand [IP83] expressed strong doubts about the current ability of science to understand and predict the outcomes of the use of genetic modification and suggested that:

> The inherent uncertainties of the technology itself mean that it poses inescapable risks in New Zealand, both to human health and to the environment. Genes do not operate in isolation; the transgene will affect, and be affected by, the other genes in the cell, and by where it is positioned and how many copies of it are inserted. Currently none of this can be controlled by genetic engineers when they create new chimaeric organisms.

This submission was particularly concerned about a number of hypothetical pathways, inherent in the nature of the recombinant process itself, by which unpredictable disruptions of biological systems could occur. It stressed the need for further research before the risks associated with the use of the technology could be fully ascertained and a decision made on its use in the community.

Several submissions also expressed uncertainty about the safety of the technology and recommended the application of the "precautionary approach" or "precautionary principle" to the use of genetic modification. Submissions that advocated the precautionary principle did not, however, appear to have a shared understanding of the meaning of the term[1]. In some submissions the term was taken to mean that no use of genetic modification should be permitted until uncertainties about its safety and impact had been thoroughly researched and satisfied. The submission from Friends of the Earth (New Zealand) [IP78] applied the principle, as set out in the Hazardous Substances and New Organisms Act 1996, to advocate the compulsory labelling of all genetically modified products and products containing genetically modified ingredients.

Other submissions suggested that adoption of the precautionary principle was neither necessary nor appropriate to ensuring the safety of genetic modification.

[1] For a discussion of varying interpretations of the precautionary principle, and its use internationally and in New Zealand, see Appendix 1 ("Current status of genetic modification in New Zealand: Genetic modification and the precautionary approach").

Biotenz [IP25] pointed out that there was no internationally accepted formulation of the principle and suggested that calls for its application were politically motivated and would lead to political rather than scientific decisions on the safety of genetic modification.

Proponents of genetic modification neither considered that the technology was unpredictable nor believed that the risks were inherent in the technology itself. Risk, several submissions stated, arose from the use of the technology and not from the technology itself. The actual risks associated with a particular use of genetic modification could be identified and managed only on a case-by-case basis. The submissions were confident that sufficient reliable research information existed, or was being rapidly developed, "to allow society's decision-makers to have a workable understanding of the risks of the technology" and considered it unnecessary to delay the use of genetic technology until there was less or no uncertainty. Some submissions also shared the view expressed by New Zealand Biotechnology Association [IP47] that:

> ... research investments into the uncertainties of GM needs to be increased. While this is seen as integral to any research strategy/proposal involving GM a heightened awareness will help alleviate public concerns.

Opponents of genetic modification did not share this confidence and expressed considerable uncertainty as to whether current science had developed sufficient knowledge of the actual risks of genetic modification to give adequate assurances of safety before the technology was used. The submission from Bio Dynamic Farming and Gardening Association in New Zealand [IP61] said:

> It is reasonable to expect those who would expose us, our food, and our natural and agricultural environments to genetically modified organisms to demonstrate that they can manage the risks to very high standards ... Risk management should be empirical. It should be based principally on observation of behaviour. ... In the long run, the only way to know what an organism does in particular circumstances is to observe it. Anything else is conjecture ...

Level of risk

The proponents of genetic modification saw the demand for complete certainty as being a requirement that proposed uses of the technology satisfied a "zero risk" standard. Several of the submissions suggested that the standard was "unrealistic and unachievable" and suggested that the appropriate response to public uncertainty was to identify and assess the risks of a particular use of genetic and to manage those risks effectively to reduce their negative impacts.

Submissions that took a more neutral stance on the use of genetic modification also suggested that absence of risk was unrealistic, although many stressed the need for caution in adopting the technology and for ongoing scientific research into its uncertainties. The submission from Rural Women New Zealand [IP52], for example, said:

> It is in the nature of developing technologies — where the level of empirical knowledge is low — that various levels of uncertainty are inevitable and that risks may not be fully calculable. These uncertainties must be recognised.
>
> The only real certainty is of our lack of certainty. Honest science is modest and cautious ... Science gets into trouble when it takes on spurious certainty in aid of commerce or government ...

Scientific risk management

In response to uncertainty about the risks of genetic modification, many of the submissions from research organisations and from private companies involved in the research and development of genetically modified products, suggested that an acceptable level of risk management would be achieved through properly conducted, scientific risk assessment processes. The submission from New Zealand Dairy Board [IP67] suggested:

> The proper approach to the uncertainties involved in any new technology or scientific discovery is to research the possible known consequences, and to assess the risk of possible unforeseen consequences, by proper scientific methodology.

Other submissions supported the view that science allowed for a reduction in uncertainty by ensuring appropriate risk management. Many submissions also added that a robust regulatory system would ensure that a proper scientific assessment of the risks was undertaken. Approval of the current regulatory framework was expressed by several submissions from organisations working within the primary sector and within health and medicine research. Some of the opponents of genetic modification, however, expressed strong doubts about the ability of regulatory authorities such as Australia New Zealand Food Authority and Environmental Risk Management Authority to respond appropriately to public uncertainty about the use of genetic modification.

Scientific uncertainty

Submissions from opponents of genetic modification were not confident that scientific method would offer certainty that the risks could be managed. The submission from Safe Food Campaign [IP86] sought to "conceptualise what the level of 'scientific uncertainty' ... means". The submission pointed out that traditional risk assessments were based on quantifying the probability of

occurrence based on past events. It suggested that:

> Genetic modification defies traditional risk estimates as both the probability of occurrence of harm and level of possible harm are unknown.

This submission concurred with that of Bio Dynamic Farming and Gardening Association [IP61] that current risk assessment was based on "conjecture" rather than on empirical fact.

The strongest expressions of uncertainty about the lack of long-term scientific research came in the submissions from consumer networks and associations expressing concerns about the effects of genetic modification on food and, as a consequence, on human health. Submissions from organisations in the area of food and food ingredient production, however, emphasised the safety of their products and cited the effectiveness of the relevant regulatory agencies in ensuring food safety.

Proponents of genetic modification considered that sufficient knowledge had been developed over the 20 years in which the technology had been used to ensure the safety of current use of genetic modification. Some submissions also stated that the technology was more precise in achieving desired outcomes than the equivalent traditional methods, particularly in relation to the development of specific traits in plants by genetic modification rather than by conventional plant breeding techniques. Submissions from organisations in the health sector suggested that genetically modified products, such as human insulin from recombinant DNA production methods, were purer than pharmaceuticals produced by conventional means. It was not accepted, therefore, that use of genetic modification necessarily involved an unacceptable level of risk.

Opponents of genetic modification not only were uncertain about the ability of the scientific method and of current scientific knowledge to identify and accurately assess the risks of using genetic modification in New Zealand but also were distrustful of scientists and of the context in which genetically modified products were developed. This distrust was clearly evidenced in the submission from Royal Forest and Bird Protection Society, Nelson/Tasman Branch [IP43], which stated:

> Scientists themselves have given us a feeling of uncertainty and unpredictability. They have been influenced by a world view which is manipulative and exploitative. To carry out research they have had to canvas funding from vested interests which gives an emphasis to exploration but not to environmental effects. Their world focuses narrowly on genes, without consideration of organic wholes, such as organisms, ecosystems, societies and communities. Globalisation is pushing genetic engineering biotechnology with quick profit the goal. Government has been helping, with power and kudos as well as profit, the goal.

Submissions from research organisations emphasised that scientists themselves had a responsible attitude to ensuring the safety of genetic modification, genetically modified organisms and products. Several submissions explained that, in addition to satisfying any regulatory requirements, concerns and potential risks had been addressed by agencies voluntarily developing their own policies and best practice procedures and by establishing committees to oversee and monitor such activities.

AgResearch [IP13], one of the organisations involved in primary sector research and development, outlined its internal risk management and best practice policies. The submission referred to the inclusion of an environmental research strategy in its research projects that had environmental outcomes. It also mentioned contributions of its staff to the exploration of the ethical dimensions of biotechnology through a number of forums.

Amongst the private companies involved in the development of genetic modification, the submission from Monsanto New Zealand [IP6] described in detail the environmental and health and safety assessments undertaken by the company, in response to public concerns, during the research and development stages of its products.

Access to scientific information

Several submissions mentioned the importance of information in allaying uncertainties about genetic modification. Sometimes the reference was to information by way of general knowledge or education. Some submissions, however, stressed the importance of information to risk management. Concern was expressed in some submissions over difficulties in accessing scientific information relevant to the risks of genetic modification. A number of submissions from opponents of genetic modification, for example, suggested that the barriers to accessing test results and other research information, particularly information held by private companies, led to uncertainty about the safety of the technology, and also raised ethical doubts about its development. The submission from Golden Bay Organic Employment and Education Trust [IP104] stated:

> Since unbiased and independent short and long term testing of GE, GE organisms, and GE products is not available and since the data that has been made available has been provided by the corporations, institutions and scientists who stand to profit monetarily, the level of uncertainty is very great.

Comvita New Zealand [IP74], a private company dealing in bee products, had a particular interest in ascertaining that the use of genetically modified crops would not result in contamination of honey and other bee products. The submission commented on the scarcity of good science information relating to

this question, "at least in the public domain" and referred specifically to research on bees carried out in Canada, the results of which had not been made available because of "the work was confidential". Other submissions, from both the proponents and the opponents of genetic modification, also referred to the difficulty of gaining access to research information held by private companies. Concern was expressed that the development of genetic modification by private interests would result in research information essential to risk management becoming increasingly less available.

Uncertainty about impacts

The submissions demonstrated that the uncertainty about the impact of genetic modification focused mainly on the likely environmental impacts, on the impacts on human health from the ingestion of genetically modified food and on the commercial and economic impact of the use, or avoidance, of genetic modification. Medical research organisations and the universities expressed concern about the impact that prohibition of genetic modification in New Zealand would have on research and tertiary education and there was some discussion of the social impact of either the use of genetic modification or its avoidance.

Environmental impacts

The submissions indicated uncertainty about the possible environmental impacts of the use of genetic modification. The submissions from the opponents of genetic modification, in particular, were uncertain about the safety of releasing genetically modified organisms into the New Zealand environment. The submissions expressed concern that the impact of genetic modification on non-target systems would threaten ecosystems, weaken biodiversity and increase the possibility of the development of plant diseases and insect pests more resistant to control measures. Several submissions pointed out that much of the research on the impact of genetically modified organisms had been carried out overseas: insufficient research had been done to predict with any accuracy the likely impact on the New Zealand environment, particularly on indigenous flora. Particular concern was expressed in some submissions about the possible impacts of genetic modification on soil and on honey bees.

The submissions from private companies and from organisations involved in the primary production sector emphasised that there was sufficient scientific evidence to prove that no adverse environmental impacts would be caused by the current uses of genetic modification. Nevertheless, they agreed that there was a need to carry out research specifically in relation to the New Zealand environment.

Submissions from the Parliamentary Commissioner for the Environment [IP70], as well as from environmental agencies such as Greenpeace New Zealand [IP82] called for additional research into the potential environmental and ecological effects of genetic modification, as did a number of the Crown research institutes.

Submissions from some of the research organisations and particularly from Landcare Research [IP12] referred also to the potential environmental benefits that would result from the use of genetic modification. The submissions suggested that, within the next decade, it would be possible for the technology to be used for the management of pests, diseases and endangered species and for the avoidance of environmental degradation and promotion of sustainability.

Health impacts

The majority of submissions that discussed the use of genetic modification for therapeutic or pharmaceutical purposes considered that the impact, at least for individual patients and their families, would be beneficial. Several submissions, including some that concentrated mainly on the environmental impacts, did not consider this usage of the technology. Only a few submissions suggested that there might be "difficulties" with the use of genetic modification, genetically modified organisms and products in the treatment of disease or genetic conditions. The submission from Nelson GE Free Awareness Group [IP100], for example, stated: "There is much proof that there are many problems in the medical application of Genetic Engineering", and raised issues about the approval of drugs overseas and the role of pharmaceutical companies in the promotion of genetically modified products. Submissions also expressed concern that focusing on the development of genetic technology could result in the neglect of research into alternative, non-genetic strategies.

Patient representative groups and medical research organisations were, however, more concerned about the impact of the withdrawal of genetically modified treatments if use of the technology were to be prohibited in New Zealand. All the submissions stressed the increasing importance of retaining and extending the use of genetic modification for therapeutic and diagnostic purposes and the potential for new developments in the treatment of diseases that were presently difficult to treat.

Despite the general acceptance of genetic modification for medical purposes, several submissions suggested that genetic modification would have a negative impact on human health through the ingestion of genetically modified food. Submissions from organisations such as Safe Food Campaign [IP86], Green

Party [IP83] and Pacific Institute of Resource Management [IP84] expressed strong doubts about the safety of eating genetically modified food. Other submissions also suggested that the public is more uncertain about the impact of genetic modification in food than it is about the medical use of the technology. The submissions suggested that uncertainties stem either from a concern about the effect that genetically modified food might have on individual health, or because of ethical concerns, or for some other undefined "unease", particularly with transgenic food.

Commercial and economic impacts

Several submissions indicated that there was uncertainty about the commercial impact of genetic modification, genetically modified organisms and products, particularly on the primary production sector.

Submissions from organisations involved in the research and development of genetic modification for application in the primary production sector and in forestry emphasised the benefits these products would have for primary sector industries through increased productivity and lower production costs. Submissions also suggested that New Zealand could not remain internationally competitive unless the use of genetic modification was permitted.

Some submissions from organisations opposing the use of genetic modification suggested, however, that primary industry would not necessarily benefit from genetic modification. Submissions cited overseas information that suggested that the yield from genetically modified crops would not be as great as was expected. Submissions also pointed to shrinking markets for genetically modified food as a result of international concern and rejection of the technology. Many suggested that, rather than having a positive economic benefit, the use of the technology was likely to result in less than expected returns from conventional farming, together with a missed opportunity for the country to take advantage of the growing demand for organic food.

Several submissions expressed concern at the impact that the use of genetic modification would have on overseas markets for organic and natural products. Submissions from organisations involved in the marketing of natural and organic products were concerned that adoption of genetic modification would lead to a removal of certification from their products. Submissions stressed the importance of taking into account marketing and economic issues as well as safety issues when applications for the use of genetic modification were considered.

The joint submission from New Zealand Vegetable and Potato Growers' Federation/New Zealand Fruitgrowers' Federation/New Zealand Berryfruit Growers' Federation [IP75] also suggested that the possible impact on other

industries should be taken into account when permitting the use of genetic modification in New Zealand. The submission referred to the importance of New Zealand's "clean green" marketing image and suggested that the impact of permitting the use of genetic modification on this image is uncertain. The submission also indicated that, because of an apparent rejection of genetically modified food by consumers, the Federations' members were unlikely to produce genetically modified products in the short-term. The use or avoidance of genetic modification was, however, a matter of individual grower choice. Other submissions from food producers suggested that the use of genetic modification would be avoided in the short term because of the likely impact on product sales.

The joint submission of New Zealand Feed Manufacturers Association/Poultry Industry Association of New Zealand/Egg Producers Federation of New Zealand [IP35] was concerned about the impact that avoidance of genetic modification would have on the industry. The submissions suggested that additional costs would be incurred by the industry if it were required to authenticate the source of its products. The submission suggested it would be difficult and costly, for example, to obtain "authenticated GE free soya meal" for stock feed, if labelling were required or if genetic modification were prohibited. The submission also pointed out that the poultry industry would have no control over decisions on the use of genetic modification taken by the overseas sources of breeding stock, on which the New Zealand industry is dependent.

A few submissions questioned whether there was a need for genetic modification in agriculture. Sustainable Futures Trust [IP51] suggested that, because current food production was sufficient to meet the country's needs, there was no need for the technology to increase food production. BIO-GRO New Zealand [IP58] also questioned the need for genetic modification to increase food production. BIO-GRO suggested that sustainable food production was best met by encouraging the development of organic food production rather than by using genetic modification, genetically modified organisms and products.

Research and education impacts

Submissions from research organisations and the universities were particularly concerned about the impact that avoidance of genetic modification would have on research and on tertiary education in New Zealand. Universities in particular suggested that avoidance of the technology would affect not only New Zealand's research capabilities, but also, because of the international importance of biotechnology in research and learning, teaching at undergraduate and graduate level. Submissions suggested that students, particularly overseas students, would

not attend New Zealand universities if teaching in the area of gene technology were prohibited, and there would also be difficulties in staff retention and recruitment.

The use of genetic technology for research purposes, however, was not a contentious issue in most of the submissions, and submissions from both proponents and opponents of genetic modification tended to accept the use of the technology in the area of teaching and research. There were, however, some uncertainties that might impact negatively on research, particularly research into genetic modification. Several submissions opposed the conduct of field trials of genetically modified plants and animals. Clinical trials of genetically modified medicines were not, however, addressed in the submissions. There was also opposition to the use of transgenic animals for research purposes from SAFE (Save Animals From Exploitation) [IP85] and other submissions concerned about the use of genetic modification.

Social impacts

Submissions suggested there was uncertainty about the social benefits that would result from the use of genetic modification. Doubt was expressed over the effect of using genetic technology in ways unacceptable to the public, or without public knowledge, particularly in respect of genetically modified food. Submissions urged that the social costs, including the cost to the ethical and cultural beliefs of individuals and ethnic groups, should be taken into consideration when assessing the benefits of using the technology.

Several submissions referred to the social as well as the economic cost of ignoring, or of unnecessarily withholding, the benefits of genetic modification from the population. New Zealand National Commission for UNESCO [IP90], for example, pointed out that if the technology resulted in positive benefits, "then these benefits for humanity cannot be foregone." The submission, however, suggested that there was a need for further research and for open access to information to reduce the level of uncertainty and apprehension.

Concluding observations

The submissions all recognised that there was a high level of uncertainty amongst the general public about the use of genetic modification, genetically modified organisms and products in New Zealand. Most of the submissions accepted that concern about the safety of gene technology was the main cause of uncertainty but disagreed as to whether this concern was justified.

Submissions generally accepted that there were less uncertainty about the use of genetic modification for therapeutic purposes and also accepted the use of genetic modification for research purposes. The two main areas of uncertainty about the use of genetic modification were in relation to environmental impacts and its use in food.

Despite the uncertainty about the use of genetic modification, genetically modified organisms and products in New Zealand that was either expressed or recognised in the submissions, few submissions called for a total and permanent ban on the use of genetic modification. Neither did any of the submissions advocate unrestricted use of the technology. Submissions across the range of organisations called for a cautious approach to the use of the technology but differed significantly in their views of the manner in which caution should be exercised.

Many of the opponents of genetically modified organisms saw caution as requiring a delay in releasing genetically modified organisms into the environment until research in laboratory confinement had created a sufficient body of scientific knowledge to ensure the safe use of the technology. Even in relation to genetically modified food, most submissions did not call for a total and permanent ban. The majority of submissions expressing uncertainty about genetically modified food required increased assurance as to its safety and the implementation of labelling of all food products which were genetically modified, or which contained genetically modified products or which were the result of a production process involving gene technology.

Proponents of genetic modification agreed to the need for a cautious approach. These submissions, however, suggested that caution should be exercised on a case-by-case basis, in relation to a specific use of the technology. This approach required a robust regulatory system and effective regulatory authorities to ensure that appropriate risk assessment and risk management measures, based on scientific principles, were applied before the use was approved. Although a number of submissions agreed that there was a need for research into specific impacts of genetic modification, particularly environmental impacts, they did not agree that field trials posed any risk to the environment. Submissions from organisations whose activities related to the production and marketing of genetically modified food did not agree that there was any risk to human health, but recognised that consumer resistance might affect the use of genetic modification in the food chain.

From the responses to Warrant item (c), it appears that:

- There is general agreement that genetic modification for research purposes should be permitted in New Zealand, but there is disagreement that

laboratory research should include field trials of genetically modified plants or animals.

- There is general agreement about need for further research into the impacts of genetically modified organisms on the New Zealand environment, but there is disagreement as to whether this research should be undertaken in relation to specific proposed uses or whether it should be undertaken only at laboratory level.
- There is uncertainty as to whether consumption of genetically modified food poses a sufficient risk to human health to warrant a total ban on all genetically modified food or food ingredients, or whether it is sufficient to permit people a choice by requiring the labelling of food that has been genetically modified or has been produced using genetic modification.
- There is disagreement over the acceptable standard of risk.
- There is disagreement over the effectiveness of the current regulatory authorities in ensuring the safe use of genetically modified organisms.

appendix 2

Outcomes of Consultation: Submissions from Interested Persons

Section contents

3.8 Risks and benefits

Introduction

Warrant item (c) required the Commission to consider:

> 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

Submitter profile

Of the 48 submissions that made substantial comment on this Warrant item, 12 were from industry networks or associations, 10 from research organisations and six from other advocacy networks or associations. Four private companies, four consumer networks and associations and three Maori organisations made substantial comment on the Warrant item. Two religious and spiritual organisations made comment, two government bodies and two occupational or professional associations. One submission came from an organics organisation and two from uncategorised organisations.

The majority of the submissions that made significant comment on this Warrant item were either 'strongly for' or 'tended to be for' genetic modification (31). Less than half the submissions came from organisations that had indicated that they were against genetic modification. Three of the submitting organisations were neutral in their stance.

Content of the submissions

The submissions considered whether benefits, in terms of positive outcomes, would result from the use or avoidance of genetic modification. Most of the submissions sought to respond by identifying the specific benefits or risks that accompanied the use or avoidance of the technology and to comment on advantages and disadvantages that would result.

Although submitters used the term "risk" to identify and discuss hazards that might result from the use of genetic modification, many also used "risk" to mean the cost to resources, values or opportunities that would be imposed by the use or

avoidance of genetic modification. To reflect these different uses of the word, this section uses the word "risk" when describing submitters' views on the possible adverse *events* and the word "cost" when describing the possible adverse *effects* or impacts of the use or avoidance of genetic modification technology.

Key themes

The central theme that emerged from the submissions was the relationship between the submitters' perceptions of the risk of genetic modification and of benefit. Submissions from both the proponents of the technology and its opponents, as well as from those organisations that took a more neutral stance towards the use of the technology, recognised that benefits would result only if the risks of its use did not outweigh any possible benefits. Many of the submissions, therefore, included extensive discussion on:

- the risks and safety of the technology
- the benefits and costs of its use
- the advantages or disadvantages that would result from its use or avoidance.

Risks and safety

The submissions could be divided into two main categories: those that were from "proponents" of genetic modification, in that they emphasised the benefits that would flow from its use; and those that were from "opponents" of technology, who tended to stress the risks of the technology. None of the submissions from proponents of genetic modification, however, advocated the unrestricted use of genetic modification. Many of the submissions referred to conditions under which the technology could be used safely, such as ensuring that a robust risk assessment process was carried out under the supervision of appropriate regulatory agencies before any release of genetically modified organisms. Several submissions also emphasised the need for community acceptance of the proposed use of the technology and for a range of non-scientific factors to be taken into account as part of the risk assessment process.

Similarly, not all the submissions from opponents excluded the possibility of the future release of genetically modified organisms and products or suggested that there could never be any benefit in use of such technology. The majority of the submissions from opponents of genetic modification emphasised the inherent unpredictability of the technology and the risk that its use could cause irreversible and widespread harm. Some submissions also expressed concern about the difficulties of controlling and monitoring the technology once it had been released

and, in particular, the risks of accidental escapes and cross-contamination (of non-genetically modified systems by genetically modified ones). Nevertheless, many of these submissions also accepted that there was already some benefit being realised from the use of genetic modification in research and for medical purposes, where the technology was used in laboratory containment. Some submissions also contemplated the future use of genetic modification outside of laboratory containment, but not until extensive research had been undertaken and sufficient knowledge of the technology developed to permit a proper assessment of the risks. Until then, the risks of using the technology outside laboratory containment outweighed the benefits.

Risks of the use of genetic technology

Both the proponents of genetic modification and its opponents identified several possible risks associated with its use. Environmental risks from horizontal gene transfer to non-target plant and animal species and from the contamination of non-genetically modified plants by pollen from modified varieties were discussed in many of the submissions. Such risk was the focus of the majority of the concerns. Several submissions expressed concern about the risk that horizontal gene transfer posed to soil; some commented on the risk that pollen from genetically modified plants posed to bees.

Several submissions, such as that from Safe Food Campaign [IP86], emphasised concerns about the risks of genetically modified food, particularly of the development of unexpected allergenicity properties in genetically modified food sources and increased resistance to antibiotics through the use of antibiotic resistance as marker genes.

Whereas some submissions suggested that genetic technology was risky because of the unpredictability of the technology, others suggested that it was risky because of the difficulties of ensuring that genetically modified agricultural products did not contaminate unmodified products (either through cross-contamination by pollen or because of human mistakes in handling genetically modified commodities). The submissions from Commonsense Organics [IP66] and Greenpeace New Zealand [IP82] cited various overseas events that had resulted in unauthorised releases of products (eg, Starlink corn); they also quoted evidence to show that there had been instances both of cross-contamination by pollination and of product contamination.

Safety of the technology

Most of the submissions that supported the use of genetic modification acknowledged possible risk but emphasised that there was evidence that the use of

the technology was safe. Organisations involved in the research and development of genetically modified plants claimed that, during the 20 years over which the technology had been used, there had been no evidence of any adverse incidents. Other organisations, such as those involved in the production and distribution of food, pointed to the work of the relevant regulatory bodies in ensuring the safe use of genetic modification. Medical research organisations, and groups representing patients, particularly emphasised that no risks had been identified from the use of gene therapies.

Although many submissions expressed confidence in the safety of genetic modification, most were cautious in their approach to issues of risk management. Submissions pointed out that no technology was risk free and that science could not, therefore, give an unconditional guarantee of safety. Submissions, particularly from the Crown Research Institutes, referred to the need for "responsible" use of genetic modification and for a robust risk assessment process to be carried out within a credible regulatory framework.

The submissions from the opponents of genetic modification, however, expressed doubts whether the technology could be used safely, either because of concern about the inherent risks of the technology or because of doubts that the adverse impacts of genetically modified organisms released into the environment could be managed.

Green Party of Aotearoa/New Zealand [IP83] placed particular stress on the inherent unpredictability of genetic technology and provided witness evidence to demonstrate the possibility of unexpected effects resulting from the use of genetically modified organisms. The submission referred to the identification of "risk pathways" that suggested modified organisms could behave, under certain conditions, in ways that had not been predicted during the risk assessment process.

There were two main convergences in concerns about the safety of the technology: environmental risks and risks posed by genetically modified food. Submissions from organisations such as Safe Food Campaign [IP86] and GE Free New Zealand (RAGE) in Food and Environment [IP63] emphasised the inadequacy of the tests carried out by the Australia and New Zealand Food Authority to ensure the safety of genetically modified food. Several submissions called for the banning of genetically modified food because of safety concerns; others, such as that of Green Party [IP83], suggested there was a need for robust and appropriate pre-market safety testing to ensure the safety of genetically modified foods before they were made available to consumers. Submissions also stressed the need for enforcement of labelling requirements so consumers could avoid the risks of genetically modified food.

Many of the submissions from the opponents of genetic modification pointed out that, even where there was no evidence of harm having resulted, there was also no evidence that the technology could be used safely in the future. Several also pointed out that, in relation to food, the long-term effects on human health of ingesting genetically modified food were unknown.

Assessing the risk

Several submissions from organisations involved in the research and development of genetically modified food pointed out that benefits from its use could not be realised until an assessment of the risks and benefits established that the risks would not outweigh the benefits. The proponents of genetic modification, however, emphasised that this risk-benefit analysis could be carried out only in relation to specific uses of genetic modification and could not be done in relation to the technology as a whole.

There was general agreement among the supporters of genetic modification that risk assessment should be based on scientific principles. Several submissions, such as that from New Zealand Dairy Board [IP67], suggested that non-scientific factors should not be allowed to impinge upon or distort the objective process of risk assessment. Submissions from other proponents of genetic modification, however, considered that a decision on the use of genetic modification could not be based solely on an objective scientific approach to risk because a scientific assessment could not take into account the cultural, social, political and economic factors that influenced perceptions of risk. Although science might be able to identify and determine the benefits of the use of the technology in relation to the size and probability of risk, it could not determine whether the level of risk associated with the use would be acceptable to the community. Any use of genetic modification without community acceptance would be unethical and, possibly, unwise. New Zealand Life Sciences Network [IP24] said:

> 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 ... the balance to be achieved between acceptable and unacceptable risk can be informed by science but not determined.

Submissions advocating a risk assessment process based, at least partially, on scientific principles were confident that the behaviour of the technology could be predicted and that the current knowledge and understanding of the technology was sufficient to identify the risks and to assess the probability of harm occurring. Submissions from the opponents of genetic modification, however, emphasised that the technology was unpredictable; therefore, the risks and potential harm

were also unpredictable and could neither be assessed nor be managed. Several of the submissions stated that the risks of genetic modification were "unknown and unknowable" and any assessment of risk would, therefore, be based on conjecture. Some submissions, such as that from Bio Dynamic Farming and Gardening Association in New Zealand [IP61], called for the assessment of the risks of genetic modification to be empirical and based principally on observation of behaviour. Other submissions, such as that from Sustainable Futures Trust [IP51], pointed out that:

> The risks of GM, being a scientific endeavour, are assessed by those schooled in the scientific method of objective rationality. When both the risks and their consequences are uncertain and potentially catastrophic, the processes of assessment need to be open and inclusive of all the stakeholders, where subjectivity, values, morals and consensus enter into the discourse. This is the emerging realm of post normal science (Ravetz 1999)[1]

Other submissions, particularly those from Maori organisations, called for an inclusive risk management assessment that would take into account the range of factors that influence perspectives on the use of genetic modification. An inclusive assessment process would ensure that genetic modification, genetically modified organisms and products were not released into the community until after an accepted level of risk had been determined.

Benefits and costs

Benefits of use

Except in relation to the use of genetic modification for research and for medical purposes, only the submissions from proponents of genetic modification were confident that benefits would result from the use of the technology.

Particular emphasis was placed on the range of commercial benefits that were expected to result from the use of genetic modification. Submissions identified benefits to agriculture, horticulture and forestry through improved production methods, increased productivity, lower production costs and new or improved products. Because of the level of concern expressed about genetically modified food, some submissions, particularly those from organisations involved in food production and distribution, emphasised the benefits in taste, quality and safety that consumers of genetically modified food were expected to experience.

[1] Ravetz J (ed). 1999. Post-normal science. *Futures* (special issue), 31 (7): 641–757.

Several of the submissions from organisations that otherwise supported the use of genetic technology doubted that benefit would result from its use in relation to food. Submissions from New Zealand Vegetable and Potato Growers' Federation/ New Zealand Fruitgrowers' Federation/New Zealand Berryfruit Growers' Federation [IP75], Meat New Zealand [IP31] and New Zealand Game Industry Board [IP33] all suggested that their members were unlikely to use genetic modification until there was clear indication that its use was acceptable to consumers.

Some submissions also suggested that new commercial opportunities would arise from the use of genetic modification, both in the area of primary production and for medical and health purposes. Genesis Research and Development [IP11] referred to various new opportunities that had resulted from its involvement in gene technology. Dairy Board [IP67], in addition to identifying benefits in relation to existing dairy products, noted that new opportunities would arise from "the production of new products, particularly those with functional foods, nutriceutical and pharmaceutical applications."

Much of the discussion in the submissions focused on the possible future benefits of genetic modification and indicated that there was a need for further research before the uses would be developed. Submissions from research and development agencies often discussed research currently under way into specific uses; and some submissions, particularly those from companies involved in the research and development of genetically modified crops, suggested that the introduction of genetically modified crops would result in an immediate benefit in New Zealand. Other submissions were more speculative in their discussion of both the uses and the benefits of genetic modification. Several submissions from medical research agencies referred to the increase in medical applications of the technology after completion of the Human Genome Project.

The discussion in most submissions, however, suggested that, although several New Zealand organisations were involved in research, it was unlikely that the research would result in the release of genetic modification, genetically modified organisms and products for commercial purposes in the near future.

Many of the submissions that discussed the commercial benefits that were expected to result from the use of genetic modification also suggested there would be flow-on benefits to the national economy. Several of the submissions suggesting that the future profitability of the primary sector depended on the use of genetic modification particularly emphasised the importance of that sector to the New Zealand economy. Other submissions suggested that economic benefits would

result from the development of new businesses and creation of new commercial opportunities through the use of the technology.

Some submissions suggested that the use of genetic modification would result in environmental benefits, both direct and indirect. Genetic modification in agriculture and horticulture would result in the use of processes and products less damaging to the environment and to natural resources than those currently used. Conservation genetics and other environmental management tools would extend the knowledge of New Zealand's native species, decrease the threat from imported pests and ensure the protection of the natural biodiversity.

Submissions from health service providers and medical research organisations discussed the benefits to patients arising from the use of genetic modification for diagnostic and therapeutic purposes.

Several of the submissions emphasised the benefits that were expected to result simply from continued research into genetic modification. Submissions from organisations involved in primary production and in medical research suggested that, even if it were decided to prohibit the use of genetic modification, genetically modified organisms and products in the wider environment, continuation of research in laboratory containment could result in benefit. Continued laboratory research would not only ensure that New Zealand's knowledge of gene technology remained current but would also allow the development of valuable intellectual property. Other research organisations, however, emphasised the importance of field trials to the research process. To the opponents of genetic modification, any use of gene technology outside laboratory containment, including field trials for research purposes, would incur a high level of environmental risk and should not be permitted.

Some of the submissions from opponents of genetic modification also accepted that benefits could result from the use of genetic modification. The submission from Green Party [IP83], for example, identified gene technology as contributing to understanding inheritance and diagnostic techniques:

> Gene technology, including in some cases the creation of GMOs in the laboratory has contributed worthwhile knowledge about the genetic basis of some diseases, heritability, and provided diagnostic techniques useful in treating disease in humans, plants and animals. These techniques can also be used to speed up conventional breeding by determining whether natural progeny have the desired traits or not.

The use of gene therapy for these purposes was approved, and also for the development of medicines such as insulin, but only if the technology was used in laboratory confinement where the risks of its use could be contained.

Costs of use

As well as being concerned about the risks of using genetic modification, submissions suggested costs that would result from its use.

The introduction of genetically modified crops was of particular concern. Many submissions suggested that the introduction of genetically modified crops would result in costs to the organics industry if cross-pollination of organic crops by genetically modified crops led to the loss of organic certification. The submissions suggested that the risk of organically grown crops being contaminated by genetically modified crops was high and would lead to loss of the required organic certification. Several submissions pointed out that additional financial costs would be imposed on organic growers if they were required to set aside part of their land to create a buffer zone to protect against possible contamination of organic crops through cross-pollination.

The submissions pointed out that, because of concerns about the safety of genetically modified food, overseas consumers were increasingly rejecting genetically modified food in preference for food that was not genetically modified. The rejection of genetically modified food, the submissions suggested, had resulted in a significant increase in the demand for organic products and increased sales overseas of New Zealand-grown organic produce. Contamination would not only adversely affect the ability of the organics industry to take advantage of this increased demand, but also had the potential to restrict overseas demand for conventionally grown New Zealand products. Concern about possible consumer rejection of genetically modified food was also expressed in submissions from organisations currently involved in conventional food production, which suggested that their members might chose not to use genetic modification for food production.

The submission from ZESPRI International [IP46] considered the impact that use of genetic modification could have on products that did not necessarily use organic production techniques. The submission stressed the importance of the export market to countries where there was growing consumer resistance to genetic modification. It suggested that use of genetic modification could lead to the creation of non-tariff barriers to market access. The submission said:

> A decision to allow commercial GM food production in New Zealand could be used as a pretext to refuse New Zealand non-GM food products. Retailers could judge the publicity as undesirable for sales. Our marketing evidence is that the GM status for New Zealand commercial food production calls into question the GM status of all New Zealand food produced.

The potential for significant commercial costs to be imposed on the bee products export industry if products were found to be contaminated by pollen from genetically modified crops was a specific concern raised in two submissions from organisations commercially involved in the industry.

Many submissions from both the opponents and the proponents of genetic modification suggested that New Zealand's "clean and green" image was a useful marketing tool that would be compromised by the introduction of genetically modified crops. The joint submission from Vegetable and Potato Growers' Federation/Fruitgrowers' Federation/Berryfruit Growers' Federation [IP75], which accepted that there were likely benefits to the horticultural industry from the development of genetically modified crops, commented that:

> The potential impact associated with the first releases of commercial GM crops on New Zealand's "clean, green image" will need to be considered as part of the regulatory processes assessment of economic risks and benefits. We are not implying that GM is 'un-clean and non-green", but "clean and green" is a real marketing tool and may be affected by the production of GM crops in New Zealand.

Whereas several of the submissions from proponents of genetic modification suggested that there would be benefits to the agricultural sector from the use of genetic modification, submissions from the technology's opponents suggested that the introduction of genetically modified crops would result in financial costs. The submissions pointed to evidence from overseas that the yields from genetically modified crops had not been as high as was suggested and that the need to recover the high development costs had resulted in a premium being added to the price of the seed. Some submissions also suggested that the use of genetic modification would result in a loss of agricultural diversity and, because of restriction on the saving of seed from the previous year's crops, in a growth of dependence on a few major companies.

The submissions from Maori organisations were particularly concerned about the cost to cultural and spiritual beliefs that would be imposed if genetic modification were permitted in New Zealand.

Benefits of avoidance

Many submissions suggested that, because of the increasing overseas demand for organic produce, there would be significant economic benefits not only in protecting organic crops from possible contamination, but also in actively promoting the growth of the industry by prohibiting the release of genetically modified organisms. Extension of the industry, submissions suggested, would help differentiate New Zealand products, making them more than commodity products.

Rather than preventing the development of new industries, submissions suggested, the avoidance of genetic modification could encourage the establishment of a range of new industries that capitalised on New Zealand's genetic modification-free status.

Costs of avoidance

In most of the submissions from proponents of genetic modification, the anticipated costs of avoiding the technology were opposite to the expected benefits. Without genetic modification, it was expected that there would be costs to industry sectors, particularly the primary production sector, through loss of international competitiveness, financial costs to sector industries through being unable to access technology and products that would increase productivity and decrease production costs. There would be environmental costs, particularly in the area of pest control and resource management.

Although many of the costs identified were "passive" costs (ie, the cost would be incurred because the benefit was not realised), some submissions suggested that avoidance of genetic modification would be to the detriment of the status quo in certain areas. Several of the submissions, for example, stressed that avoidance of genetic modification not only would prevent future benefits to human health but also could mean that patients currently dependent on genetically modified medicines would have difficulty in accessing alternatives. Few submissions, however, suggested that avoidance of genetic modification should be extended to prohibit the use of genetically modified diagnostic techniques or medicines.

The universities in particular were concerned that avoidance of genetic modification would result in difficulties in recruiting and retaining suitably qualified staff. This, in turn, would result in costs both to current research programmes and to graduate and undergraduate teaching.

In the area of pure research, concern was expressed that avoidance of genetic modification would result in the curtailing of current research projects and could prevent the continued use of transgenic animals for research purposes. Although SAFE (Save Animals From Exploitation) [IP85] expressed strong concerns that the use of animals for research purposes was likely to increase as a result of genetic modification, few other submissions expressed opposition to the continued use of genetic modification for research and teaching purposes.

Some of the submissions considered the social costs that might be experienced if genetic modification were avoided in New Zealand. The submissions from several of the tertiary institutions mentioned that, without access to the technology, New Zealand would not be able to develop a "knowledge economy". Other

submissions expressed concerns that, if New Zealand limited its involvement with genetic modification, the potential for future benefits would be curtailed, to the detriment of the population as a whole. University of Canterbury [IP7], when emphasising the importance of retaining research and teaching staff, stated that:

> Uneducated societies are more at risk of being exploited on issues of biotechnology than educated societies. Likewise they are more likely to miss out on some of the acceptable benefits of adopting biotechnology.

Advantaged and disadvantaged groups

The submissions responded in several different ways to the requirement under Warrant item (c) that consideration of the risks and benefits of genetic modification should include consideration of the groups of persons likely to be advantaged by the benefits and disadvantaged by the risks of genetic modification.

Submissions from organisations involved in research and development of genetic modification, genetically modified organisms and products tended to specify the users of the products and other commercial interests, including those with a financial interest in the promotion of genetic modification, as the groups that would be advantaged or disadvantaged.

Submissions that emphasised the risks of genetic modification, and therefore stressed the disadvantages of its use. often illustrated the potentially widespread nature of the harm that the technology could cause. Thus, they suggested that the advantage of avoidance or disadvantage of use would be incurred by "society" or by "the New Zealand public".

Groups were identified more specifically when the advantage or disadvantage would be incurred because the use of the technology would either benefit or threaten special characteristics or needs of the group members. The submission from Comvita NZ Ltd [IP74], for example, identified people involved in the honey and bee products industry as being likely to be disadvantaged from its use. Patient representative groups, such as Lysosomal Diseases New Zealand [IP99], stressed the importance of genetic modification to their members.

Several submissions emphasised the disadvantage that would be experienced by Maori if their traditional lore and cultural and spiritual beliefs were breached by the use of genetic modification technologies.

The submissions tended to reinforce a view of the predominance of either risk or benefit of genetic modification. They expressed this either by referring to broad groups of people as advantaged or disadvantaged, or by identifying the groups whose specific needs would be met or denied by use of the technology.

Concluding observations

The submissions on the benefits and risks of genetic modification divided into two main categories: those that saw the use of the technology as predominantly beneficial and those that considered the risks of its use usually outweighed any benefit.

Submitters' perceptions of the predominant risk or safety of the technology shaped their views on the likely benefits or costs of its use. Because benefits could arise only from the use of the technology, the proponents of genetic modification emphasised the risk assessment and risk management processes that were undertaken to ensure that the technology was used safely. Opponents of genetic modification emphasised that it could not be used safely because current scientific understanding of the effects of the technology was too limited to be able to predict and assess possible risks.

Opponents of genetic modification agreed that there were benefits arising from the laboratory use of genetic modification for research and medical purposes, where any adverse outcomes could be contained. Opponents particularly emphasised the potential damage to the environment that could result from unintended and unforeseen effects of genetic modification.

Proponents of genetic modification acknowledged there were risks associated with the use of the technology but were confident that there was sufficient knowledge to identify and assess the risks. None of the submissions from the proponents of the technology suggested that genetic modification should be used without regulatory controls to ensure its safe use.

The view expressed in the submissions diverged sharply over the likely benefits of genetically modified food. Some submissions recognised that consumer rejection of genetically modified food would limit its benefits but suggested that, in general, genetic modification used in relation to food and food crops was beneficial. Other submissions expressed strong doubts about the safety of genetic modification in food and either called for a complete ban on its use or suggested that it should be subjected to a rigorous safety procedure.

The submissions identified a range of groups that would be advantaged or disadvantaged by the use of the technology. Except where the technology would benefit or adversely impact on the special characteristics or needs of a specific group, the submissions tended to describe the affected groups in general terms.

appendix 2

Outcomes of Consultation: Submissions from Interested Persons

Section contents

3.9 International obligations and implications

Introduction

The issues raised by Interested Persons in response to two Warrant items dealing with international aspects of New Zealand's decisions on genetic modification have been combined into one section of this report. Several submitters included implications of the obligations under Warrant item (d) which calls for the identification of the applicable obligations, or referred to their response on one of the Warrant items when commenting on the other.

The Warrant under item (d) called for information and views on:

> the international legal obligations of New Zealand in relation to genetic modification, genetically modified organisms, and products

and Warrant item (l) called for information on:

> 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

The request for information on these items recognises that New Zealand does not operate in isolation in considering the strategies and processes open to it in relation to genetic modification. Consideration must be given to the international agreements and arrangements New Zealand has entered into, the obligations that arise under those agreements, and the implications that flow from them.

Fifty-six submitters specifically addressed one or both of these Warrant items. Of these, 23 made substantial comments on New Zealand's international obligations. Seventeen submitters provided substantial comments on the international implications for those obligations (and for New Zealand's foreign and trade policies, as well as associated costs and risks) of measures that might be taken in respect of genetic modification in New Zealand. (This was the smallest number of substantial submissions made on any of the Warrant items.)

In terms of the sectoral focus of submitters who responded to the Warrant item on international obligations, 10 submitters were from the economic/production

sector. Eight submitters had the environment, health and cultural/ethics sectors as their sectoral focus; the remaining five were identified as from 'other' sectors.

The principal sectoral focus of most submitters who commented on the international implications of New Zealand's response to genetic modification was the economic/production sector. The other submitters came from the environment sector (two submitters) and other sectors (three submitters).

The majority of the submitters who made substantial comments on international issues were in favour of genetic modification. That stance was mostly 'strongly for'. In comparison, four and three submitters were identified as 'strongly against' under Warrant items (d) and (l) respectively.

The category most represented, in terms of submitter type, were industry networks/associations, with research organisations and other advocacy networks/associations running a very close second. Among the remaining submitter types, in relation to substantial comment on these two Warrant items, were two private companies, one Maori organisation, an organics group and an occupational/professional group.

The remaining submissions of the group of 56 also broadly followed the distribution of sectoral focus and submitter type of the more substantial submissions made on these topics.

Key themes

Several themes emerged as submitters addressed issues arising from New Zealand's international obligations and the implications for those obligations of any measures New Zealand that might take with regard to genetic modification.

First, submitters identified as relevant a range of international agreements, instruments and membership of organisations giving rise to:

- applicable international obligations

Then, the implications that submitters saw as flowing from those obligations are considered under the following themes:

- sovereignty/autonomy
- cultural and ethical implications
- opportunities and benefits of international agreements and cooperation
- compliance and compatibility with trading partners
- economic and commercial considerations
- New Zealand's international reputation and influence.

In responding to these Warrant items, some submitters identified obligations but were neutral as to implications. Submissions from Maori organisations tended to focus on obligations under United Nations declarations and their relationship with Treaty of Waitangi obligations. The remaining submissions expressed two notably distinct viewpoints. One group submitted that New Zealand's participation in the international arena on genetic modification issues was a hindrance or a threat to the country's sovereignty or autonomy (particularly in protecting our environment and culture) in determining the basis for regulating the use of genetic modification technology and products. The other group identified the risks that non-compliance with international treaties and agreements might pose to New Zealand's relationships and trade in the event of banning (or limiting access to) genetically modified products. This group also noted the benefits that accrue to New Zealand, economically and scientifically, from involvement in international fora, agreements and organisations.

Applicable international obligations

International instruments and obligations identified by submitters as applicable to genetic modification technology were:

- various United Nations (UN) declarations, charters, conventions, agreements and protocols, together with the agencies or organisations responsible for developing and setting standards and/or best practice
- World Trade Organization (WTO) and the agreements and decisions promulgated by the WTO
- bilateral agreements and arrangements entered into between New Zealand and Australia and the bodies that give them effect.

In this context it is worth noting that the Hazardous Substances and New Organisms (HSNO) Act requires the Environmental Risk Management Authority (ERMA) to consider New Zealand's international obligations when determining applications to import or release genetically modified organisms.

United Nations instruments and organisations

The Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety (Biosafety Protocol) were singled out as the most significant of the United Nations-sponsored instruments relevant to genetic modification and to which New Zealand is a party.

Submitters also noted as relevant obligations: the Universal Declaration of Human Rights; the Declaration of the Human Genome and Human Rights; the

International Covenant on Economic, Social and Cultural Rights; the Ottawa Charter (relating to health and health services); and the Draft Declaration of the Rights of Indigenous Peoples.

Submitters also noted the International Plant Protection Convention (IPPC), a specific agreement relating to plants under the aegis of the Food and Agriculture Organization of the United Nations (FAO), which has been in force (and ratified by New Zealand) since 1952.

Also under the UN umbrella is the Codex Alimentarius Commission, which was set up jointly between FAO and the World Health Organization (WHO) in the early 1960s. It sets food safety standards which are used internationally, particularly in relation to WTO agreements such as the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement).

Other international instruments and organisations referred to were:

- World Intellectual Property Organization (WIPO)
- World Organisation for Animal Health (Office International des Épizooties (OIE)).

World Trade Organization agreements

Submitters' views on the WTO were sharply divided. Submitters from industry associations and networks expressed very clear views that compliance with WTO agreements such as the TBT Agreement, SPS Agreement and Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) was required for New Zealand's assured and competitive access to global markets. These submitters commented that only scientific evidence would be acceptable under these agreements for any restrictions or requirements on the import and export of genetically modified organisms and products by New Zealand.

Submitters from other sectors, such as consumer networks and other advocacy networks and associations, argued that WTO decisions had accepted that restrictions for environmental reasons were acceptable and could be upheld through any dispute process. Greenpeace New Zealand [IP82] provided a lengthy analysis to support this interpretation. It also noted that, in implementing any measures to protect the environment or public health and safety, it would be prudent for New Zealand to follow international agreements (particularly the Biosafety Protocol) and to carry out consultations with other states on the measures; in addition, it should ensure that measures were applied in a consistent and transparent fashion and that they complied with the allowable exceptions to

the general principles (such as "most-favoured-nation" and "national treatment") under the WTO Agreement.

Organic Product Exporters Group [IP53] also noted that both exports and imports must adhere to the same regime in order to avoid WTO action. The example given was that if New Zealand were to require labelling of all imported genetically modified organisms and products, then exporters would also have to adopt such labelling.

Trans-Tasman agreements

Submitters also noted the effects of the Australia New Zealand Closer Economic Relations Trade Agreement (ANZCERTA) and the Trans-Tasman Mutual Recognition Arrangement (TTMRA) between Australia and New Zealand.

Several submitters referred in some detail to the combined agreements, legislation and agencies set up by New Zealand and Australia to deal with food safety and labelling issues. These were generally dealt with under the heading of the Australia New Zealand Food Authority (ANZFA).

Other multilateral organisations and agreements

A few submitters also briefly referred to:

- International Union for the Protection of New Varieties of Plants (UPOV), established by the International Convention for the Protection of New Varieties of Plants
- Organisation for Economic Co-operation and Development (OECD)
- Asia-Pacific Economic Cooperation (APEC).

Submitters' views on the implications for New Zealand's international obligations and foreign and trade policy of measures that might be taken in relation to genetic modification, genetically modified organisms and products are discussed below.

Sovereignty and autonomy

Several submitters, including Sustainable Futures Trust [IP51] and Royal Forest and Bird Protection Society, Nelson/Tasman Branch [IP43], made very clear and succinct statements to the effect that any international obligations that hindered or prevented the New Zealand Government protecting the interests of its citizens had to be renegotiated or reassessed.

Submitters raised concerns that membership of bodies such as WTO obligated New Zealand to compromise or to accept processes and products that were contrary to the ethical, spiritual and cultural values of New Zealanders. The

general sentiment expressed was that New Zealand's autonomy or sovereignty in respect of decisions about genetic modification must take precedence over any international obligations.

Submissions by Maori groups also raised the concern that New Zealand's membership of such agreements and organisations and the paramountcy given to the associated obligations represented a threat to their "sovereignty" over their traditional resources and knowledge. Te Runanga o Ngai Tahu [IP41] particularly argued that these agreements reinforced a belief that all property was available to ownership and exploitation by individuals (including individual corporations), whereas Te Runanga believed that the biodiversity of New Zealand should belong to all New Zealanders and any agreements that undermined that were not in the best interests of New Zealand.

Nelson GE Free Awareness Group [IP100] submitted that New Zealand should reclaim food standards and labelling issues from the domain of the bilateral arrangements with Australia because the current arrangements were a compromise and detrimental to New Zealand's sovereignty.

Submitters who commented on this issue also noted that entering into or giving effect to binding international agreements should not occur without full public disclosure and proper time allowed for submissions.

Golden Bay Organic Employment and Education Trust [IP104] submitted that all New Zealand's current international arrangements and membership of organisations should be publicly reviewed to determine democratically whether these were acceptable and not destructive to New Zealand's national interests such as public health and the environment.

Opportunities and benefits of international agreements and cooperation

Submitters from health and research organisations very clearly stated that limitations or avoidance of the use of genetic modification technology or products would have serious implications for research and for access to medicines and medical treatments in New Zealand.

Lysosomal Diseases New Zealand [IP99] raised the point that for New Zealand to deny patients access to medicines and therapies involving genetic modification would be in breach of instruments such as the Ottawa Charter and UN conventions and declarations on human rights and health to which New Zealand is a signatory. It would also cause potential stress and harm to patients and their families.

Other submissions under this heading stressed the importance to medical and scientific communities of participating in current developments, including genetic modification research and therapies. If access to genetic modification technology were limited, New Zealand's doctors' and scientists' skills and contributions would diminish and their reputations (both domestic and international) would suffer.

New Zealand Organisation for Rare Diseases [IP98] submitted that it would not be tolerated if the result of regulation of genetically modified organisms or products in New Zealand was to deny individuals the right to obtain or use genetically modified medicines, which were available and accepted overseas.

Crop and Food Research [IP4] commented on an aspect of the interaction with the international research or knowledge community that benefited New Zealand. It estimated that New Zealand contributed 0.13% toward the total global investment in research. However, we shared access to the total pool of knowledge and used a far greater portion than that produced. New Zealand's investment in crop and animal breeding programmes gave reciprocal access to international programmes, which had been important in maintaining and improving the genetic diversity of New Zealand's crop species. From this perspective, the submission noted, it was important to remain a member in good standing in the international community and comply with any legal obligations that entailed.

Compliance and compatibility with trading partners

Submitters from industry networks and associations, research organisations and private companies noted that New Zealand was highly dependent on access to global markets for its exports. Any attempts to restrict genetically modified imports would bring retaliation in the form of litigation or disputes under the WTO and restricted or no access for New Zealand goods.

These submitters raised the issue that if New Zealand sought to restrict the entry of genetically modified organisms and genetically modified products it must comply with the WTO agreements (TBT, SPS and TRIPS Agreements), which required that such restrictions be:

- scientifically justified
- based on risk assessment
- no more restrictive than necessary
- non-discriminatory
- not a disguised trade barrier.

Federated Farmers of New Zealand [IP34] also pointed out the tension for New Zealand in that producers needed access to other markets but they also required protection from any biosecurity risks that might arise from imports or development in New Zealand. The Federation was of the view that the existing processes under the HSNO Act as carried out by ERMA complied with the requirements of the WTO agreements.

The main theme of these submitters was succinctly stated by Biotenz [IP25]:

> It would be inappropriate for New Zealand to opt out of international obligations. Opting out would do more damage to New Zealand's economy and international relations than good. There would be no environmental benefit.

Economic, trade and commercial considerations

Several submitters pointed to the value of the exports that New Zealand produces. Submitters noted that the New Zealand economy relied heavily on the ability to export food and other agricultural products:

- "Horticulture contributes in the vicinity of $2 billion per year in export earnings to the New Zealand economy" (New Zealand Vegetable and Potato Growers' Federation/New Zealand Fruitgrowers' Federation/New Zealand Berryfruit Growers' Federation [IP75]).
- The New Zealand dairy industry supplied "20% of total exports" (New Zealand Dairy Board [IP67]).

Cultural implications

Maori views

There were four submissions from Maori organisations (Te Runanga o Ngai Tahu [IP41], Nga Wahine Tiaki o te Ao [IP64], WAI 262 claimants, Ngati Wai, Ngati Kuri, Te Rarawa [IP69] and Maori Congress [IP103]) which discussed one or both of Warrant items (d) and (l).

Nga Wahine Tiaki o te Ao [IP64] and Maori Congress [IP103] referred to the UN's 1993 Draft Declaration on the Rights of Indigenous Peoples, and specifically Article 29, which states:

> Indigenous peoples are entitled to the recognition of the full ownership, control and protection of their cultural and intellectual property.
>
> They have the right to special measures to control, develop and protect their sciences, technologies and cultural manifestations, including human and other genetic resources,

> seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs and visual and performing arts.

Nga Wahine Tiaki o te Ao described the Draft Declaration as imposing an obligation on Government to honour this international legal obligation and enact the special measures that would heed the call of Maori "which is a clear and resounding NO to GM and GMO in Aotearoa". Maori Congress also said the Draft Declaration was an important consideration, but noted that the Declaration had not yet been ratified by New Zealand and, even after ratification, although signatories were expected to comply, there were no legal sanctions for failure to do so.

Submitters also referred to the CBD and the obligations under it that, as a signatory and ratifying party, New Zealand was required to observe. WAI 262 claimants [IP89] noted that evidence presented to the Waitangi Tribunal by international experts in cultural and biological diversity was relevant and important to the Commission in carrying out its task. The evidence could be summarised as "cultural diversity is the key to biological diversity": that is, that indigenous and traditional communities were repositories of important aspects of biodiversity and they also provided "the essential ingredient to a complete understanding of the consequences" of genetic modification.

Maori Congress [IP103] submitted that the CBD, and Article 8(j) in particular, was concerned with the shared role of indigenous peoples and signatories in the regulation of traditional resources, knowledge and processes and of rights to their use. The Congress also argued that the Article required, at the very least, that there be some form of joint ownership by states and the indigenous people over these resources, in order to give effect to the CBD's aims of respecting, preserving and maintaining them.

All Maori submitters forcefully submitted the right of Maori to manage, preserve and protect their peoples' knowledge, resources, innovations and practices. They claimed that these rights were reinforced by the international legal obligations of Government and must be respected and protected by any government measures in respect of genetic modification.

Other views

Friends of the Earth (New Zealand) [IP78] submitted that Government had duties to Maori under the CBD to provide for sustainable development of flora and fauna as part of biodiversity. Friends of the Earth also submitted that Maori are entitled to special assistance under Article 19 of the CBD (quite apart from the Treaty of Waitangi) to preserve and protect their rights to indigenous resources

and processes. The submission also noted that the CBD and the 1992 Rio Declaration on Environment and Development stated the right of all persons to a healthy environment consistent with the right to develop these resources; because corporates and researchers in genetic modification could not guarantee environmental safety, New Zealand could find its ability to comply with the Convention compromised, presumably if New Zealand allowed environmental release of genetically modified organisms and products.

Royal Society of New Zealand [IP77b (social sciences)] in its submission also stated the view that threats to New Zealand's unique biological diversity might also threaten its national and cultural identity.

Ethical considerations of international obligations

Several submitters raised ethical considerations when discussing New Zealand's international obligations and their implications in relation to genetic modification.

Royal Society [IP77b (social sciences)] pointed out that, although signatories to international agreements such as those under the WTO could not set standards or regulations to protect their domestic industries, a number of developed countries had been adopting the "precautionary principle" in relation to environmental and food safety risks of imports, while many developing countries did not have effective regulatory mechanisms to ensure or prove their products met international standards. Because of contradictions in the WTO approach to the genetically modified food debate, attempts to harmonise trade and product safety rules had actually consolidated and legitimised centuries-old trade barriers "between the First and Third Worlds". The Society went on to submit that New Zealand had obligations under the CBD to protect biodiversity and the values of tangata whenua. It pointed out that intellectual property rights, which were inherent in the development of biotechnology, might have the effect of hindering sustainable development in less developed countries and could also threaten biological diversity.

Submissions from Public Questions Committee (Methodist, Presbyterian, Churches of Christ, Quaker) [IP93], Interchurch Commission on Genetic Engineering [IP49], Pacific Institute of Resource Management [IP84] and New Zealand National Commission for UNESCO [IP90] echoed these concerns. These submitters stated it was important that decision-makers remember that New Zealand's international obligations extended beyond free trade agreements, to sustainable development, maintaining biodiversity, respect and protection for

indigenous communities' knowledge and practices, and a commitment to equitable sharing of the benefits of sustainable development. They further commented that all and any claims for the benefits of genetically modified organisms and genetically modified products and medicines had to be open to full and careful public scrutiny.

Environmental protection

Several submitters referred to the Convention on Biological Diversity and its first protocol (the Biosafety Protocol) as the most significant of the relevant international instruments relating to environmental issues and genetic modification. They all noted that the "precautionary approach" was the essential principle or feature of the CBD and the Protocol.

Greenpeace [IP82] submitted that the principle was triggered in cases where there was potential for serious or irreversible harm. Policy-makers were not required to prove to a level of scientific certainty that the threat of serious or irreversible harm would be realised: rather, they needed to show that, on the basis of current scientific understanding, the identification of the threat was justified. Greenpeace also submitted that the Biosafety Protocol was the last agreement in time ("lex posterior" in legal terms) and the most specific instrument addressing genetically modified organisms and living modified organisms (LMOs). According to legal principles, "generalia specialibus non derogant" (ie, the general does not override the specific). Therefore, the parties to the Protocol intended that it, as the latest and most specific agreement dealing with genetically modified organisms, should prevail over a more general instrument such as the SPS Agreement dealing with general sanitary and phytosanitary issues.

Other submitters such as organic producers, consumer networks and other environmental groups were also of this view that the Biosafety Protocol would allow the invocation of the precautionary approach to permit restraints on the import, development or release of genetically modified organisms in New Zealand.

Green Party of Aotearoa/New Zealand [IP83] submitted that the Biosafety Protocol did not override, nor was overridden by, WTO trade rules. Its submission argued that the WTO required non-discriminatory practices: for example, a country could not ban imports of Bt corn when its own farmers grew it. Green Party was of the view that, in the event that a ban on genetically modified organisms were taken under dispute to the WTO, the trade discrimination or barriers issues would have to be balanced against the right to protect consumers

and the environment from possible risk, taking into account the precautionary principle. It submitted that the WTO was "in a state of flux" over the approach it should take on trade restrictions based on genetic modification concerns.

Greenpeace [IP82] noted that recent decisions under Article XX of the General Agreement on Tariffs and Trade (GATT) (delivered by the WTO's Appellate Bodies on restrictions imposed for environmental reasons) explicitly stated that: "Members have a large measure of autonomy to determine their own policies on the environment (including its relationship with trade), their environmental objectives and the environmental legislation they enact and implement. So far as concerns the WTO, that autonomy is circumscribed only by the need to respect the requirements of the *General Agreement* and the other covered agreements."[1]

New Zealand's international reputation and relations

Some submitters raised concerns about the effect on New Zealand's international reputation and credibility as an innovative and knowledgeable member of the international community if genetic modification were banned or restricted in this country.

Although Dairy Board [IP67] did not specifically identify the CBD, it did submit that New Zealand must not jeopardise its credibility and reputation by breaching either the spirit or the letter of international obligations and creating unjustifiable barriers to trade. The Board noted that its experience with international trade regulation led it to believe that some trading partners might well be using genetic modification concerns tactically to disadvantage New Zealand in bilateral trade negotiations or by invoking WTO dispute procedures. The Board believed that New Zealand was well placed to set an example on the achievement of compliance with international obligations while protecting the country's interests.

New Zealand Grocery Marketers Association [IP54] noted that, although New Zealand was presently a non-ratifying party to the Biosafety Protocol and therefore not bound by it, application of the Protocol required that New Zealand did not do anything to defeat its aims and purposes. However, the association felt that the quarantine issues associated with the trans-boundary movement of living modified organisms and genetically modified organisms were provided for under Ministry of Agriculture and Forestry (MAF), ERMA and ANZFA regulation, so

[1] 20 May 1996. *Gasoline Appellate Report*, AB-1996-1, WT/DS2/9: 30. (Available through WTO Document Dissemination Facility at http://www.wto.org/)

the Protocol would have little effect on the current arrangements, "almost to the point of being unnecessary".

Further to the debate on the precedence of international instruments (see above, "Environmental protection"), New Zealand Arable-Food Industry Council [IP56] submitted that the Biosafety Protocol did not supersede the WTO SPS Agreement, although the Council did accept that the Protocol implicitly endorsed the precautionary approach, and that governments might justify trade restrictions on the basis of risk assertions, "even where there is no credible evidence that a risk exists".

The Council took the view that, under the rules of the SPS Agreement, if the precautionary principle were invoked to justify restrictions in the absence of scientific evidence this could be only a temporary measure. The Council submitted that if the New Zealand Government imposed such restrictions, the onus would be on it to find the evidence necessary to make a science-based judgment. It also submitted that Government should base its risk assessment of genetic modification on probable, not hypothetical, risks, and oppose international protocols or agreements that "violate scientific principles".

Vegetable and Potato Growers' Federation/Fruitgrowers' Federation/Berryfruit Growers' Federation [IP75] noted in the joint submission that Article XX of GATT was an important exception to the WTO agreements. (Article XX states that GATT should not be construed to prevent the adoption or enforcement of measures necessary to protect human, animal or plant life or health, or of measures relating to the conservation of exhaustible natural resources, if such measures are made effective in conjunction with restrictions on domestic production.) Given this provision, the Federations believed that New Zealand had an ability to argue against the importation of genetically modified products, just as another member country might for New Zealand exports. The Federations urged that New Zealand should be conscious of decisions or influences by trading partners arising from New Zealand's stance on genetic modification that might limit New Zealand exports.

Several other submitters from industry sectors focused on the WTO and UN standards bodies, such as the Codex Alimentarius, and did not mention the CBD and its Biosafety Protocol or, if they did identify them in their recitals of the relevant agreements, did not discuss in any detail the implications in relation to these instruments of New Zealand's approach to genetic modification.

Dairy Board [IP67] submitted that an influential though small country such as New Zealand could add to, and take important information from, the collective knowledge of the international organisations responsible for genetic modification.

The access to the expertise in science and risk management was important to New Zealand, and its effective utilisation required New Zealand companies and individuals, as well as government, to develop and maintain international contacts and alliances.

The Board noted that New Zealand also had acknowledged expertise and positions in certain international fora (eg, the chair of Codex Committee for Milk and Milk Products) and the Board's submission was that these positions and alliances might be endangered by adoption of a position in relation to genetic modification that cut New Zealand out of the international community.

section 3.10 |

appendix 2

Outcomes of Consultation: Submissions from Interested Persons

Section contents

3.10 Liability issues

Introduction

The Warrant under item (e) called for information on:

> 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

The issue of liability arises in relation to genetic modification as a result of questions of liability regarding any adverse, or unintended effects from the use of genetic modification technology.

Thirty-three submitters made substantive comment on the issue of liability. Of these 33 submitters, the highest number were from the economic/productive sector (15 submitters), followed by the environmental sector (seven submitters) and the health sector (three submitters). Only two submissions were received from groups with a cultural or ethical focus. The remaining six submitters were from other sectors, such as governance.

The 33 submitters were from various types of organisations, with the most notable being industry associations or networks (six submitters), followed by research organisations (five submitters), advocacy networks (five submitters), private companies (four submitters), consumer groups (four submitters), Maori groups (four submitters) and the remaining submitters comprising government, organic and "other" organisations. No religious organisations made substantive comment on the issue of liability.

Of the 33 submitters offering comment on liability, the stance on genetic modification was polarised, with a higher proportion taking a 'strongly for' stance (15 submitters) compared with those who were 'strongly against' (eight submitters). The remaining submitters were almost evenly distributed between the 'tending to be for', 'neutral', or 'tending to be against' stances on genetic modification.

The key themes on liability that were identified by submitters included:

- establishment of liability
- types of liability

- regulatory framework for liability
- liability insurance.

Each of these themes is discussed below.

Establishment of liability

Submitters presented a range of views on how to establish liability and identify liable parties. Comments on this theme covered these aspects:

- nature of the effects of genetic modification
- differing approaches to liability
- government responsibility
- government liability if genetic modification is not allowed
- "polluter-pays" approach to liability
- liability of beneficiaries
- European decision on liability.

Nature of the effects of genetic modification

Submitters commented on the nature of the effects of genetic modification activities that could pose problems in establishing liability. The principal difficulties identified were that:

- effects might be identified only in the longer term
- effects might be diffuse
- the extent of the effects might be difficult to establish.

Twelve submitters commented on the difficulties in establishing liability where the impacts are diffuse or where the effects might take a long time to become evident. Bio Dynamic Farming and Gardening Association in New Zealand [IP61] commented that the law should provide for long periods of liability, such as 30 years after the event. Parliamentary Commissioner for the Environment [IP70] made the point that liability frameworks should be "ongoing in perpetuity" as effects of genetic modification might become evident only in the long term. Greenpeace New Zealand [IP82] and Safe Food Campaign [IP86] also commented that liability that may eventuate from genetic modification could be hard to trace and to attribute because of time delays.

Landcare Research [IP12] noted: "… risks and liabilities for use of GM products to control wild populations of pests will be widely distributed in space … Possums, for example, occupy more than 95% of New Zealand."

Bio Dynamic Farming and Gardening Association [IP61] commented on the wide-ranging effects possible if genetically modified organisms were released into the environment, when costs might be incurred by "innocent bystanders", such as those "whose health is damaged such as by allergens" and those "whose livelihood is damaged by contamination", such as organic, biodynamic and other farmers, as well as "the public generally, where eradication or environmental degradation is caused".

In addition, Safe Food Campaign [IP86] thought it was unlikely that any harm that might eventuate from genetically modified foods or genetically modified organisms could be traced back to the producer because of the complexity of the task. Friends of the Earth (New Zealand) [IP78] raised the issue that liability might be "incalculable" and stated:

> It is possible that the nature and scale of the harm which could be caused by GM products may be such that no amount of financial compensation or punitive action will undo the damage.

Differing approaches to liability

Environmental Risk Management Authority (ERMA) [IP76] outlined two philosophical approaches to liability, one where the state relieved people of the liability of unexpected results ("socialisation of risk") and the other where the operator must accept liability.

Nelson GE Free Awareness Group [IP100] was of the opinion that "at present we have a situation in New Zealand where liability is neither assumed by the company, or regulatory agency" and that the public was left to "pick up the bill" in the event of any problems arising from genetic modification field trials. Public Questions Committee (Methodist, Presbyterian, Churches of Christ, Quaker) [IP93] commented that, where there was no certainty as to who would accept liability for consequences, "importation of any products or processes that involve risks" should be prohibited.

Government responsibility

Interchurch Commission on Genetic Engineering [IP49] noted that government bodies that approved the use of genetically modified products, as well as those that manufactured them, would be legally and financially responsible for "any adverse effects, to individuals or to the environment, which result". Pacific Institute of Resource Management [IP84] also noted that the "state should be originally responsible and made liable for all activities carried out by private entrepreneurs" and made comparisons with nuclear conventions where the state "bears ultimate responsibility if the operator is unable to make full payment".

Landcare Research [IP12] commented that the "liabilities associated with GM products for pest control should fall on government as the primary user". However, Eubios Ethics Institute [IP96] noted that unless government regulatory authorities were found to be negligent for a known risk they should be exempt from liability.

ERMA [IP76] noted that "if the Government wishes to be proactive in encouraging innovation, then … it may well decide to bear … a large part of the risk".

Government liability if genetic modification is not allowed

Several submitters raised the issue that Government might be exposed to some level of liability if it decided not to allow genetic modification. New Zealand Life Sciences Network [IP24] and Federated Farmers of New Zealand [IP34] commented that there would be some liability on Government "should it decide to stop what has hitherto been a legitimate commercial pursuit".

New Zealand Organisation for Rare Diseases [IP98] and New Zealand National Commission for UNESCO [IP90] noted that Government could face liability issues from the lack of use of beneficial genetic modification technology in the health arena. Both of these submitters gave the example of the "significant claim" against Government where it failed to introduce hepatitis C screening when first internationally available. Auckland Healthcare Services [IP91] stated that if the use of genetic modification technology was restricted in medical science then "healthcare professionals are likely to find themselves in breach of a number of consumer rights under the Code of Health and Disability Services Consumers' Rights", such as rights to services that optimise quality of life and allow informed choices.

"Polluter-pays" approach to liability

The philosophical approach to liability that the operator should bear responsibility (also known as the "polluter-pays" approach) was presented by a range of submitters. Thirteen submitters noted that there were difficulties in making the polluter pay where there is contamination.

Meat Industry Association of New Zealand [IP32] commented that the "producer of a product always remains liable for the failure of that product to be fit for purpose" and did not think that would change with gene technology. Nelson GE Free Awareness Group [IP100] concurred with this view, noting that "the onus should rest on all companies to prove the safety of their products". Eubios Ethics Institute [IP96] noted that the ethically responsible approach to liability is that the polluter pays.

The increasing emphasis in environmental legislation to impose a "polluter-pays" regime was highlighted in the submission by Carter Holt Harvey/Fletcher Challenge Forests [IP17] which also noted that experience with this approach to contaminated sites had proved the difficulty of identifying the liable party. Friends of the Earth [IP78] commented that in the short term liability should rest with corporations that produce genetically modified products. Golden Bay Organic Employment and Education Trust [IP104] was of the opinion that "the biotechnology industry should be held 100 percent accountable for any harm caused to people, the soil, the air, the water, …" and that the use of genetic modification should end until liability was fully established. Maori Congress [IP103] summed up the polluter-pays position on liability with its comment that:

> The worst case scenario is that we could be faced with the privatisation of our genetic heritage — the corporate enclosure of our genetic commons — without the protection and knowledge that the polluter–biopiracy agent must be liable.

Sustainable Futures Trust [IP51] noted that "we should not create a culture of non-responsibility" with respect to genetic modification. Federation of Maori Authorities [IP69] commented that liability for release of harmful organisms/genetic material lay in the hands of the applicants responsible for the project. Bio Dynamic Farming and Gardening Association [IP61] agreed that those who released genetically modified organisms or intentionally used them should be held liable for the effects, but noted that "this is insufficient protection, because it is likely to be impossible to recall a genetically modified organism once it is released".

Liability of beneficiaries

Several submitters, such as Green Party of Aotearoa/New Zealand [IP83] and Pacific Institute of Resource Management [IP84], stated that those who benefited from genetic modification should be prepared to reimburse costs to those harmed. Maori Congress [IP103] noted that:

> Should scientists wish to enjoy the benefits of their 'discoveries' and to reap the riches that intellectual property right patents may bring, they must also be prepared to deposit sufficient security to pay liability should their research cause health or environmental damage.

European decision on liability

Several submitters provided comment on a recent European decision where producers of genetically modified plants were absolved from liability.

Parliamentary Commissioner for the Environment [IP70] and Sustainable Futures Trust [IP51] cited a recent decision of the European Parliament that ruled by 287 votes to 202 **against** legislation that producers of genetically modified plants should be held legally responsible if the food products of these plants turned out to be harmful to humans or the environment. Although this legislation was voted down, Green Party [IP83] noted that the legislation "was intended to safeguard organic farmers, as well as giving Europeans the power to sue GM companies and force them to pay damages if they harmed health, the environment or livelihoods".

Types of liability

Submitters described different sources of liability arising in relation to genetic modification, as well as different categories of liability. They also provided some practical examples of differing types of liability.

Sources of liability

Submitters suggested that sources of liability might include situations where work involving genetic modification was not conducted in line with procedures, where there was a lack of monitoring or a breach of regulations. Other sources of liability noted by submitters included circumstances where the outcomes of genetic modification applications were foreseeable, as well as situations where outcomes were unexpected. New Zealand Dairy Board [IP67] identified two different types of "harm" from genetic modification: one where the "harm" might be reasonably foreseeable and the other where the "harm" might be entirely unanticipated. ERMA [IP76] commented that dealing with unexpected effects is "problematic" and the issue would be deciding how much risk Government would be willing to bear.

University of Canterbury [IP7] recognised two sources of liability: "those that could result from the conduct [of] GE work; and those that could result from inadequate monitoring of GE work overseas".

Association of Crown Research Institutes (ACRI) [IP22] noted that "where procedures are not followed" liability might arise, for example "environmental damage through the impacts of wild GM crops (or organisms) or through waste from GM production". Dairy Board [IP67] commented further that under New Zealand's existing laws "a person who causes damage (other than personal injury) to others, [has] a liability to compensate the persons suffering that damage, under the law of negligence or nuisance". In addition, the Board noted that, where statutory controls existed for an activity, liability might arise if such duties were breached.

Both Meat New Zealand [IP31] and New Zealand Game Industry Board [IP33] noted that "while potential liability resides in an escape or an unintentional spread of an organism", the most significant liability associated with genetic modification might be the potential for "loss" associated with New Zealand's "key strategic genetic assets" and "depletion of our scientific resource base".

Categories of liability

AgResearch [IP13] differentiated liability according to legal liability and civil liability, noting that there would be "legal liability for negligently allowing dangerous or harmful organisms or effects to damage people or the environment" and that "if a dangerous or harmful organism was released into the environment, it could give rise to civil liability for nuisance or negligence". New Zealand Life Sciences Network [IP24] identified two categories of liability, the first involving "compensation for reduction or cessation of existing rights to research and develop GM products" and the other comprising "civil liability for consequences of [a] major incident involving GMOs".

AgResearch [IP13] and New Zealand Biotechnology Association [IP47] both identified the potential for loss of public standing or professional credibility as a form of liability in addition to legal liability and civil liability. Organic Product Exporters Group (OPEG) [IP53] provided a practical example of this form of liability noting that if organic products were "contaminated" by genetically modified elements then this would result in "loss of the organic certification for the product" and would lead to "a loss in the reputation of the company and the company's brand value", as well as having a "negative impact on the whole New Zealand organic sector's market reputation".

Practical examples

Submitters provided practical examples of situations where liability issues might arise in relation to genetic modification. Environment and Conservation Organisations of New Zealand [IP102] listed some of the current known liability issues as:

- Starlink corn
- contaminated seeds in Europe
- Monsanto prosecuting farmers for saving seed
- BSE crisis in England.

Federated Farmers of New Zealand [IP34] noted that "liability may arise from an event which has a health, safety or environmental impact, … [it] may also arise

from cross-pollination … [or it] may become an issue when immediate steps are not taken to adjust the regulatory regime in the event of new knowledge".

Meat Industry Association of New Zealand [IP32] commented that it faced potential liability issues whenever it sold products and that liability issues "will remain for any products that are based on gene technology". The Association also highlighted the need for New Zealand to consider the liability implications of "imported disease and pests and the risk of a 'gm disaster'".

ACRI [IP22] and Nelson GE Free Awareness Group [IP100] noted that liability might arise from the use of genetically modified products in the health arena. The latter commented: "The liability issues arising from medical uses of genetic engineering are immense and extremely varied." Haemophilia Foundation of New Zealand [IP48] raised the issue that "past errors associated with HIV and HCV" must not be "repeated with genetic technology in medicine" and suggested that a service advisory group that contained people with clinical problems likely to be impacted by genetic technologies should be set up to advise Government and Ministry of Health.

Several submitters made comment on cross-boundary contamination issues with respect to liability. Nga Wahine Tiaki o te Ao [IP64] stated that there was a "need to be wary … of cross contamination and infection of organic, clean crops and species". Golden Bay Organic Employment and Education Trust [IP104] commented that in the United States "genetic drift" was "one of the GM hot potatoes that nobody wants" and that "there are no existing regulations to deal with it". BIO-GRO New Zealand [IP58] also identified cross-boundary contamination in its submission as a potentially serious liability issue. In an accompanying witness brief, BIO-GRO noted:

> With corn pollen able to travel up to six miles, it is difficult if not impossible to determine who caused the contamination. Farmers are certainly not in the financial position to sue everyone within six miles of their farm … Cross pollination contamination opens the door for potential legal problems because a farmer doesn't know who to go after.

OPEG [IP53] also acknowledged the "potential financial and other losses that would arise from organic products and farms being contaminated by GM elements and the liability issues associated with these events". In particular, OPEG noted the potential for "loss of the ability to supply and access high value markets and the possible collapse of the organic industry" and commented that "legal avenues for compensation in such events are unclear".

Regulatory framework for liability

Submitters presented a range of views on regulating for liability in relation to genetic modification. Comments covered these aspects:

- necessity for specific liability provisions
- existing regulatory framework for liability
- adequacy of existing regulatory framework
- inadequacy of existing regulatory framework
- recommended changes to liability regulation.

Necessity for specific liability provisions

Several submitters commented that no specific liability provisions are needed for genetic modification. New Zealand Association of Scientists [IP92] noted that liability should not be different for genetically modified and non-genetically modified products and that "the issue of liability in relation to GM is fuelled by the erroneous belief that GM products and organisms are inherently dangerous". New Zealand Forest Research Institute [IP2] also commented that genetic modification technology should not result in any organism with a greater magnitude of risk compared with organisms produced by conventional breeding and that there was "no recognised liability for users of forest trees derived from conventional breeding". Monsanto New Zealand [IP6] concurred that liability for genetically modified organisms "should be the same for GM and non-GM plants", and stated that "there is no risk to GM plants that is specifically caused merely due to the fact that they are produced through biotechnology".

Aventis CropScience [IP14] also considered that no specific liability regime was justified for genetically modified organisms and cited the results of a global debate of international expert groups in the framework of Organisation for Economic Co-operation and Development, Food and Agriculture Organization and World Health Organization that concluded "products of modern biotechnology are not more or less dangerous than their traditional counterparts". New Zealand Biotechnology Association [IP47], Biotenz [IP25] and New Zealand Agritech [IP73] all commented that there was no reason for genetically modified organism technology to be treated differently from other technologies with respect to liability.

Existing regulatory framework for liability

AgResearch [IP13] identified some of the key regulations for liability that were in place under the existing Hazardous Substances and New Organisms (HSNO)

legislation, including:

> Section 109 of HSNO makes it an offence to knowingly import, release or possess a new organism without the appropriate approval. It is also an offence to fail to comply with any controls imposed by an approval. The penalty for any such offence is imprisonment for a term not exceeding 3 months or a fine not exceeding $500,000 …
>
> It is an offence under section 109 HSNO for a manufacturer, developer or importer of a new organism to knowingly fail to report any significant new information of any adverse effect of that hazardous substance or new organism … [this carries penalties] …
>
> … a Court may order the person who committed an offence against section 109 to mitigate or remedy any adverse effects on people or the environment (section 114(5) HSNO). The Court may also order that the new organism be destroyed (section 114(5) HSNO).

Meat New Zealand [IP31] and New Zealand Game Industry Board [IP33] also noted that "the HSNO Act provides for significant penalties".

Researched Medicines Industry Association of New Zealand [IP55] noted that, in addition to the HSNO legislation, New Zealand "has a variety of statutes, and the law of negligence, under which product liability issues can be pursued".

Adequacy of existing regulatory framework

Fourteen submitters made comment that the existing liability laws were adequate to deal with genetic modification. Forest Research Institute [IP2] stated that:

> New Zealand has a very comprehensive procedure to assess and minimise risk associated with genetic engineering. The HSNO Act specifies procedures for laboratories to follow to minimise risk. Further, the Act provides measures to minimise risk related to contained field trials of genetically engineered organisms.

ACRI [IP22] commented that "provided GM practitioners fulfil the obligations of the HSNO Act and the ERMA requirements, the current liability framework will be effective". Dairy Board [IP67] concurred that the existing law was adequate to deal with "any reasonably foreseeable harm" from genetic modification and noted "our law does not, and should not, seek to create a risk-free environment". New Zealand Life Sciences Network [IP24] commented that the existing liability regime which comprised "insurance contracts and law" was "sufficient to address potential risks" of genetic modification. New Zealand Feed Manufacturers Association/Poultry Industry Association of New Zealand/Egg Producers Federation of New Zealand [IP35] considered that there was no liability "with GE products that cannot be handled within New Zealand's current legislation", which it identified as involving labelling through the Commerce Commission and Australia New Zealand Food Authority (ANZFA), and safety through ERMA and the HSNO Act.

Inadequacy of existing regulatory framework

Sixteen submitters considered that the current liability law was not adequate with respect to genetic modification. Parliamentary Commissioner for the Environment [IP70] stated: "Liability issues are not resolved in New Zealand and are an important consideration in developing a strategic approach to GM technologies in New Zealand."

Greenpeace [IP82] and Green Party of Aotearoa/New Zealand [IP83] did not consider New Zealand's current liability regime to be adequate to deal with genetically modified organisms. Greenpeace commented: "Liability regimes are not equipped to redress the kind of damages wrought by the irreversible release of genetically modified organisms."

Dairy Board [IP67] considered that New Zealand's existing laws were not adequate in terms of liability "where damage is not reasonably foreseeable" and stated:

> The existing law does not necessarily provide a mechanism for transferring risks which are unforeseeable, from the persons suffering damage if it does occur to the persons obtaining the benefits of the technology.

However, the Board noted further that if laws were modified so as "to impose absolute liability on any person using GM technology for any harm, foreseeable or not", then the benefits of genetic modification might be lost "for fear of risks which will probably never happen". Therefore, it suggested that existing laws should not be changed but that appropriate risk management controls for genetic modification be adopted.

Federated Farmers of New Zealand [IP34] put forward a range of measures to control liability from unintended outcomes that did not include changes to the existing regulatory regime. These measures included: "working within legislative guidelines under HSNO", "adopting industry quality assurance programmes", "using trained and registered operators where appropriate", "applying comprehensive communication regimes" and "purchase of commercial insurance".

Greenpeace [IP82] considered "monitoring and absolute liability regimes will need to be established to address illegal importation of genetically engineered organisms or accidental contamination of imports". Te Runanga o Ngai Tahu [IP41] also made comment that "the issues of liability prove that monitoring has not been adequately addressed". Royal Society of New Zealand [IP77] cautioned against stringent legislative regimes noting:

> One argument against this sort of intensive regulation and legislation is that it will infringe on the individual liberties of farmers who want to gain a competitive advantage by using GM products. However, given the 'unknowns' surrounding GM, it seems only just

> that those who are not gaining financially from the products are protected from any possible adverse events.

Physicians and Scientists for Responsible Genetics New Zealand (PSRG) [IP107] noted "ERMA is inadequate to police this industry" and provided examples of transgressions in New Zealand in relation to genetic modification.

Recommended changes to liability regulation

Changes to liability regulation for genetic modification were recommended by several submitters. Pacific Institute of Resource Management [IP84] raised the issue that "liability and compensation clauses should be incorporated in any legislation relating to the use of gene technology as the risk of harm … is transnational in character and major in degree". Nelson GE Free Awareness Group [IP100] commented that "the public cannot be fully protected unless [there are] strict rulings covering liability issues" and suggested that "liability funds" such as those implemented in Spain be set up. Canterbury Commercial Organics Group [IP65] stated that:

> The Royal Commission … has a responsibility to establish full liability to companies developing GE technologies for economic and other losses caused by genetic drift and other environmental effects created through genetic engineering.

ERMA [IP76] made the point that there "is merit in having … a bond to cover the clean-up of adverse effects" and likened this proposal to provisions provided in the Resource Management Act 1991. The need for clarity as to who would meet the costs of unintended effects or accidents was a concern noted by Parliamentary Commissioner for the Environment [IP70].

Liability insurance

Another theme of the submissions was that of liability insurance in relation to genetic modification. Submitters commented on: availability of liability insurance, New Zealand's position on liability insurance and international approaches to liability insurance.

Availability of liability insurance

Several submitters, principally those from environmental organisations, raised the issue of liability insurance in relation to genetic modification. The key issue raised was that "problems" arising from genetic modification activities might be too great to be covered by liability insurance.

Friends of the Earth [IP78] made comment that there was a "strong possibility that liability insurance will not be available to manufacturers of GM products". Safe

Food Campaign [IP86] noted further that "scientific uncertainty surrounding [genetic modification] and the threat of serious and irreversible harm … defies liability concepts of bonds or insurance".

Greenpeace [IP82] also raised the issues that "society cannot simply rely on insurance to cover all risks" and that genetically engineered products "could cause such enormous insurance problems" that "insurance companies cannot be relied upon to shoulder the burden". PSRG [IP107] supported this view and made the point that "hazards" arising from genetic modification may not be able to be quantified and therefore not insured, stating:

> No insurance companies will provide indemnity against the eventuality of harm arising from a genetically engineered organism. This is because the potential hazards cannot be assessed let alone quantified.

New Zealand's position on liability insurance

ERMA [IP76] commented that public liability insurance "to date has been … at the discretion of the approval holder" and that taking out a bond or public liability insurance could be regarded as an unnecessary compliance cost. Parliamentary Commissioner for the Environment [IP70] noted that "the insurance industry in New Zealand does not yet have an official position on issues involving genetically modified organisms in the environment" but also added comment from an insurance industry spokesperson that "there is a general feeling amongst the industry that the risks involved with GMOs in the environment are just too great for insurance companies to accept". Nelson GE Free Awareness Group [IP100] also noted "insurance companies have refused to insure genetically engineered crops".

International approaches to liability insurance

Parliamentary Commissioner for the Environment [IP70] and Greenpeace [IP82] outlined several international approaches to liability insurance.

Greenpeace [IP82] noted the Insurance Council of Australia's position on insuring genetic modification, which was that "general insurers are reluctant to accept incalculable risks where it is difficult to predict what loss scenarios will arise". Greenpeace also mentioned the comments of Swiss Re, an "influential" European re-insurance company, which regarded genetic engineering as one of the most "exposed technologies of the future". Parliamentary Commissioner for the Environment [IP70] made comment on the insurance position in the United States where "the insurance industry has consistently refused to write policies covering liability for harm caused by genetically modified organisms".

appendix 2

Outcomes of Consultation: Submissions from Interested Persons

Section contents

3.11 Intellectual property issues

Introduction

The Warrant under item (f) called for information on:

> the intellectual property issues involved, now or in the future, in relation to the use in New Zealand of genetic modification, genetically modified organisms, and products

In the context of genetic modification, intellectual property (IP) may become an issue when people who develop novel processes or products using genetic modification technology seek intellectual property protection, primarily through patents and Plant Variety Rights (PVR).

Thirty-eight submitters made substantial comment on intellectual property issues. Over half of these submitters were from organisations in the economic/productive sector (22 submitters). The principal sector focus of other submitters making substantive comment on this issue included the environmental sector (five submitters) and cultural/ethical sector (four submitters), with the remaining submitters being from a range of other categories. The most notable category, in terms of submitter type, was industry associations/networks with 13 submitters commenting on intellectual property issues. Other significant groupings of types of submitters commenting on this issue included research organisations (five submitters) and Maori organisations (five submitters out of a total of six Maori submitters).

With reference to the stance on genetic modification taken by the 38 submitters offering substantial comment on intellectual property issues, it was evident that more of these submitters were in favour of genetic modification than against. Half of the 38 submitters took a 'strongly for' stance on genetic modification, with far fewer (eight submitters) taking a 'strongly against' stance on genetic modification and the balance spread almost evenly among the intervening categories of 'tending to be for', 'neutral' or 'tending to be against'.

Key themes

Submitters tended to address issues in relation to intellectual property around several key themes including:

- capture of innovation and development
- issues of public interest
- indigenous issues
- economic issues
- adequacy of current regulatory mechanisms.

These matters are addressed in the corresponding sections below.

Capture of innovation and development

Submitters provided commentary on how information from innovation and development of genetic modification is captured in intellectual property. Submitters made specific comment on the nature of patents, identifying that they had time limits, that they required disclosure of information, and that a range of uses could be patented.

Patents have a time limit

Association of Crown Research Institutes [IP22] pointed out that patents were only short term in nature and that "in general the intellectual property regime is designed to optimise the benefits by allowing exclusive private use for a limited period". New Zealand Biotechnology Association [IP47] also mentioned that "a granted patent restricts the ability of other parties to utilise the invention" and that "a patent creates only a limited term monopoly". Life Sciences Network [IP24] commented further, with respect to patents, that their "exclusive right is restricted in time to a maximum of 20 years and limited in scope to the invention disclosed in the patent".

Disclosure of information

Royal Forest and Bird Protection Society, Nelson/Tasman Branch [IP43] expressed the opinion that "intellectual property rights close up public processes and the availability of information" and noted concern that the public needed information to determine risks that "genetically engineered organisms" might have on the environment. However, Life Sciences Network [IP24] did not agree with this position and noted "patents require full disclosure and availability of the results of genetic modifications in return for the exclusive right granted". New Zealand Institute of Patent Attorneys [IP71] expressed the opinion on the contractual

nature of patents that:

> The grant of a patent has its basis in social contract … in return for public disclosure of information about an invention … the inventor receives a time-limited, exclusive right to commercially exploit the invention.

What can be patented?

New Zealand Institute of Patent Attorneys [IP71] identified that "a gene in its natural state cannot be patented but once research is done to isolate the gene and identify its function this may be patented". Monsanto New Zealand [IP6] commented: "Patents relating to gene technology are process patents rather than patents of genetic codes … the 'code of life' is not patented, rather the process that expresses the code."

Submitters provided examples of the use of patents across different industries. Researched Medicines Industry Association [IP55] expressed the view that intellectual property protection "is the cornerstone of the pharmaceutical and biotechnology industries" and "is essential to the availability of new medicinal therapies". New Zealand Dairy Board [IP67] identified that "biotechnology patents are increasing exponentially worldwide". New Zealand Transgenic Animal Users [IP45] made comment that "patenting of GM animals is a contentious and complex issue that is not yet fully resolved" as it raises issues of debate around the ethics and morality of "patenting life". Another example of patenting of a genetically modified product was provided by Nelson GE Free Awareness Group [IP100], which noted that "Vitamin A ['Golden'] rice developed … by public sector worldwide research" was "covered supposedly by 70 patents".

Issues of public interest

A range of submitters, mainly from religious, environmental and Maori organisations, expressed views on what might be acceptable to be patented and what should not be able to be patented for ethical and moral reasons.

Patenting of human genetic material

Fifteen submitters raised issues around the potential for privatisation of genetic material and seven submitters made specific comment on the patentability of the human genome.

Submitters, principally from religious, environmental and Maori organisations, expressed the view that human genetic material should not be able to be patented. Interchurch Commission on Genetic Engineering [IP49] remarked that its

members "affirm turning down patents for human genetic material, on spiritual grounds [because] we belong to God". However, it did note that, although against patenting human genes, it would accept "patenting of specific applications using genetic information".

A range of groups concerned with environmental issues (including Friends of the Earth (New Zealand) [IP78], Nelson GE Free Awareness Group [IP100], Golden Bay Organic Employment and Education Trust [IP104], and Safe Food Campaign [IP86]) were all of the opinion that life forms should not be patentable. Green Party of Aotearoa/New Zealand [IP83] also recorded "strong objection" to patenting of life and the Maori Congress [IP103] noted its fears that "patenting of life forms" may happen. Greenpeace New Zealand [IP82] supported these views and sought "a halt to the granting of any patents on life, its parts, products and processes".

Federation of Maori Authorities [IP69] advocated that patents should not be able to be held on "organs, cells or proteins of naturally occurring organisms". The Green Party [IP83] objected to patents on "genes, cell lines and new organisms" and considered that "only genetic processes should be patented". In a similar context, Physicians and Scientists for Responsible Genetics New Zealand (PSRG) [IP107] stated that granting patents on genes was "totally unjustified or unjustifiable" and that such patents "threaten food security and violate basic human rights and dignity". PSRG commented further: "Intellectual property law has been developing using a set of concepts and precedents [that] cannot be applied to living organisms or genes."

Moral aspects of patenting

Submitters from a range of organisations raised moral questions in relation to patenting. Friends of the Earth [IP78] believed that the "moral components of patents should be recognised". Eubios Ethics Institute [IP96] was also of the opinion that the "morality of patents is one of the more controversial aspects of biotechnology". Similarly, Maori Congress [IP103] noted that it was "unethical that intellectual property rights are being discussed in isolation of ... ethical and moral observations". Association of Crown Research Institutes [IP22] considered that: "Most of the concerns about patenting GMOs are values-based [and] not benefit-based."

Auckland Uniservices [IP23] commented that, although "there may be issues around the ownership of human DNA sequences … this is an international, not a national matter to resolve". Greenpeace New Zealand [IP82] also highlighted the fact that internationally many governments were looking more deeply at the implications of allowing the patenting of life.

Nelson GE Free Awareness Group [IP100] raised questions as to the ethics of some intellectual property issues relating to genetic modification. This group asked what access "may in future be granted" to the national "heel prick DNA data".

New Zealand Institute of Patent Attorneys [IP71] concurred that "wide-ranging moral questions have been raised about genetic modification" and noted that "the issues are not specific to the patent system and are better addressed by legislative controls". The Institute identified that section 17 of the Patents Act allowed refusal of a patent application "on the grounds that it is contrary to morality" and noted that "the administration of the patent system is not the appropriate place" for such decisions to be made. The Institute also commented that "action is needed to clarify ... patentability of humans and intellectual property rights of indigenous peoples".

Ethics versus economics

Public Questions Committee (Methodist, Presbyterian, Churches of Christ, Quaker) [IP93] noted concern about the "effect of the profit motive on genetic research and the development of genetic organisms" and expressed the opinion that "ethical criteria must always outweigh commercial considerations". Maori Congress [IP103] also commented that "it is ethically wrong that genetic heritage could be owned by a handful of companies and government research institutes".

Indigenous issues

Submitters raised a series of intellectual property issues specifically related to indigenous species or of concern to indigenous peoples, including:

- patentability of indigenous flora and fauna
- the WAI 262 claim
- western views and indigenous views on property ownership
- international approaches to indigenous issues.

Patentability of indigenous flora and fauna

Ten submitters raised issues relating to the patentability of indigenous flora and fauna.

Environmental Risk Management Authority (ERMA) [IP76] made the point that "the issue of 'ownership' of genetic information" is a matter of intense debate and rejection of the notion of ownership "is particularly deep within indigenous peoples". Te Runanga o Ngai Tahu [IP41] observed that "intellectual property

issues in relation to genetic modification are [of] concern to iwi" and needed more attention before decisions were made. Royal Society of New Zealand [IP77b (social sciences)] commented that "Maori stated quite specifically that genetic information is owned by whanau, hapu and iwi". The Society also noted that there "are substantive issues about whether scientific views of genetic information are relevant to Maori, who map their being through whakapapa, which can never be alienated".

One of the principal concerns raised by Ngai Tahu [IP41] was that patenting traditional knowledge and use of products removes ownership from indigenous people. Ngai Tahu stated that:

> While traditional knowledge and use, including medicinal use of indigenous flora, could provide economic benefit for indigenous peoples, the fact of patenting a process, or slightly modifying an indigenous species so that it is a new organism, serves to steal these opportunities and ownership away from indigenous people.

Federation of Maori Authorities [IP69] stated that it did not support "the claiming to ownership of species or varieties of naturally occurring organisms by individuals, companies or organisations" but did consider that the existing legislative framework "should include the protection of traditional knowledge of native flora and fauna by Maori". An alternative view was presented by Royal Forest and Bird Protection Society, Nelson/Tasman Branch [IP43], which noted that it did not support any form of property rights for indigenous species. The Society commented "indigenous flora, fauna and fish belong here in their own right" and that "they do not belong to any person". This group remarked further that "we have guardianship and the responsibility to keep nature intact for the future".

Submitters raised a number of other issues on the patenting of indigenous flora and fauna. New Zealand Wool Board [IP30] considered that for indigenous species there was a need "to develop a just and efficient property right to cover the genetic material and scientific discoveries relating to it". Safe Food Campaign [IP86] expressed "concern" about the possibility of intellectual property rights for indigenous species being held offshore. Association of Crown Research Institutes [IP22] expressed the opinion that "Maori concerns over GM exploitation of indigenous species can be met through the current legislation".

WAI 262 claim

Several submitters raised the issue of the WAI 262 claim[1], which relates to the ownership by Maori of the genetic material from indigenous flora and fauna. WAI

[1] The WAI 262 Indigenous Flora and Fauna Claim was registered with the Waitangi Tribunal in December 1991.

262 claimants, Ngati Wai, Ngati Kuri, Te Rarawa [IP89] outlined that "intellectual property issues are a primary focus of the WAI 262 claim to the Waitangi Tribunal". The Claimants identified some of the "concerns" involved in the claim:

> In New Zealand burgeoning industries such as pharmaceuticals have created concerns amongst Maori, and in particular WAI 262 claimants, about the proprietorial rights being asserted over plant and genetic resources.

ERMA [IP76] noted that "in the New Zealand context, the WAI 262 claim is the strongest possible expression of Maori feeling toward ownership of native flora and fauna". Ngai Tahu [IP41] considered that: "There is inadequate legal protection of traditional biodiversity-related knowledge."

Royal Society [IP77b (social sciences)] also raised the issue of the WAI 262 claim, commenting that it was an important case relating to New Zealand's biodiversity and outlined that the claim sought "to re-establish te Tino Rangatiratanga in respect of the knowledge of native plants and animals and cultural taonga".

Landcare Research [IP12] noted that it had developed specific policies about intellectual property in New Zealand "which respond to the issues raised in the WAI 262 claim" and that such policies included "not seeking an ownership position in native flora- and fauna-based intellectual property until the WAI 262 claim is resolved".

Interchurch Commission on Genetic Engineering [IP49] identified a key principle of the United Nations Convention on Biological Diversity ("that each country owns its own genetic resources") which carried with it an obligation that "intellectual property rights be respected". The Commission's view differed from that of WAI 262 claimants, as the Commission was of the view that indigenous resources belong to all New Zealanders, and stated:

> The genetic resources of New Zealand inherent in our indigenous flora and fauna belong to all New Zealanders under the partnership Treaty, and any granting of access to those resources must be done in accordance with Treaty obligations.

New Zealand Institute of Patent Attorneys [IP71] expressed the viewpoint that, although Maori were seeking clarification of the extent of their control over indigenous genetic resources through the WAI 262 claim, the Institute did not consider this approach to be compatible with the existing patent system. The Institute recommended that New Zealand took an active role in the World Intellectual Property Organization to attempt to develop "a separate international instrument on protection of traditional knowledge and folklore".

An issue of concern raised by Greenpeace New Zealand [IP82] was that Government intended to reform the Patents Act 1953 but that the timetable for this review pre-empted the WAI 262 claim which was lodged in 1991.

Western views and indigenous views on property ownership

A range of submitters, mainly Maori and environmental organisations, discussed the differing perspectives of indigenous people and western approaches to property ownership. The following viewpoint provided by Ngai Tahu [IP41] outlines the differing approaches to property ownership:

> At the core of such intellectual property issues there is a fundamental difference between the western based "private ownership approach" and that of indigenous communities such as iwi. The intellectual property approach adopts the inappropriate application of the term property to traditional resources of indigenous communities. This concept of ownership and the ability to transfer ownership which are fundamentally common law notions of property are foreign and incomprehensible to indigenous people such as iwi.

WAI 262 claimants [IP89] commented further that "the western intellectual property rights (IPR) legal system has increasingly found itself on a collision course with the cultural and intellectual heritage rights system of indigenous and traditional peoples" and noted that there were "fundamental differences" in the ideological underpinnings of these two approaches. The Claimants noted: "The IPR system is concerned with private economic rights whilst those of indigenous peoples are collectively based ..."

Federation of Maori Authorities [IP69] made the point that "traditional knowledge of New Zealand's taonga should be recognised as taonga in itself and receive protected status". Greenpeace New Zealand [IP82] commented that the patent system does not recognise traditional knowledge of indigenous peoples. Along the same lines, Safe Food Campaign [IP86] expressed the view that intellectual property rights "belong within a reductionist paradigm that fails to take account of the interconnectedness of life". In addition, Ngai Tahu [IP41] pointed out that "indigenous knowledge is transgenerational and communally shared".

Royal Society [IP77b (social sciences)] made reference to "the Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous Peoples" which recognised "that indigenous peoples are the guardians of their customary knowledge and ... have the right to create new knowledge based on cultural traditions". With regard to this declaration, WAI 262 claimants [IP89] expressed the view that this "Draft Declaration on the Rights of Indigenous Peoples is the most important statement of basic principles for protection of their rights".

Nga Wahine [IP64] commented that "anything created in Aotearoa will be subject to Maori claims for ownership as kaitiaki". Nga Wahine commented further "we will continue to exercise our rights as Maori and prevent the

introduction of GM and GMO experimentation into Aotearoa".

International approaches

Submitters made comment on a number of international treaties and conventions that affect indigenous people and indigenous resources. Biotenz [IP25] commented: "New Zealand should continue to argue internationally for IP laws which continue to give indigenous people access to their traditional uses of biological products." Maori Congress [IP103] expressed concern in relation to international treaties that might result in patenting of indigenous resources and stated:

> ... international treaties such as WTO and the Convention on Biological Diversity legally codify the right of gene hunters to seize and patent the bodies and resources of indigenous people and it restricts the ability of governments to control or to regulate the process.

Pacific Institute of Resource Management [IP84] noted that a United Nations human rights body had called into question the impact of the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) "on the human rights of peoples and communities, including farmers and indigenous peoples worldwide".

Economic issues

Submitters, principally those who were users of biotechnology raised certain economic issues on intellectual property including:

- investment costs and returns
- cost to access intellectual property.

Investment costs and returns

New Zealand Biotechnology Association [IP47] made comment that "patents are property and can be bought and sold". New Zealand Dairy Group [IP88] identified an increasing interest in "the role of intellectual property in wealth creation". AgResearch [IP13] also made the point that intellectual property rights allowed investors to obtain an economic return from their investment, and noted that the granting of patents covered "not only production processes but the products from those processes". From a differing perspective, Dairy Board [IP67] commented that "the ability to patent intellectual property is the commercial driver that leads to new scientific discoveries".

Monsanto [IP6] highlighted the magnitude of investment, noting that its intellectual property is the "outcome of billions of dollars of investment in biotechnology" and made the point that although it selectively protected its

intellectual property, it "currently shares, free of charge, a substantial amount of intellectual property". Similarly, Agcarm [IP29] estimated that data packages required as part of the Environmental Risk Management Authority's approvals process "can cost well in excess of $100 million to generate and are of considerable commercial value". Researched Medicines Industry Association [IP55] outlined the significant investment in medical industry intellectual property and commented that "without solid IP protection, companies could not afford to invest the average of over $US500 million per product that reaches the market".

Cost to access intellectual property

Lincoln University [IP8], in an accompanying witness brief, made the point that, although "key GM techniques are freely available throughout the world", increasingly "applications of the technology are becoming proprietary in nature". Dairy Board [IP67] commented that intellectual property in many areas of genetic modification "is already closed off" and gaining access meant paying royalties. It noted that "currently the Roslin Institute in Edinburgh owns most of the intellectual property involved in the production of cloned or transgenic animals". The Board also identified that "there is a strong likelihood that the New Zealand dairy industry will be forced to carry additional costs to access the benefits of intellectual property".

Friends of the Earth [IP78] observed that biological scientists "no longer publish their preliminary results or freely discuss experiments" and identified concerns in relation to costs associated with patents, commenting:

> London Hospital, which provided cystic fibrosis tests for free, must now pay a royalty to the University of Toronto [which owns the patent on the cystic fibrosis gene] each time it tests a person for the disease.

A number of submitters raised the "freedom-to-operate" issue with respect to licence arrangements for intellectual property. AgResearch [IP13] noted: "Increasingly, the ability to apply new technologies in New Zealand will be subject to obtaining freedom-to-operate licence arrangements from the owners (often international) of intellectual property covering genes and transgene technologies". AgResearch also believed that the "ability to trade New Zealand-owned technologies will be an increasingly important means" of being able to obtain freedom-to-operate licence agreements.

Current trends in intellectual property

Submitters identified a series of current trends in intellectual property including:

- the 'race' to capture intellectual property

- the 'use it or lose it' trend
- the need for access to global intellectual property
- ownership and control of intellectual property.

The 'race' for intellectual property

Submitters, principally those from the productive sector, highlighted issues around "the race" that is on to secure intellectual property derived from genetic modification applications. The following quote from New Zealand Wool Board [IP30] provides an example of sentiment on this "race" for intellectual property:

> If biotechnology is regarded as a race to assemble a "hand of cards", then IP is the formal name for what we are creating. As a new form of economic currency, the ability to buy, sell, trade and leverage gene knowledge (that may or may not involve GM) is crucial for advances in biotechnology, the technology that is expected to be one for the foundations for economic success in this century. As a biologically dependent economy this is especially so for New Zealand.

HortResearch [IP5] exemplified how this "race" for intellectual property might affect important crops:

> Around the world there is intense activity in high throughput sequencing of plant genes. The race is on to sequence the genes of important crops, determine the functions of important genes, and then to patent their utility. Once patented, the application ... is controlled by the patent holder, who may demand high licence fees for applications of the gene.

New Zealand Biotechnology Association [IP47] agreed that New Zealand "must remain competitive in the race to patent gene sequences" otherwise "it will be unable to compete on an international level [and would] have to pay licence fees". Safe Food Campaign [IP86] identified that since the advent of genetic modification the "use of patenting has expanded".

The 'use it or lose it' trend

Eight submitters raised issues around "biopiracy" in relation to intellectual property arising from genetic modification technology. University of Canterbury [IP7] observed a "disturbing trend" in the "loss" of intellectual property from New Zealand. The University stated that intellectual property was "flowing to countries with enlightened policies in teaching and research".

Meat New Zealand [IP31] and New Zealand Game Industry Board [IP33] stressed that "we must protect against others gaining intellectual property" and "use it or lose it". New Zealand Wool Board [IP30] agreed with this stance and commented "unless New Zealand captures, creates and utilises our own IP in gene knowledge,

other countries will simply take what they want".

HortResearch [IP5] made a similar point, noting "there is an urgent need to sequence and protect genes in crops of importance to New Zealand". HortResearch also commented that if New Zealand did not do this, "competitors elsewhere will beat us to patenting genes from crops important to New Zealand" and "industries will be asked to pay high licence fees … and lose the opportunity to exercise their autonomy and extend their competitive advantages".

Access to global intellectual property

Crop and Food Research [IP4] noted that "access to global IP is also key for New Zealand's economic development". Crop and Food Research identified difficulties in gaining access to global intellectual property, including where "major multinational biotechnology companies are restricting access to certain genes and tools of biotechnology through patents and other methods" and where the use of the intellectual property is for "commercial products" rather than for research. AgResearch [IP13] also commented "New Zealand will increasingly need to obtain rights to intellectual property held by international partners". In addition, AgResearch noted "access to key underpinning genomic patents will be essential if New Zealand is to be able to practise genetic modification technologies".

Federated Farmers [IP34] noted concern that farmers need access to intellectual property and that "as technology becomes increasingly privatised and patented internationally it is vital for New Zealand to develop its own intellectual property". Meat Industry Association [IP32] expressed the opinion that to date, in the pastoral industries, New Zealand had developed intellectual property as a result of New Zealand research. The Association was worried that "if New Zealand does not conduct the necessary research, it will either not be done, or will not be available for New Zealand to utilise". Dairy Board [IP67] also made the point that New Zealand must be able to obtain intellectual property from its research so that it could "protect and enhance its competitive advantage, … acquire royalties or licence fees, … acquire access to intellectual property".

Other producer groups, such as New Zealand Vegetable and Potato Growers' Federation/New Zealand Fruitgrowers' Federation/New Zealand Berryfruit Growers' Federation [IP75], agreed that "the ability to access and use protected intellectual property is critical", particularly as New Zealand is a small country to which "many key patents may not be extended". The Federations noted further that New Zealand researchers "must be able to maintain the ability to develop and protect their own IP" which they can use "as a bargaining tool to gain access

to multinational IP".

New Zealand Life Sciences Network [IP24] outlined what genomic information is in the public domain, stating that:

> Recent developments overseas suggest a new international consensus is developing which will accept that basic genomic information is in the public domain but that research organisations will be able to patent applications developed from that knowledge.

Ownership issues

Fifteen submitters discussed issues around the monopoly control of intellectual property by genetic modification patent holders. Environmental and other advocacy groups tended to express concern about the trend of increasing global control of gene technology. Friends of the Earth (New Zealand) [IP78] noted that "the patent system supports the development of international cartels" and that "six major industrial groups … control most of the technology which gives the freedom to undertake commercial R&D in the area of GM crops". Safe Food Campaign [IP86] highlighted the reliance of New Zealand farmers on transnational agrochemical companies and noted that five "gene giants" had "control over GM foods globally". Nelson GE Free Awareness Group [IP100] identified that, in 1999, "patents on life forms … reached a total of nearly 700, 56% of them American owned".

Specific ownership issues relating to indigenous resources have been addressed in the indigenous issues section.

Future opportunities for New Zealand

Submitters, principally from producer and research organisations, identified a range of opportunities that might result from the development of intellectual property. Twenty-three submitters noted specifically that New Zealand needed to capture its own intellectual property.

Intellectual property opportunities in the productive sector

Wrightson [IP3], in an accompanying witness brief, submitted that intellectual property would be "developed and traded" and that "acquisition of intellectual property is crucial to Wrightson's commercial success" and "provides the revenue necessary to undertake further research and development". New Zealand Veterinary Association [IP28] also identified opportunities for "creating value from intellectual property acquired during domestic research, development and

manufacture of GM-based animal remedies" and noted that such opportunities should be "preserved and if possible enhanced".

HortResearch [IP5] observed that New Zealand "has some of the best germplasm collections for kiwifruit, apples and berryfruit in the world" and that "HortResearch has established a genomics programme which aims to identify and protect genes/functions/products in these key crops".

New Zealand Wool Board [IP30] identified New Zealand's knowledge and expertise around the sheep genome as an opportunity "which needs to captured and utilised for the benefit of the country". The Wool Board also commented that the "creation and defence of IP around gene knowledge … will be a major strategic issue for the sheep industry". Similarly, Meat New Zealand [IP31] identified that New Zealand's "genetic resources in the form of sheep and beef genomes provide a unique window of opportunity to secure a strong position in developing large animal genomics programmes".

New Zealand Game Industry Board [IP33] made the point that "genetic resources in the form of the deer genome" provide opportunities, particularly as New Zealand "leads the world in identifying the deer genome". Both Meat New Zealand [IP31] and New Zealand Game Industry Board [IP33] commented that New Zealand "must establish a priority position in the ownership of critical IP". Dairy Board [IP67] identified the potential of "selling intellectual property to increase milk production in protected markets" as "one way of overcoming trade barriers".

Biotenz [IP25] and Agritech [IP73] both commented that "New Zealand must continue to develop intellectual property to ensure that we have the freedom to operate in the future" and that "failure to develop intellectual property will mean significant costs for New Zealand in the future".

Opportunities to trade intellectual property

In an accompanying witness brief, Lincoln University [IP8] expressed the opinion that the "potential for New Zealand to reap financial and social benefits from the development and ownership of [genetic modification] technology is great". Other opportunities to be derived from intellectual property identified by the witness brief were that "the development of such desirable technologies will permit New Zealand to trade this intellectual property on the international market" and that intellectual property "will represent the forerunner of Biocurrency, the currency of the future". Monsanto [IP6] also observed: "A potential impact for countries like New Zealand is that intellectual property may impact international trade patterns."

AgResearch [IP13] made the point that New Zealand must be able to trade in patented products, for example transgenic animals, otherwise it "will be locked out of international markets". Crop and Food Research [IP4] also noted that it had been able to use its own protected intellectual property as "a bargaining tool" to gain access to multinational intellectual property that might otherwise have been denied.

Regulation of intellectual property

Submitters raised issues around the regulation of intellectual property including:

- international agreements
- adequacy of the current regulatory framework
- future approaches to intellectual property.

International agreements

Submitters made reference to New Zealand's involvement in international intellectual property treaties and agreements, in particular the Agreement on Trade-Related Aspects of International Property Rights (TRIPS Agreement). New Zealand Life Sciences Network [IP24] pointed out that:

> New Zealand, as a member country of the World Trade Organization, is obliged to provide intellectual property right protection to the standards set in the Trade-Related Intellectual Property Rights (TRIPS) part of the WTO Marrakesh Agreement.

Life Sciences Network commented further that "New Zealand's intellectual property rights laws do meet these minimum standards". A range of other submitters, including Meat New Zealand [IP31], New Zealand Game Industry Board [IP33] and New Zealand Feed Manufacturers Association/Poultry Industry Association of New Zealand/Egg Producers Federation of New Zealand [IP35], all made reference to the fact that "New Zealand is party to international patent and other IP agreements" and noted that "it is important to protect our assets and leverage benefit from other IP owned outside of New Zealand".

Friends of the Earth (New Zealand) [IP78] expressed the opinion that the TRIPS Agreement "has shifted the balance too far in favour of property owners".

Current framework is adequate

A range of submitters considered the current regulatory system for intellectual property in New Zealand to be adequate. Carter Holt Harvey/Fletcher Challenge Forests [IP17] identified the current intellectual property regime as "sufficiently robust to protect true innovation and subsequent commercial advantage" and

noted that this regime included the "Trade Marks Act 1953; Patents Act 1953, Designs Act 1953; Fair Trading Act 1986; and Copyright Act 1994". Association of Crown Research Institutes [IP22] was also of the opinion that the current intellectual property regime "is effective". New Zealand Institute of Patent Attorneys [IP71] expressed the view that "the patent system has proven a robust form of intellectual property protection in the technological age".

Current framework is inadequate

Twenty-eight submitters considered that intellectual property issues relating to genetic modification were not adequately addressed. Submitters commented on operational difficulties with the current approval process for genetic modification applications processed through the Environmental Risk Management Authority (ERMA), as well as several other problems that legislation or regulation did not adequately address.

Seven submitters made specific comment on the loss of intellectual property and/or patentability because of the disclosure of confidential information during the review process. AgResearch [IP13] expressed concern at the level of information disclosure required for ERMA applications and was of the opinion that if the information were made publicly available then the "novelty" might be lost and intellectual property protection might not be able to be achieved. Meat New Zealand [IP31] and New Zealand Game Industry Board [IP33] also raised the issue of the requirement to provide descriptive information in ERMA applications and the possibility that the applicant "may lose the quality of novelty and thereby forfeit patent protection". Similarly, New Zealand Biotechnology Association [IP47] was of the opinion that "disclosure of information to ERMA … may result in intellectual property protection being unavailable".

On the issue of information disclosure, Agcarm [IP29] noted that "a better balance needs to be struck between competing interests" and that "applicants need to be able to better quantify their chances of success with an application".

New Zealand Institute of Patent Attorneys [IP71] agreed with the above submitters and noted that:

> … the protection for confidential information in regulatory approval processes for genetic modification and genetically modified organisms are inadequate and need to be urgently addressed.

Environmental Risk Management Authority [IP76] also expressed concerns that the Official Information Act and the Hazardous Substances and New Organisms Act (HSNO Act) did not "provide sufficient protection of commercially sensitive

information" and that "the mere identification of the organism on the public register could compromise commercial interests".

On a similar note, Agcarm [IP29] commented that unfair commercial use of information could arise from "cross-referencing by regulatory authorities … [and by] release to competitors, either directly, or indirectly by release to the public" and suggested that a data protection provision was needed in the HSNO Act. Agcarm also expressed concern regarding the provision under the Official Information Act where a decision to withhold information could be overturned by the Ombudsman, and noted the impacts this had for the release of information in ERMA applications. Agcarm suggested that the commercial information provisions of Australia's Gene Technology Bill 2000 (section 45) could present an example to follow. This Bill provides that the:

> Regulator must not use certain information in considering licence application If: (a) a person (the first person) applies for a GMO licence; and (b) the first person provides information to the Regulator for the purposes of the Regulator's consideration of the application; and (c) the information is confidential commercial information; the Regulator must not take that information into account for the purposes of considering an application by another person for a GMO licence, unless the first person has given written consent for the information to be so taken into account.

AgResearch [IP13] commented that the length of time required to complete the HSNO process caused a considerable reduction in the period for which patent protection was available.

Wrightson [IP3], in a witness brief, voiced concern regarding the Plant Variety Rights system and stated that the system put the protection of the company's intellectual property at risk. New Zealand Arable-Food Industry Council [IP56] was of the opinion that "New Zealand plant breeders can obtain protection for their cultivars under the Plant Variety Rights Act (1987)" but that this Act "requires revision to allow protection of GM cultivars". The Council raised the question "of whether GM cultivars and products can be protected by a patent in New Zealand". Friends of the Earth [IP78] provided an alternative view that New Zealand plant breeders' rights are "adequately protected" by the Plant Variety Rights Act.

Crop and Food Research [IP4] raised the issue that current patent laws mean that New Zealand cannot export products to jurisdictions in which the intellectual property is patented, noting:

> As NZ is a small jurisdiction with little market power, we have found that many key patents are not extended to New Zealand. While this gives us unfettered rights to use the

> knowledge for our own purposes within New Zealand, this is of limited use for an exporting country. Current applications of patent law mean we cannot export the products made with the protected IP to the jurisdiction in which that IP is patented.

Monsanto [IP6] made the point that "adequate legislative protection of intellectual property is fundamental" to its "participation in the New Zealand market".

Future approaches to intellectual property

Crop and Food Research [IP4] and Biotenz [IP25] made the point that whatever approach New Zealand adopted to intellectual property for genetic modification it must be consistent with the rest of the world. New Zealand Life Sciences Network [IP24] noted: "Intellectual property rights protection systems are internationally accepted as effective and essential economic tools."

University of Canterbury [IP7] raised the issue that "it is important that regulations minimise disincentives to the beneficial use of knowledge derived from GE". Dairy Board [IP67] also commented that it was "essential that New Zealand's policies and intellectual property laws enable the New Zealand dairy industry to capture the benefits of biotechnology research, including GM research". New Zealand Veterinary Association [IP28] noted that it did not want to see domestic research and development harmed by "unreasonable regulation and control". Life Sciences Network [IP24] commented that "New Zealand's intellectual property laws … should not be limited as a result of this Commission's enquiry".

New Zealand Institute of Patent Attorneys [IP71] noted that "the patent system in New Zealand currently meets international minimum requirements for intellectual property protection" and stated that "such protection should not be eroded". Dairy Board [IP67] concurred that "the Commission should not make any recommendations that would erode the current level of [intellectual property] protection that can be obtained".

section 3.12 |

appendix 2

Outcomes of Consultation: Submissions from Interested Persons

Section contents

3.12 Responsibilities under the Treaty of Waitangi

Introduction

Warrant item (g) invited representation on and investigation into:

> the Crown's responsibilities under the Treaty of Waitangi in relation to genetic modification, genetically modified organisms, and products

Responses to this item ranged from no commentary to full commentary.

Of the 107 Interested Persons, 31 made substantive comments in their submissions, 23 made cursory comments and 53 made no comment or stated that they took no position. In percentage terms, 50% of the submissions did not address this item. On the other hand, around 30% of the submissions (31 submitters) provided detailed commentary.

In terms of type of submitter, the majority of substantive comments came from industry or consumer associations and networks (16 submitters). Three Crown agencies, three private-sector companies, and six (of seven) Maori organisations also provided substantive comments, as did two religious groups.

This section deals first with the seven submissions from Maori organisations, and then the 48 submissions from non-Maori sources. Some of the submissions in this latter category drew on commentary from Maori witnesses.

Two preliminary points emerged from the submissions:

- For some submitters with concerns about genetic modification, the very Commission itself and its processes were a breach of the Treaty of Waitangi.
- In some submissions it appeared that the concepts of Treaty obligations (ie, as specified in the Warrant item) and Maori cultural issues were merged.

Key themes

Overall, the key themes in both Maori and non-Maori submissions included:

- role of the Treaty of Waitangi
- the Crown's duties under the Treaty
- tikanga principles and genetic modification
- participation in economic benefits.

In addition, the following topics attracted considerable comment, particularly in the Maori submissions, but are dealt with in detail in other sections of this report:

- protection of traditional ownership and knowledge of native flora and fauna
- international developments involving indigenous peoples and genetic modification issues
- changes to the regulatory framework.

Maori terms

Note that a glossary of the Maori terms used in this report is provided in the "Glossaries" section of this volume.

Submissions from Maori organisations

There were seven submissions from Maori organisations as Interested Persons, all of them containing reference to the Treaty of Waitangi. The organisations included two national representative bodies (New Zealand Maori Council and New Zealand Maori Congress), a national body representing Maori landowning authorities, Trust Boards and Runanga (Federation of Maori Authorities (FoMA)), claimants to the Waitangi Tribunal with an interest in intellectual property rights (WAI 262 claimants, Ngati Wai, Ngati Kuri, Te Rarawa), two tribal organisations (Te Runanga o Ngai Tahu and Muaupoko Co-operative Society) and an organisation representing views of a group of Maori women (Nga Wahine Tiaki o te Ao).

The comments ranged from the statement by Muaupoko Co-operative Society [IP57] that it would provide oral submissions on "partnership provisions and development — Treaty of Waitangi" to detailed commentary from New Zealand Maori Congress [IP103] on how the Crown should deal with proposals involving genetic modification techniques.

Role of the Treaty of Waitangi

Submitters identified the responsibilities of the Crown under the Treaty as a major issue. Views ranged from those who saw the obligation to honour the Treaty as an essential first step to those who saw a case-by-case consultation with Maori on genetic modification proposals as acceptable. Thus, some stated that constitutional change to honour the Treaty was required before anything else; others were prepared to consider a system of assessing genetic modification proposals

providing Maori participated in the assessment and decision-making processes.

Nga Wahine Tiaki o te Ao [IP64] described Crown processes, including the Commission, as operating in breach of the Treaty. This submitter indicated that the New Zealand Government must move towards constitutional change to honour the Treaty, and that, until this took place, all activities in relation to genetic modification should cease.

For New Zealand Maori Council [IP105], the "key element" in the attitude of Maori to genetics was Article the Second (Article 2) of the Treaty, which gives Maori exclusive rights to their taonga.

Te Runanga o Ngai Tahu [IP41] saw the Treaty of Waitangi, and its provisions, as a fundamental cornerstone to any consideration of genetic modification in New Zealand.

Maori Congress [IP103] affirmed the Treaty and stated:

> Te Tiriti o Waitangi is the only starting point for any recommendations concerning the possible move to permitting genetic modification in Aotearoa/New Zealand.
>
> Te Tiriti o Waitangi as the Magna Carta remains within our country as a duly constituted agreement between two sovereign nations to advance the future of two peoples.

WAI 262 claimants [IP89] regarded the Treaty as the "only reason the Crown is entitled to assert any form of governance in this country", and added that it must be accorded primary attention by the Commission.

The Crown's duties under the Treaty

Maori Congress [IP103] referred to the following specific duties of the Crown under the Treaty:

- a duty of active protection of Maori interests to the fullest extent practicable
- a duty to consult Maori
- a duty of equity and redress.

A common element in the submissions was the Crown's failure to meet its obligation to acknowledge Maori rangatiratanga, particularly over Maori resources. The Congress also saw the "lack of equity in terms of allocation of research funding" as a breach of the Treaty.

Te Runanga o Ngai Tahu [IP41], representing Ngai Tahu whanui, also commented on the Crown's responsibility for active protection of Maori interests in "their use and management and relationship with the forests, lands, freshwater, and marine resources". In Te Runanga's view, if the Crown allowed genetic modification without respecting and "actively protecting" Maori interests it would be failing

to fulfil its obligations as expressed in Article 2 of the Treaty.

Some submitters noted that an aspect of the duty to consult is the question of informing the community about the topic that is the subject of the consultation. Federation of Maori Authorities (FoMA) [IP69] referred to "the low level of understanding" among the general public of issues surrounding genetic modification, but added that this was especially so among Maori and saw this as "an inadequacy that needs to be urgently addressed".

Te Runanga o Ngai Tahu [IP41] stated that time should have been taken for public education on issues surrounding genetic modification and that "resources should have been made available for iwi to inform themselves on the issues and to come together to korero on the issue and form a considered opinion". Te Runanga saw the fact that only seven Maori-related groups had obtained Interested Person status as testimony to the deficiency of the education process to date. Maori Congress [IP103] referred to the urgent need for a nationally focused education campaign with a view to honouring Treaty obligations.

FoMA [IP69] summarised the Crown's responsibilities under the Treaty as:

- providing for Maori participation in any regulatory body
- providing education for Maori on biotechnology issues
- protecting traditional knowledge of flora and fauna
- recognising the cultural and spiritual relationship between Maori and the land and taonga.

Tikanga principles and genetic modification

The submissions from Maori organisations indicated that the rules of behaviour embodied in tikanga were central to any consideration of genetic modification. There was a range of views about the impact of tikanga, from those who saw it as a complete bar to genetic modification in New Zealand to those who considered that genetic modification could be accommodated provided there was recognition of the cultural and spiritual relationship between Maori, the land and ancestral taonga.

All the Maori submissions referred to tikanga, and some specifically referred to the Maori world view (te taiao) as their framework for assessing genetic modification. Commentary on tikanga was presented in some submissions as an expression of rangatiratanga. Te Runanga o Ngai Tahu [IP41] indicated that legal recognition of rangatiratanga was crucial to allow other tikanga principles (kaitiakitanga) to be put into effect. For Maori Congress [IP103], rangatiratanga denoted the mana (or authority) "not only to possess what is yours but to control

and to manage it in accordance with your own ethical and moral behaviour".

Tikanga principles are the source of the Maori value system, and govern the Maori approach to managing environmental issues. It was a major concern for submitters that these principles would be disregarded in dealing with genetic modification issues.

Nga Wahine Tiaki o te Ao [IP64] expressed the view that "Aotearoa is Maori land", and that any organism grown in New Zealand would be subject to tikanga Maori, which provided a collective basis from which to care properly for the environment and distribute resources. WAI 262 claimants [IP89] said that a central part of the claimants' case to the Waitangi Tribunal was the lack of recognition of Maori values and practices relating to genetic modification. The submission advocated that genetic modification be opposed "until tikanga Maori forms the basis of decision making of these issues" and that there should be no consent to technologies which further disrupted Maori and the Maori world view. Nga Wahine Tiaki o te Ao stated that based on ancestral traditions there should be no genetic modification in Aotearoa.

Tikanga principles

Submitters referred to the following concepts in their discussions of tikanga:

- whakapapa
- kaitiakitanga
- mauri
- mana
- atua
- ira tangata (the human element of life).

Whakapapa was generally described as the link between peoples and, in turn, other species. Kaitiakitanga was described by Te Runanga o Ngai Tahu [IP41] as the exercise of guardianship by the tangata whenua of an area in accordance with tikanga Maori.

For Te Runanga o Ngai Tahu, the concepts of whakapapa and katiakitanga meant that humans were an integrated part of the natural order and had as much an obligation towards the earth and that upon it as they had towards parents, siblings and other members of the whanau. Te Runanga indicated that the Maori world view was that humans were part of nature, in contrast to the Judaeo-Christian view that "people are created in God's image".

WAI 262 claimants [IP89] noted that acknowledging the spiritual dimension of the universe and respecting the mauri of everything was fundamental to Maori.

Anxiety about the effect of genetic modification arose for submitters because using genetic modification was seen by most as 'playing God', with consequent implications for the exercise of responsibilities in accordance with tikanga. Te Runanga o Ngai Tahu [IP41] expressed abhorrence for those involved with genetic modification and saw it as an interference with the "blueprint of life". Moreover, Te Runanga considered the risk to Ngai Tahu spiritual and cultural beliefs and mental health far outweighed any possible benefits, for instance "supposed" health benefits.

Nga Wahine Tiaki o te Ao [IP64] stated the following:

> 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.

The results would be to place the natural order of life itself under threat (WAI 262 claimants [IP89]). In addition, failure to meet kaitiaki obligations would diminish mana and thereby weaken safeguards against harm for individuals.

Some submitters stated that the mixing of human genes with those of other species was unacceptable (eg, Maori Congress [IP103]), or acceptable only in exceptional circumstances (FOMA [IP69]), but that overall a regulatory framework incorporating protections for tangata whenua could be considered.

Protection of traditional knowledge

Specific concerns about issues of patenting indigenous flora and fauna and the failure of the current legal system to provide protection for traditional knowledge and ownership of flora and fauna are dealt with in more detail in comment on Warrant item (f) (see "Intellectual property issues").

More generally, WAI 262 claimants [IP89] noted that the matauranga (or knowledge of living things, especially of native flora and fauna) accumulated by Maori is held by the whanau and hapu, which have kaitiaki responsibilities for that knowledge.

Maori Congress [IP103] observed that the Treaty of Waitangi "affirms" the rights of Maori as tangata whenua and their relationship with flora and fauna.

Economic benefits

Economic issues, including benefits, are dealt with elsewhere in this document, including in discussion on strategy (see "Strategic outcomes") and on Warrant item (j) (iii) on areas of public interest (see "Areas of public interest: economic matters"). However, in this commentary on Maori submissions on Treaty of

Waitangi issues, some submissions referred to Maori rights over the Maori genome and control of any developments based on it. Maori Congress [IP103] stated that rights to the genome included the capacity to receive benefits from its use and advance.

FoMA [IP69] noted that Maori authorities would benefit from genetic modification advances through improved productivity, product quality and, potentially, the development of new products. The possibility was that Maori in general would benefit from a position of greater economic self-sufficiency.

Submissions from other Interested Persons

Submissions from non-Maori organisations included, in some instances, comments from witnesses identified as Maori. For example, Carter Holt Harvey/Fletcher Challenge Forests [IP17], University of Auckland [IP16] and Royal Society of New Zealand [IP77b (social sciences)] included or referred to commentary from Maori witnesses. The commentary on the Treaty in such submissions was often more detailed than in submissions with no apparent, direct, Maori input.

As with the submissions from Maori organisations, the following themes emerged:

- role of the Treaty of Waitangi
- the Crown's duties under the Treaty
- tikanga principles
- participation in economic benefits.

In addition, there was comment on health benefits for Maori.

Role of the Treaty of Waitangi

Views on the role of the Treaty varied. Some submitters thought the Crown's role under the Treaty in this area was unclear. Others saw the Treaty as providing a "context", a "framework" or a "living document" with the views of the Treaty partners carrying equal weight (eg, Green Party of Aotearoa/New Zealand [IP83]). A few submitters took the view that it was premature for the Commission to address this item while there were legal proceedings still outstanding at the time of submission, for instance the WAI 262 Indigenous Flora and Fauna Claim or the appeal to the High Court against a decision of the Environmental Risk Management Authority (ERMA) on insertion of a human gene into cattle (New Zealand Life Sciences Network [IP24], Pacific Institute of Resource Management [IP84]).

New Zealand Wool Board [IP30] considered that the extent of the Crown's obligations under the Treaty was uncertain. From a "pragmatic point of view", the Board felt that it was vital for the Crown to act in good faith, on behalf of all New Zealanders, to help to secure national benefits from genetic modification. The Board was concerned that years might be spent attempting to incorporate the Treaty into a regulatory framework. It considered that this would be "self-defeating": "By the time we came up with a solution, others would have won the game."

Some submitters seemed to approach the Treaty as a specifically Maori issue. Life Sciences Network [IP24] commented that the "extent to which the Treaty of Waitangi grants Maori special rights other than for native flora and fauna is still unclear". New Zealand Dairy Board [IP67] suggested that, in taking into account Treaty principles, the "cultural beliefs of Maori" needed to be examined.

On the other hand, Hamilton City Council [IP20] expected that Government would consult Maori to determine if there were Treaty responsibilities relating to genetic modification. Interchurch Commission on Genetic Engineering [IP49] expressed support for a bicultural framework, and recognised the importance of the Treaty as a partnership. For AgResearch [IP13], the Treaty provided a "context" for its relationship with Maori.

The Crown's duties under the Treaty

Submissions from non-Maori sources referred to the following Crown duties under the Treaty:

- active protection
- acting in good faith
- consultation
- reasonableness
- mutual cooperation and trust
- obligations to promote wellbeing and health.

For Carter Holt Harvey/Fletcher Challenge Forests [IP17], the Crown's Treaty responsibilities were sufficiently "recorded" in the Hazardous Substances and New Organisms Act 1996 (HSNO Act). The Act required ERMA to take into account the principles of the Treaty, and the relationship of Maori with "their culture" and taonga.

ERMA itself [IP76] referred to a duty of "active protection", as well as to principles of consultation and acting in good faith. It saw the latter as well provided for in its

processes. On "active protection", ERMA believed that the principle should not be applied so as to be inconsistent with the government's right to govern under the Treaty.

Other submissions referred to duties or principles of reasonableness, mutual cooperation and trust, and to obligations to promote wellbeing and health. One submission in particular (Friends of the Earth (New Zealand) [IP78] in an accompanying witness brief) contained an extensive outline of principles developed from case law and Waitangi Tribunal reports. This submitter saw the concepts of sovereignty and governance as also relevant to genetic modification. Safe Food Campaign [IP86] summed up the relevant Crown responsibilities as meaning "relating issues about GM back to the principles of partnership, protection and participation".

A duty to consult was upheld by most submissions that commented on the Crown's duties under the Treaty. Some submitters outlined the processes they adopted to consult Maori (AgResearch [IP13], Carter Holt Harvey/Fletcher Challenge Forests [IP17]). In an accompanying witness brief, Carter Holt Harvey/Fletcher Challenge Forests described a process of identifying tangata whenua, consulting, and ultimately relying on ERMA for decisions. New Zealand Transgenic Animal Researchers [IP45], adopting views expressed in a witness brief on behalf of University of Auckland [IP16], noted that it was important that the Commission process consult those Maori who might be adversely affected by loss of genetic modification methodologies and therapies.

Some submitters believed the duty to consult conferred on Maori a "special right" to consultation on genetic modification issues relating to native flora and fauna (but not to imported species). Sciences Network [IP24] took this view, saying that the right was in return for the right of governance to be exercised by the Crown. For Association of Crown Research Institutes (ACRI) [IP22], Article 2 of the Treaty implicitly recognised Maori responsibilities to protect native flora and fauna. However, the Association went on to say in relation to Article the third (Article 3) of the Treaty:

> In a pluralistic society, the core spiritual values arise from societal debate and consensus. Maori concerns of this nature have the right to be expressed through their rights as citizens, but there is no greater right for Maori in this respect than any other citizen group. "Some citizens are not more equal than others."

Other submitters were concerned that views expressed through consultation should actually be heard. Interchurch Commission [IP49] stated that:

> The Crown has a responsibility to give real expression to treaty principles through establishing a new process whereby Maori views in relation to genetic modification,

> genetically modified organisms and products can be treated with greater respect than has thus far been the case. … The extent to which Maori spiritual concerns in relation to GE are genuinely heard will indicate the depth of our commitment as a nation, to the Treaty upon which our nation is founded.

Safe Food Campaign [IP86] stressed the need for consultation that did not merely ignore Maori perspectives once they were gathered and did not "marginalise" Maori views. Reference was made to New Zealand's signing of the General Agreement on Tariffs and Trade (GATT) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) without consultation with Maori. This was seen as contrary to the Treaty.

For Wool Board [IP30], Meat New Zealand [IP31] and Meat Industry Association of New Zealand (MIA) [IP32], the Crown's obligation was to act on behalf of all New Zealanders to secure national benefits.

Tikanga principles

Some submissions made comments about specified principles of tikanga, notably kaitiakitanga and whakapapa.

Others spoke of Maori spiritual beliefs. Interchurch Commission [IP49] saw Maori as guardians of indigenous spirituality and stated that the Treaty "enables us all to adopt a more holistic approach to issues of genetic modification".

AgResearch [IP13] referred to ERMA's conclusion that there was no practical mechanism to avoid the effects of genetic modification research on spiritual beliefs unless the work was carried out offshore, and commented that this was "neither desirable nor practical". By way of a solution, Wool Board [IP30] suggested the same "utilitarian ethical framework" used to consider values and ethics of genetic modification be used for Treaty issues. Royal Society [IP77a (biological sciences)] noted Maori concern about cultural traditions including whakapapa and matauranga Maori, and referred to "no-go zones" for genetic experimentation in relation to matters such as the transfer of genes between species.

Organic Product Exporters Group [IP53] referred to the compatibility of kaitiakitanga and organic forms of production. ACRI [IP22] saw biodiversity responsibilities as overlapping with kaitiakitanga, which was defined by Life Sciences Network [IP24] as "stewardship". Kaitiakitanga was further described by Life Sciences Network as a "right of citizenship". The Network observed that katiakitanga could have more than one interpretation, and that the relevant status of tikanga principles was debated amongst Maori.

On tikanga generally and whakapapa in particular, Parliamentary Commissioner

for the Environment [IP70] referred to experience with Maori consultation on possum control measures, and recommended that the issues and concerns expressed there be explored as part of a strategic response to genetic modification. The Commissioner noted that "the need to protect whakapapa, its tapu and its integrity, was fundamental to the unanimous rejection of genetic modification of native plant species as a way of delivering a biocontrol to possums".

There was a divergence of views about the extent of the Crown's responsibilities in relation to whakapapa. Life Sciences Network [IP24] saw Government's obligation to provide for the economic and social wellbeing of Maori as predominating over an obligation "which may or may not exist" concerning the impacts on a "claimed" whakapapa relationship with plants and animals. On the other hand, Pacific Institute of Resource Management [IP84] commented that the Crown was under an obligation to respect the intellectual and property rights that flowed from the Treaty, and to pay attention to mauri and whakapapa. In a similar vein, Friends of the Earth [IP78] in an accompanying witness brief saw Maori rights to preserve their taonga, including whakapapa and mana, as a "high priority".

Physicians and Scientists for Responsible Genetics New Zealand [IP107] stated that:

> … the Crown has a duty to do much more than simply consult with Maori on these issues in the manner we have observed to date. In particular we wish to see force given to Maori concerns of Mauri, Wairua and Whakapapa as a duty of partnership under the Treaty.

Participation in economic benefits

Several submissions identified economic and development issues as a major Treaty component. Life Sciences Network [IP24] stated that the Treaty was intended to enhance Maori development and should be read in that context. ACRI [IP22] was optimistic that, "with a stronger economic base", more Maori would cautiously embrace new genetic modification opportunities. Submissions from the primary production sector stressed Maori involvement in that sector and the economic benefits for all — Maori and non-Maori — that could flow from the adoption of genetic modification techniques in the primary production sector.

Meat New Zealand [IP31] expressly stated that:

> Key to the Crown's Treaty obligations is the need to promote economic opportunity for all New Zealand citizens, including Maori.

For Meat New Zealand, this followed from Article the first (Article 1) of the Treaty, which required the Crown to promote the wellbeing of all people and, in

particular, to "seek enhanced economic prosperity at all levels". It was said that this should not be at the expense of the environment or any "interest group". The submission went on to observe that many Maori believed that the potential economic benefits of genetic modification were considerable enough to warrant their use, and noted that many Maori worked in biologically based production sectors that would benefit from application of the new gene technology. New Zealand Game Industry Board [IP33] expressed similar views.

MIA [IP32] stated that it was a large employer and significant contributor to the economy and thus to the wellbeing of all New Zealanders, including tangata whenua. The Association commented that it could only maintain this if it had access to the technology required:

> Providing for the flexibility that we believe is required with gene technology will assist the Crown in meeting those aspects of its Treaty responsibilities that rely on a strong economy.

Wool Board [IP30] was concerned about delays in adopting new technologies, and suggested that "waiting around" and not being involved in such technologies, including genetic modification, was "tantamount to giving away everyone's birthright".

Health benefits

A particular theme of some submissions concerned medical research and benefits for Maori. Transgenic Animal Users [IP45] commented that there must be a balance between Maori rights under the Treaty with "the integral part that GM animals play in modern medical research".

In an accompanying witness brief, University of Auckland [IP16] stated that the Treaty guaranteed Maori retention of their taonga including health, while also guaranteeing the "ordinary" rights of New Zealand citizens. The witness brief went on to observe that diseases such as diabetes and hepatitis B were of major concern for Maori and stated that:

> Therapy of these diseases is currently underpinned by genetic modification, genetically modified organisms and their products. Loss of these methods and techniques would result in a significant down grading of medical care for Maori, thereby preventing the Crown from carrying out its responsibilities under the Treaty.

Haemophilia Foundation of New Zealand [IP48] recorded that there was a 50% greater incidence of haemophilia amongst Maori than amongst Pakeha, and that the therapy for this was underpinned by genetic typing. Similarly the Foundation saw any loss of genetic modification techniques in this area as affecting the Crown's responsibilities under the Treaty.

section 3.13 |

appendix 2

Outcomes of Consultation: Submissions from Interested Persons

Section contents

3.13 Global developments and issues

Introduction

The Warrant under item (h) called for information on:

> 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

Global developments and issues raised by submitters in relation to genetic modification tended to focus around several themes including:

- global environmental issues
- globalisation of resources
- global competition
- consumer responses to genetic modification
- globalisation of indigenous issues
- global legal obligations
- national biotechnology strategies.

Thirty-eight submitters made substantive comment on the issue of global developments. In terms of type of submitter, the highest proportion (17 submitters) came from industry networks or associations. Of the 38 submitters who commented on global developments, the largest sectoral responses were received from biotechnology (eight submitters), primary production (four submitters) and environmental advocacy (four submitters). Findings from cross-tabulation of data on the submitters who made substantive comment on global developments showed that almost two-thirds of this group (24 submitters) took a 'strongly for' stance on genetic modification.

The majority of submitters focused on developments that might influence the use of genetic modification in New Zealand, with fewer submitters commenting on issues that might limit the use of genetic modification. Some of the submitters made comment on global developments and genetic modification without relating these comments specifically to New Zealand. Most submitters discussed global

developments in terms of genetic modification in general, rather than making specific reference to genetically modified organisms or products.

Some submitters, such as New Zealand Biotechnology Association (NZBA) [IP47], identified a range of global developments including population growth, human health, consumer trends, new industries, sustainable development and climate change as being issues that might be influenced by genetic modification.

Global environmental issues

The growth in environmental resource pressures was identified as a key theme by submitters: such pressures included world population growth, food shortages, loss of arable land, increasing salinity, water shortage, climate change, pests and pollution. Association of Crown Research Institutes (ACRI) [IP22] identified that global environmental problems were occurring on a large scale and that solutions to such problems would require a major effort.

Submitters put forward arguments for and against the use of genetic modification as a means of addressing these global environmental problems. In particular, submitters focused on potential solutions that genetic modification might offer in boosting global food production.

Global food production solutions offered by genetic modification

Several submitters outlined ways in which genetic modification could help reduce pressure on global food supply by:

- increasing overall global food production
- reducing food distribution problems through helping countries to develop self-sufficiency in food production.

They also commented on fair and appropriate use of biotechnology in dealing with global environmental issues.

Ability to increase global food production

A range of submitters identified the potential of genetic modification to increase global food production as a factor that might encourage use of the technology. Several agricultural crop producers and research companies made comment on this issue. New Zealand Feed Manufacturers Association/Poultry Industry Association of New Zealand/Egg Producers Federation of New Zealand [IP35] commented that many developing countries "desperately need some of the potential benefits of GE food". Monsanto New Zealand [IP6] noted in its submission that food security would drive expansion in the use of genetically

modified crops, particularly in the developing countries. Aventis CropScience [IP14] also noted that its crop production enterprise was driven by global needs for food safety, sustainability and a cleaner environment; and that it saw biotechnology as playing a critical role in feeding the world's population (projected to be nine billion by 2025). Crop and Food Research [IP4] agreed that ensuring the sufficiency and security of world food supply would provide strong incentives for other parts of the world to pursue genetic modification.

Several religious organisations also provided comment on the potential for genetic modification to help alleviate pressures on world food supply. Interchurch Commission on Genetic Engineering [IP49] stated that vitamin A ("golden grain") rice was one application of genetic modification that might improve the nutritional status of millions of people.

However, other submitters rejected the arguments that genetically modified foods could solve food supply problems. Pacific Institute of Resource Management [IP84], for example, suggested that there were "risks to food security through some GM disaster in agriculture affecting food production".

Global food distribution issues

Ensuring an adequate global food supply was not the only problem identified. Some submitters considered distribution of food to those in need to be a more significant issue. ACRI [IP22] noted in its submission that, although technically the world "produces sufficient food for the moment, there is no likelihood that in the immediate future food will be readily available to those in greatest need". The Association commented further that genetic modification technologies provided powerful tools to help address problems of world hunger and, along with other biotechnologies, they were the key to helping nations become self-sufficient in food production.

The need for equitable solutions

Interchurch Commission [IP49] noted that it was necessary to look at culturally and ethically appropriate means of addressing global nutritional deficiencies. Public Questions Committee (Methodist, Presbyterian, Churches of Christ, Quaker) [IP93] supported this view, commenting that social problems needed social answers and that genetic engineering was not the only solution for social problems. New Zealand Catholic Bishops' Conference [IP38] also dealt with ethical issues when it stated that the benefits of genetic modification should be shared fairly and equitably, and decisions should "take into account the needs of the poorest and most vulnerable".

Submitters identified developing countries as being most in need of genetically modified crops. New Zealand Arable-Food Industry Council [IP56] provided an

example of this view, quoting from another source: "The African continent, more than any other, urgently needs agricultural biotechnology."

ACRI [IP22] noted: "New Zealand has a role to play in sharing its biotechnology 'know-how' with its neighbours."

Negative environmental effects of genetic modification

Submitters also identified potential negative environmental effects arising from the use of genetic modification, and saw these as reasons for limiting its use. For example, Pacific Institute of Resource Management [IP84] noted that genetic modification destroyed biodiversity in agriculture and that it could result in the threat of "super-weeds" or "super-pests".

Environmental issues in relation to genetic modification are addressed in more detail in connection with Warrant item (j) (ii) (see "Areas of public interest: environmental matters").

Although global environmental pressures might seem distant from New Zealand, ACRI [IP22] emphasised that New Zealand could not take its own comfortable situation for granted and that New Zealand's global future could not be considered in isolation from the rest of the world.

Globalisation of resources

The increasing global mobility of people, goods, services and knowledge was a key theme that submitters commented on in relation to the use or limitation of genetic modification.

Researched Medicines Industry Association of New Zealand [IP55] noted in its submission that the pharmaceutical and biotechnological industries operated on a global scale and that the products of these industries were becoming available in the principal markets of the United States, Europe and Japan in an increasingly "synchronous" manner. NZBA [IP47] also commented on global pharmaceutical trends, noting that genetic modification offered opportunities for large-scale production of existing substances that would otherwise not be available in sufficient quantities, for example, human insulin. University of Auckland [IP16] outlined the issue of growth in international tourism and travel and the implications for New Zealand if tourists had medical conditions for which they needed access to genetically modified products for treatment. National Testing Centre [IP44] highlighted the global nature of medical treatment, noting in its submission that many new genetically modified treatments would become available overseas and New Zealand people might travel to receive treatment.

New Zealand Grocery Marketers Association [IP54] noted that the food industry was now intrinsically and irreversibly linked to international trade in food and the international marketplace and that there were few examples of large New Zealand manufacturing companies that were not part of an international network.

The globalisation of research was another trend identified by the submitters. Several submitters stressed the importance of New Zealand maintaining a critical mass of qualified researchers actively engaged at the cutting edge of new developments. Without the ability to use genetic modification techniques, New Zealand would lose valuable human resources, given the mobility of human capital.

Lincoln University [IP8] commented that international students now made up 21% of its student body, that research was undertaken from a global perspective and that, in order to remain viable, universities needed access to modern research techniques. The University stated that technologies such as genetic modification were accepted in all modern technologically oriented countries.

Global competition

Submitters identified a range of issues relating to genetic modification that had led to increasing competition in the global arena, including the "biotechnology revolution", comparative technological advantages and competitive opportunities from avoiding genetic modification.

The "biotechnology revolution"

Several submitters referred to the "biotechnology revolution", which was characterised by the rapid pace of change that biotechnology discoveries had generated. Submitters saw a parallel between the "biotechnology revolution" and earlier periods of rapid change in technology. New Zealand Dairy Board [IP67] noted that the science of genomics was in a position similar to that of the silicon chip 20 years ago. The fastest development had occurred in pharmaceuticals, from the first approval of a drug based on genetic modification technology in the 1980s to the "scores of GM based medicines" currently available. The Board also commented that "GM is revolutionising the food industry" and that there was "a developing convergence between the agribusiness, food, pharmaceutical and chemical industries". Auckland Uniservices [IP23] was also of the opinion that biotechnology was now regarded as the major emerging industry of this century.

Foundation for Research, Science and Technology [IP21], describing the scale and extent of change, noted that more than 2500 companies worldwide were funded by around NZ$8 billion annually to develop biotechnology products and that world

sales of biotechnology products exceeded NZ$27 billion. Monsanto [IP6] noted that worldwide the total area planted out in genetically modified crops in 1999 was nearly 40 million hectares (ie, more than New Zealand's total land area).

Factors considered by submitters to be generating momentum in the biotechnology revolution included:

- the universality of science and the speed of information flows (Environmental Risk Management Authority (ERMA) [IP76])
- access to increasing amounts of DNA-sequencing information and the development of new tools with which to use this information (Institute of Molecular BioSciences, Massey University [IP15])
- the race to secure international patent rights over gene sequences of important crops and the applications of important genes (HortResearch [IP5])
- innovation, global competition and the international search for new products and markets (New Zealand Game Industry Board [IP33])
- consumer demand for genetically modified medicines, vaccines and new diagnostic tools (Otago University [IP19])
- world food security (Monsanto [IP6]).

Several submitters reinforced the economic imperatives of New Zealand being part of the "biotechnology revolution". Auckland Uniservices [IP23] put forward an opinion that favoured active participation in biotechnology, asserting that "those countries which do not invest [in biotechnology] will be badly disadvantaged in the future", and noted that this was especially important for countries like New Zealand that relied heavily on biological production. Auckland Uniservices considered biotechnology to be possibly the "last opportunity for the foreseeable future to participate in a major knowledge-led economic transition".

Similarly, Dairy Board [IP67] considered genetic modification technologies to be the means of securing New Zealand's standard of living, noting that New Zealand was overwhelmingly dependent on biological products: farm, fish, forest and horticulture. The Board commented that biological exports exceeded 60% of New Zealand's export earnings and that: "There are no other exports which are growing rapidly enough to reduce that dependence."

Comparative technological advantage

With respect to the implications for New Zealand of increasing use of genetic modification in other parts of the world, Crop and Food Research [IP4] noted that it was likely to be difficult for New Zealand's biological industries to maintain their competitive position unless they had access to technologies that were similar to

those of their competitors. Dairy Board [IP67] also noted that New Zealand needed to maintain and enhance its competitiveness in biological product exports, which it considered to be "our only major source of international competitive advantage". The Board suggested that the major social and economic risk to New Zealand was "that the New Zealand dairy industry will be prevented from developing and using GM, while its competitors are not".

Competitive opportunities from avoiding genetic modification

Other submitters tended to see the opportunity presented by the "biotechnology revolution" differently. Many of those who identified with organic farming, for example, saw an opportunity for New Zealand to market organic produce under a generic New Zealand "GM-free" label.

Submitters also offered comment on the competitive opportunities that might arise if New Zealand avoided genetic modification. Some submitters approached it largely in marketing terms: "As the rest of the World seems to be embracing GE technology … New Zealand has the opportunity at this stage to reject it and thereby have a potential competitive advantage in marketing" (Royal Forest and Bird Protection Society, Marlborough Branch [IP40]). Others saw the "GM-free" option in terms of market differentiation.

Consumer responses to genetic modification

Consumer attitudes towards genetic modification, genetically modified organisms and products have been a significant factor in the use of this new technology, especially for food production.

Submitters considered three critical overseas developments as affecting how New Zealand should address genetic modification, including:

- consumer concern about genetic modification, especially for food products
- consumer demand for "clean, green", "safe" and "natural" products
- changing global consumer preferences towards genetic modification in response to perceived price and quality benefits.

Consumer concern about genetic modification, especially food products

Several submitters highlighted consumers' preferences about genetic modification and emphasised the importance business attached to such concerns. Submitters

saw concerns about genetic modification as particularly significant for New Zealand's business, both locally and overseas.

Arable-Food Industry Council [IP56] stressed that New Zealand "must be in a position to respond to consumer preference in a competitive international market". Carter Holt Harvey/Fletcher Challenge Forests [IP17] noted that "uncertainty about future consumer acceptance" in overseas forestry markets of "wood produced from New Zealand biotechnology and trees" had the potential to slow investment in genetic modification technology in the New Zealand forestry sector. Canterbury Commercial Organics Group [IP65] also talked of a "large and growing resistance to GE food production technology". Similarly, Environment and Conservation Organisations of New Zealand [IP102] noted a "worldwide distrust" of genetic modification, particularly in agriculture and food products.

Other submitters gave more specific responses. National Beekeepers Association of New Zealand, Poverty Bay Branch [IP62] quoted a news agency report of October 2000 that described several major international brands as "distancing themselves" from having any genetically modified organisms in their products. ZESPRI International [IP46] also cited cases where global food retailers "swiftly removed and avoided" brands associated with genetic modification. Monsanto [IP6] identified "consumer concerns" behind the slow adoption of genetically modified crops. Royal Society of New Zealand [IP77b (social sciences)] also mentioned "international consumer reaction to GM foods" as an issue. All these submitters reinforced the importance of consumer reaction for marketing strategies both within New Zealand and overseas markets.

Consumer reaction to the development of health-related technological advances in vaccines and in diagnostic and treatment options is discussed under Warrant item (j) (i) (see "Areas of public interest: human health").

Consumer demand for "safe" products

Consumer demand for "safe" or "natural" products was an additional key global development mentioned by submitters that could limit New Zealand's use of genetic modification technology. Several submitters who supported a "clean green" image for New Zealand stressed that New Zealand could, and should, differentiate itself from the rest of the world in this developing technology. Opinions expressed included:

- to be successful as a trading nation New Zealand had to differentiate ("to decommoditise its production") and being "GM-free" might be a unique opportunity to do that (National Beekeepers Association, Poverty Bay [IP62]).

- New Zealand's remoteness presented a natural advantage: the country had the opportunity to remain free of genetically modified organisms in its agriculture and environment (Bio Dynamic Farming and Gardening Association in New Zealand [IP61]).
- New Zealand could be the "control" if the rest of the world experiments with genetic modification (Royal Forest and Bird Protection Society, Nelson/Tasman Branch [IP43])
- New Zealand should take a similar stance on genetic modification to its policy on the nuclear issue of the 1970s, and declare New Zealand "GM free" (Forest and Bird, Nelson/Tasman [IP43]).

Meat Industry Association of New Zealand [IP32], in an accompanying witness brief, commented: "perversely, genetic modification may become important for maintaining the 'clean and green' image [of New Zealand]. Biological solutions may come to be seen as safer than chemical solutions."

Consumer price and quality preferences

A further global development seen as possibly affecting New Zealand's options on genetic modification was the perceived consumer preference for cheaper or for higher quality genetically modified products.

A global consumer preference trend, identified by several submitters (including AgResearch [IP13], Game Industry Board [IP33] and Meat New Zealand [IP31]), was that wealthy consumers in Europe and North America increasingly were "looking for value, health, and nutrition from knowledge-based products". Similarly, Monsanto [IP6] said that consumer acceptance would grow internationally as the biotechnology benefits moved from "current input (agronomic) traits to the next generation output (quality) traits which will result in improved and specialised nutritional food and feed products". Monsanto felt that New Zealand needed to be "well placed to capitalise on biotechnology innovations as consumer acceptance of the technology grows".

However, different markets segments (both within New Zealand and overseas) placed value on different commodities. Several submitters saw advantage in New Zealand focusing on consumers in highly developed niche markets, not low-value commodities. Some saw organic farming as catering to this specialised consumer-market segment.

Submitters offered differing evidence on which global trends were in New Zealand's economic interest.

Consumer issues in relation to genetic modification are also discussed under Warrant item (j) (i) (see "Areas of public interest: human health").

Globalisation of indigenous issues

A number of submissions referred to indigenous persons' rights and issues of genetic modification in a global context. Ngā Wāhine Tiaki o te Ao [IP64] stated that indigenous peoples internationally were resisting "biopiracy" for the purposes of genetic modification, and saw this as occurring for the benefit of "corporates". Others referred to international agreements and discussions on indigenous peoples' rights, in particular the Convention on Biological Diversity, the "Rio Declaration", the Mataatua Declaration and the Draft Declaration on the Rights of Indigenous Peoples. WAI 262 claimants, Ngāti Wai, Ngāti Kuri, Te Rarawa [IP89] commented that international awareness of the importance of respecting indigenous knowledge and practices "has gathered a momentum of its own". New Zealand Institute of Patent Attorneys [IP71] noted that intellectual property rights of indigenous peoples was an area of active international debate.

Indigenous issues in relation to genetic modification are also addressed under Warrant item (f) (see "Intellectual property issues"), Warrant item (g) (see "Responsibilities under the Treaty of Waitangi") and Warrant items (d, l) (see "International obligations and implications").

Global legal obligations

Submitters raised issues on the global regulatory responses to genetic modification in terms of worldwide obligations and the differing national regulatory frameworks that have developed. The international legal obligations are discussed in more detail under Warrant items (d, l) (see "International obligations and implications") and New Zealand's statutory and regulatory system is addressed under Warrant items (2, n) (see "Statutory and regulatory frameworks").

Several submitters saw New Zealand's current regulatory framework as a factor that might limit the use of genetic modification in New Zealand for reasons of high compliance costs and more stringent regulation than some comparative systems overseas.

Restrictiveness of New Zealand's regulatory regime

Some submitters compared New Zealand's regulatory framework for genetic modification with that in other countries, in particular Australia, and noted the differences in approaches and potential impacts that might result. Biotenz [IP25] noted that Australia currently had a more accommodating approach to genetic

modification than New Zealand:

> Australia … like most other first world countries, is actively promoting inward investment in GM technology through financial assistance and support. If New Zealand does not adopt a similar approach, then we will simply become an importer of technologies and our best scientists and engineers in this area will move off-shore. The infrastructure required to support them, which will be substantial, will also be lost to New Zealand.

New Zealand Wool Board [IP30] also raised this issue and noted that if the regulatory environment in New Zealand for genetic modification was tougher than that in Australia then activities such as research would simply shift across the Tasman. The Board commented that global developments in regulatory environments would have an impact on where investment took place. It emphasised that New Zealand was a small, biologically based nation for which isolationism was not a viable economical option. This submitter considered New Zealand to be a country where people, skills, knowledge and money were now highly mobile and where future economic success would be dependent on evolving production systems in the face of ever-changing and developing world markets.

High compliance costs

NZBA [IP47] considered that ERMA's approach to risk assessment was costly and restrictive. New Zealand Transgenic Animal Users [IP45] also commented that New Zealand had high compliance costs and that the strict requirements of the Hazardous Substances and New Organisms (HSNO) legislation inhibited the ability of New Zealand researchers "to gain from and effectively partake" in global research activity. A contradiction within the existing regulatory system was identified by Wool Board [IP30]: the Board contended that there would be no economic benefit in preventing research and development of genetically modified organisms and products in New Zealand when they could be lawfully imported from other countries. On this issue, ERMA [IP76] identified a growing international inability to control the movement of goods and organisms across borders.

National strategies for technological development

Submitters commented on national strategies for biotechnology advanced by other governments and in what areas New Zealand might develop its own national strategies for dealing with biotechnology issues.

National biotechnology strategies

Several submitters commented that New Zealand lacked a national biotechnology strategy and that such a strategy was needed in order to recognise New Zealand's biodiversity, maintain its biosecurity and provide for the needs of its biotechnology industries. For example, Institute of Molecular BioSciences [IP15] observed that New Zealand must engage in genetic modification research in order to protect "our unique biodiversity" and noted that, even if New Zealand were to pursue a policy of no commercial development of genetically modified organisms, "a graduate capacity would still be crucial to interpret global trends in GM technologies and to credibly maintain New Zealand's Biosecurity" as the use and development of products derived from genetically modified organisms increased in other countries.

Some of New Zealand's closest trading partners (and biotechnology competitors) have already adopted national biotechnology strategies to guide the development of their biotechnology industries and promote national economic growth and investment. Several submitters pointed to Australia, Canada, the United Kingdom, Ireland and the United States as examples of countries whose biotechnology strategies the Commission might wish to consult. Auckland Uniservices [IP23] commented that:

> Australia has a vibrant and growing biotechnology industry … [This] has considerable significance for New Zealand, given the two countries' … increasingly related and interdependent economies. … the Commission should closely consider what is happening with biotechnology in Australia, and only adopt a different position … after careful and detailed analysis.

National public education strategies

Governments are also responding with a variety of national education strategies designed to educate consumers and the public generally on the risks and benefits of genetic modification. Twenty-three submitters noted a concern about public education as an issue, implying that they saw a need for the New Zealand Government to mount a similar public education campaign. New Zealand Organisation for Rare Diseases [IP98], for example, observed that, as with earlier technological advances (such as vaccination, pasteurisation and microwave ovens), "the appropriate response is education and information".

section 3.14 |

appendix 2

Outcomes of Consultation: Submissions from Interested Persons

Section contents

3.14 Opportunities from use or avoidance

Introduction

Warrant item (i) invited representation on:

> the opportunities that may be open to New Zealand from the use or avoidance of genetic modification, genetically modified organisms, and products

Issues raised in connection with the opportunities to be gained from the use or avoidance of genetic modification technology essentially hinged on submitters' overall philosophy towards genetic modification. Most submitters either favoured a strategic pathway that involved use of genetic modification or favoured a pathway that avoided its use. Some submitters indicated support for a dual pathway (ie, a pathway that involved use of certain types of genetic modification technology but avoidance of other types). This perspective was most clearly evident in submitters' views on whether New Zealand could combine genetic modification, genetic modification-free uses and organic agricultural systems.

Forty-three submitters made significant comment on this Warrant item. The main sectoral focus of most submitters (27) was economic or productive. In terms of submitter type, most came from industry networks or associations. Sixteen came from industry associations or networks, nine from research organisations and four from private companies. A further seven submitters came from consumer networks (three submitters), religious groups (one submitter), Maori organisations (one submitter) and organics organisations (two submitters). Most submitters favoured use of genetic modification. A majority of submitters (31) were regarded as being 'strongly for', or 'tending to be for' genetic modification. Twelve were regarded as being 'strongly against' or 'tending to be against' genetic modification.

Submitters' views are discussed in terms of a 'use pathway', an 'avoidance pathway' and a 'dual pathway'. The latter deals primarily with submitters' attitudes on organic farming and their views on whether organic production can be combined with use of genetic modification.

Issues raised by submitters: a summary

A majority of submitters commenting on this Warrant item saw benefits in the use of genetic modification and favoured a 'use pathway'. Most of these submitters came from biotechnology companies, farming concerns and research organisations. The most common issues raised were opportunities that would advance general economic benefits, together with specific business interests such as increased productivity and increased competitiveness. Specific opportunities identified included:

- human health benefits
- general economic benefits
- increased productivity
- increased range of products
- environmental benefits
- increased profitability
- increased research capability
- development of new knowledge-based enterprises
- increased competitiveness
- maintenance of research capability
- enhanced animal welfare
- a new global role.

Submitters who favoured the 'avoidance pathway' also noted economic benefits as advantages to be gained from avoiding use of genetic modification. Competitive advantages to be gained from organic production and the competitive advantage from genetic modification-free production were particularly noted. These submitters usually came from industries that supported organic farming or "GE-free" organisations, as well as environmental advocacy groups.

Submitters favouring avoidance of genetic modification identified several opportunities for New Zealand arising from avoidance. These included:

- competitive advantage from organic production
- competitive advantage from "GE-free" production
- environmental benefits
- general economic benefits
- a new global role
- human health benefits.

Over 40% of the total number of Interested Persons (43 submitters) commented on this Warrant item. However, most submitters referred to benefits from use or avoidance of genetic modification at some place in their submissions. These attitudes are captured in Table 3.6.

'Use pathway' opportunities

Most of those submitters who saw opportunities from the use of genetic modification technology cited various human health, environmental, business and economic reasons. Of the submitters mentioning specific benefits from use throughout their submissions (ie, not necessarily in response to Warrant item (i)), more than one-third of all Interested Persons saw benefits to human health (43 submitters) as well as general economic benefits (38 submitters). The next most frequently mentioned opportunities were for increased productivity (35 submitters), an increased range of products (34 submitters) and environmental benefits (33 submitters). Data for other categories of opportunity are presented in Table 3.6.

Human health benefits

Benefits to human health were the most frequently raised benefit from using genetic modification. Forty-three submitters thought genetic modification offered opportunities for advances in human health. Significant comment came from patient advocacy groups.

Cystic Fibrosis Association of New Zealand [IP39] saw genetic modification technology as offering cystic fibrosis sufferers the "only possibility for a cure".

In addition, submitters saw it important for New Zealand to have the capacity to develop and use new technologies. New Zealand Organisation for Rare Diseases [IP98] commented that if New Zealand accepted the use of genetic-based medicines it would give "increased research opportunities, greater business development and innovation, and more exports".

General economic benefits

General economic benefits (ie, benefits other than those specifically noted to increase productivity, profitability or competitiveness) ranked as the second most frequently mentioned opportunity to be gained from the use of genetic modification. Thirty-eight submitters noted general economic benefits.

General economic opportunities identified included:

- "increased export earnings" and internationally competitive companies (New Zealand Forest Industries Council [IP9])

Table 3.6 Opportunities identified by submitters from the use or avoidance of genetic modification technology

Opportunities identified	No. of submitters identifying opportunities from:	
	Use	Avoidance
Human health benefits	43	8
General economic benefits	38	6
Increased productivity	35	
Increased range of products	34	
Environmental benefits	33	15
Increased profitability	31	
Increased research capability	30	
Develop new knowledge-based enterprises	30	
Increased competitiveness	26	
Maintain research capability	21	
Enhance animal welfare	15	
New global role	4	6
Competitive advantage from organic production		22
Competitive advantage from "GE-free" production		15
Other	6	7

Note: this information is drawn from the complete submission, not just the response to Warrant item (i).

- "the potential to lift New Zealand's economic performance and quality of life" with higher value exports (AgResearch [IP13])
- increased "contra-season" seed production and evaluation, with New Zealand growers contracted to trial new varieties of northern hemisphere genetically modified crops (Aventis CropScience [IP14])
- "the means to ... re-position the [game] industry and develop a platform for future revenue growth, resulting in innovative improvements, new products and more efficient production and processing systems" (New Zealand Game Industry Board (NZGIB) [IP33])
- "accelerated industry development" (New Zealand Arable-Food Industry Council [IP56]).

Increased productivity

The opportunity for increased productivity, particularly in the farming sector, was advanced by 35 submitters. Most comments emphasised increased land productivity.

DuPont New Zealand [IP1] saw the potential for genetically modified crops to "increase the productivity of each acre of land". NZGIB [IP33] noted:

> The opportunities for improved productivity on farm are immense eg improved pasture species (cold tolerant, water efficient, improved nutrient balance, resistance to [increased salinity]), reduced incidence of disease (eg internal and external parasites) and improved selection of animals to enhance productive traits like reproduction, growth rate, muscling, velvet growth and quality.

New Zealand Dairy Board [IP67] foresaw "enormous opportunities" for dairying. It particularly mentioned benefits to farm productivity. New Zealand Cooperative Dairy Company [IP88] felt that genetic modification "could be used to lower the farm input costs and increase the value of dairy products".

Wrightson [IP3] viewed biotechnology as contributing to "future growth in our primary industries". It was seen to offer "significant advances in productivity, product quality and development of new products".

Increased range of products

Thirty-four submitters thought genetic modification would open opportunities in New Zealand for an increased range of products.

In an accompanying witness brief, DuPont [IP1] outlined various products and processes of genetic modification technology that were currently in development or anticipated further in the future:

- novel fibres, cosmetics and adhesives

- new building blocks for polymers
- corn with improved nutritional digestibility for farm animals
- corn with improved tolerance to heat and drought
- corn for human consumption that allowed increased absorption of iron (thus reducing need for iron supplements in developing countries)
- soybean oils with increased cooking stability and health value
- stress-resistant crops that could thrive in acid or saline soils.

Environmental benefits

Opportunities for generating environmental benefits were highlighted by 33 submitters. The potential to control pests, especially possums, was the most frequently cited specific opportunity. Submitters noted other environmental benefits, including:

- reduced chemical use
- eradication of diseases posing a threat to New Zealand's flora and fauna
- reduction in greenhouse gases.

Further discussion of environmental benefits can be found under Warrant item (j) (ii) (see section "Areas of public interest: environmental matters").

Increased profitability

Thirty-one submitters cited increased profitability as an economic benefit to be gained from using genetic modification technology. Submitters generally referenced specific industry applications in their comments such as the forestry and meat industries.

In the forestry sector, two submitters made specific mention of opportunities to improve profitability provided by use of genetic modification. Forest Industries Council [IP9] felt that "biotechnology can make an already sustainable industry even more sustainable — by improving profitability and environmental performance and enhancing international competitiveness". Genesis Research and Development [IP11] argued a further benefit related to increased profitability through the use of genetic modification in that: "Increased profitability and quality of managed forestry will also reduce pressure on native timber, resulting in greater conservation of native habitat."

In the meat industry, Meat New Zealand (MNZ) [IP31], NZGIB [IP33] and DuPont [IP1] saw benefits for increased profitability in the use of biotechnology.

NZGIB [IP33] maintained that:

> Detailed analyses indicate that reliance on traditional technology alone, will not deliver the profitability necessary to compete in the international market. Competing producers of both red and white meat are likely to adopt genetic technologies placing the New Zealand pastoral sector at a disadvantage.

MNZ [IP31] felt that the "new technologies" would advance its interests in the key areas of improving food safety and the market acceptability of consumer products. In particular, it noted "potential for stepwise improvements in profitability and growth in the meat sector".

DuPont [IP1] argued that the use of genetic modification techniques would "give farmers, regardless of the size of their operations, the potential to increase their productivity and profitability by growing crops with specialised value-added traits and resistance to pests".

Maintain or increase research capability

Throughout their entire submissions, 30 submitters noted that genetic modification technology would increase New Zealand's science and research capability. Twenty-one thought it would maintain such capability. Most comments came from universities, Crown Research Institutes and other research facilities and reflected the need for New Zealand researchers to interact with the international community.

Representative of this perspective, New Zealand Forest Research Institute [IP2] stressed that using genetic modification technology enabled researchers to "maintain front-end capabilities compared to research organisations worldwide".

Similarly, Crop and Food Research [IP4] noted that, in its experience, "New Zealand benefits immeasurably from its interaction with the international community". It drew attention to an aspect of particular importance to researchers and the wider "knowledge" community in commenting:

> New Zealand is estimated to contribute only 0.13% of the total global investment in research. However, we share access to the total pool of knowledge and use a far greater proportion of it than we produce.

Crop and Food Research argued further that:

> Indeed in most cases the knowledge we produce ourselves could not be used without other information from overseas.

Institute of Molecular BioSciences, Massey University [IP15] said:

> It is important that a cadre of New Zealand graduates is produced that not only have first-hand experience in the use of these technologies but are also qualified to understand, adopt and introduce such technologies from overseas jurisdictions into New Zealand.

Similarly, University of Auckland [IP16] stressed that for it to continue as "an internationally respected, research-led institution (and in order for New Zealand to remain part of the technologically advanced world)", the University's research programmes, research infrastructure, employees and teaching programmes "must reflect and play a role in advancing the best knowledge available internationally". University of Otago [IP19] maintained that "to remain competitive, to be able to collaborate with international partners, and indeed to remain part of the global science community, New Zealand researchers must be able to access overseas GMO material rapidly as it is developed".

New knowledge-based enterprises

In a "knowledge-based" society, knowledge is the basis for creating new and innovative goods and services. Thirty submitters saw the opportunity for New Zealand to develop new knowledge-based industries as a major reason to accept the use of genetic modification technology. Several submitters saw such new enterprise as a prerequisite for New Zealand's future economic wellbeing.

Submitters stressed the importance of maintaining a critical mass of experienced researchers engaging in dialogue and working on a collegial basis with other practitioners both in New Zealand and overseas. Several institutions considered their reputations to be at stake in decisions on genetic modification technology.

Lincoln University [IP8] commented:

> Genetic modification ... brings the University into contact with international and national researchers. This contact contributes to the specific reputation of Lincoln University as a global research institute ... Denying access to this technique would, consequently, deny researchers access to a valuable research information and reduce significantly the ability of individuals to develop their research to a high intellectual standard and for industries to develop their products and markets.

The new knowledge-based economy would create a new range of industries and products. New Zealand Life Sciences Network [IP24] saw opportunities in "high value specialised products derived from second generation biotechnology, not in commodity crops". AgResearch shared this opinion. It saw that the decline in commodity product prices required New Zealand "using innovation to add value and knowledge to create new industries" building on its existing assets in environmental and agricultural resources and research capability.

Increased competitiveness

Thirty-six submitters highlighted increased competitiveness. With biotechnology revolutionising world agriculture, Wrightson [IP3] saw genetic modification as

significant for New Zealand, "a country that competes in the global economy". Institute of Molecular BioSciences [IP15] also considered "maintenance and advancement of New Zealand's competitive advantage in biologically based industries" as a key reason for using genetic modification. Association of Crown Research Institutes [IP22] argued that New Zealand's future could only be assured "if it can develop new competitive products and services able to capture premium prices."

Enhanced animal welfare

The potential to advance animal welfare was noted by 15 submitters. Benefits cited included: maintenance of species integrity, improved disease prevention and control, and humane pest control.

New global role

Four submitters saw a potential for New Zealand to have a new global role if genetic modification were adopted. Interchurch Commission on Genetic Engineering [IP49] thought that New Zealand could take a "leading position globally" with the opportunity to devise standards, regulations and testing of genetically modified foods.

'Avoidance pathway' opportunities

The most frequently cited reason for avoiding the use of genetic modification were the benefits in competitive advantage from organic production or genetic modification-free production. Taking into account submitters' views throughout full submissions, 22 submitters noted benefits of organic production and 15 cited benefits of genetic modification-free production. Other opportunities from the avoidance of genetic modification technology included: environmental benefits (15 submitters), human health benefits (eight submitters), new global leadership (six submitters), and general economic benefits (six submitters).

Competitive advantage from organic production

Twenty-two submitters identified the benefits of competitive advantage of organic production as an important opportunity arising from the avoidance of genetic modification. Submitters supporting organic production generally came from organic farming interests and environmental groups.

Submitter comments representative of those supporting organic production included:

- "Organic markets ... 'New Zealand is in a unique position to capitalise on the world demand for clean food'" (AgResearch [IP13], quoting from another source).
- "[An] important driver of the global organic market is a widespread, and increasing, level of demand by wealthy consumers for organic foods and a corresponding rejection of GM foods" (Organic Product Exporters Group [IP53]).
- "The organic market world wide is growing in leaps and bounds based on popular consumer demand. Consumer resistance to GM is growing" (Canterbury Commercial Organics Group [IP65]).
- "New Zealand farmers overwhelmingly believe that the future of New Zealand farming lies with organics rather than with GM" (Green Party of Aotearoa/New Zealand [IP83]).

New Zealand as "GM free"

Fifteen submitters cited the benefits of New Zealand being "GM free" as a major reason for supporting the avoidance of genetic modification technology. Submitters supporting this view generally came from environmental groups as well as religious organisations. Typical of submitters' comments was the response from Interchurch Commission [IP49]:

> We have the opportunity to be GM food free in New Zealand, which would respect the wishes and cultural values of many people.

Environmental benefits

Fifteen submitters mentioned environmental benefits as a major reason for supporting the avoidance of genetic modification. Royal Forest and Bird Protection Society, Nelson/Tasman Branch [IP43] commented:

> Isolation and the development of strong border controls means that we have the opportunity to protect ourselves and our environment from genetic engineering and GM organisms. ... Some species [in the Nelson Province] are endangered and some as yet have not been identified.

Nelson GE Free Awareness Group [IP100]) listed environmental benefits stemming from avoidance of genetic modification as including maintenance of biodiversity and preservation of fauna and flora for future generations. There were associated benefits of sustainable agriculture and continued primary production of quality agriculture products, timber and fish.

Human health benefits

Eight submitters mentioned overall health benefits as being an advantage from not using genetic modification technology in New Zealand. These views are discussed more fully elsewhere in this report under Warrant items (m) and (j) (i) (see sections "Strategic outcomes" and "Areas of public interest: human health").

General economic benefits

Six submitters noted general economic benefits as a reason for avoiding genetic modification technology. Most submitters supporting this view noted such advantages as benefits to tourism and other export earnings from branding New Zealand as being "clean and green" and avoiding genetic modification. Representative of comments was the statement by Green Party [IP83]:

> The avoidance of genetically modified crops and animals creates the opportunity to access higher priced markets for certified organic and GE free food.

New global role

Six submitters saw the advantage of a new global role for New Zealand if genetic modification were avoided. Most views were linked to New Zealand's "clean green" image. Typical of such views was the description by BIO-GRO New Zealand [IP58] of opportunities from the avoidance of genetic modification technologies in food production: "GE Free branding for all New Zealand food products similar to our Nuclear Free image" and enhancement of New Zealand's image as "an exporter of top quality food and beverages to lucrative markets".

'Dual pathway' possibilities

Submitters offered views on whether or not it would be possible for New Zealand to combine use of genetic modification with genetic modification-free uses and organic uses, thereby allowing a wide range of opportunities for beneficial developments. Of the 25 submitters who felt a 'dual pathway' was possible, 10 submitters were from research organisations, nine from industry networks or associations, four from private companies and two from other advocacy groups.

Several witnesses clearly envisaged the possibility of combining genetic modification technology in some areas but not in others. For example, several witnesses supported use of genetic modification techniques in human health together with avoidance of genetic modification in commercially grown crops. More controversial was the issue of organic farming where submitters had clearly different views on what was acceptable practice.

'Pathway' for organic production systems

In this Warrant item, and throughout the Interested Persons submissions generally, there was considerable discussion on whether organic farming and genetic modification were compatible. The attitude of those submitters who clearly indicated their opinion on whether New Zealand could combine genetic modification, genetic modification-free uses and organic uses was assessed. This assessment was possible for 55 submitters (approximately half of the total Interested Persons). On the proposition that New Zealand could combine genetic modification, genetic modification-free uses and organic uses: 25 submitters agreed and 26 submitters disagreed. Four submitters considered that New Zealand could "maybe" combine genetic modification, genetic modification-free uses and organic uses.

Opinion on this issue was strongly correlated with overall stance on genetic modification. Of the 25 submitters who felt that coexistence was possible, 24 were 'strongly for' and one 'tended to be for' genetic modification. Of the 26 not supporting coexistence, 20 were 'strongly against' and six 'tended to be against'.

All 10 submitters from research organisations felt that genetic modification and organic farming could coexist, as did nine of the 13 submitters from industry networks or associations and four of the five private companies. Submitters who felt coexistence was not possible tended to be from advocacy networks or associations (seven submitters) and all six of the organic groups, as well as other religious, Maori and consumer networks.

On a sector basis, the opinion was divided: 17 of those in the economic/productive sector felt that the two types of farming could coexist and 10 felt not. Two were undecided.

Compatibility of genetic modification and organic production systems

Several submitters who commented on this Warrant item explicitly stated that both organic production systems and genetic modification technologies could coexist. They included New Zealand Vice Chancellors Committee [IP18], Meat Industry Association of New Zealand (MIA) [IP32] and New Zealand Biotechnology Association (NZBA) [IP47].

NZBA felt that "organic production systems and those using genetically modified crops can readily coexist in New Zealand". It further noted it suspected that "it would be economic suicide for New Zealand to reject modern science and technology in an attempt to become the 'organic niche' nation for world agriculture". NZBA had not carried out a financial analysis

of the various options to support its view but strongly recommended that "this should be done if there is a widely held perception by the public that an 'Organic' nation is preferable to one based on our previous strengths in the biological sciences".

Vice Chancellors Committee [IP18] felt that the two technologies could co-exist "with sound risk management practices" and added that, therefore, New Zealand could "benefit simultaneously from either method". MIA [IP32] also referred to another form of compatibility, that between "the reduced use of chemicals and pharmaceuticals due to gene technology" and "the objectives of organics".

Incompatibility of genetic modification and "GM-free" production

Several submitters advanced reasons why organic production systems or "GM-free" products could not coexist with genetic modification. Canterbury Commercial Organics Group [IP65] said: "Isolating organic growing from GE contamination would be impossible given the acknowledged spread of pollen to outcross into the wild community." The Group went on to say that birds, rodents, vehicles and water races could all add to such contamination.

Comvita New Zealand [IP74] noted its particular concern (as a bee products company) at the risk of honey bees collecting resources from genetically modified crops and the consequent difficulty of ensuring that the bee products were "GM free". It made an assessment of "the risk of GMOs entering bee products from GM trial plots in New Zealand" and found that, although there was little likelihood of its own products containing genetically modified material, "10 out of 23 (43.5%) plots capable of producing bee product raw materials lacked adequate bee controls".

Uncertainty about coexistence of genetic modification and organic production systems

Four submitters were ambivalent about whether New Zealand could successfully combine organic production with genetic modification. Typical of this position was the view expressed by Hamilton City Council [IP20] that it was "unable to judge the merits" of the opposing viewpoints and it advocated "looking at all options".

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Outcomes of Consultation: Submissions from Interested Persons

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3.15 Areas of public interest: an introduction

The Warrant under item (j) invited submissions on "the main areas of public interest in genetic modification, genetically modified organisms, and products". Four main areas were identified in the Warrant:

(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

Approximately half of the Interested Persons (58 submitters) made substantial comment on this item. A majority of this group (38 submitters) were rated as being 'strongly for' or 'tending to be for' genetic modification. Of the remainder, 18 submitters were classified as being 'strongly against' or 'tending to be against' genetic modification.

Comment on these public interest issues came mostly from industry associations or networks (19 submitters) and research organisations (11 submitters), as well as other advocacy groups (six submitters) and private companies (five submitters).

A majority of Interested Persons commenting on this item (33 submitters) had an economic or production sector background, six had an environmental focus, five had a cultural and ethical background and three had a health background. The remaining 11 submitters came from other backgrounds, such as governance and intellectual property.

Issues of public interest were a significant focus of many submissions. Throughout all submissions the number of submitters identified as making substantial comment on these issues were: economic issues (53 submitters), health issues (41 submitters), environmental issues (35 submitters), ethical issues (20 submitters), Maori cultural issues (21 submitters), other cultural issues (four submitters) and spiritual issues (four submitters).

Submitters' comment is discussed in the following sections under the headings detailed in the Warrant:

- human health
- environmental matters
- economic matters
- cultural and ethical concerns.

However, the Warrant item on areas of public interest also elicited more conceptual representations on genetic modification, including wide-ranging issues of understanding, acceptability and choice.

Information, acceptability and choice

Many of the general comments offered on this Warrant item reflected various strategic issues previously raised (see section "Strategic issues"). Submitters presented issues of information, acceptability and choice, with specific comment centring on:

- the public's need for education on the issues
- the public's right to know where genetic modification was used
- the public's right to choose
- the public's opportunity for exercise of choice.

In brief, most comments:

- emphasised the need for further public education on genetic modification
- supported the basic right for consumers to know what products, and what technology, involved genetic modification
- supported the public's right to choose whether certain products, or processes, should be consumed or used
- supported the public's ability to exercise an informed choice.

Of these, the need for public education and the public's right to know and right to choose are included here because they span several of the areas of public interest as well as other aspects of genetic modification. Exercise of choice is discussed here only briefly: it is covered later in more detail in relation to food safety, consumer choice and food labelling (see section "Areas of public interest: human health").

Need for public education on issues

Many people took the opportunity under Warrant item (j) to mention the lack of public understanding of issues and the need for more public education. Overall, 23

of the total number of Interested Persons noted specific concerns about public education on genetic modification. They included industry networks and associations, research organisations and Maori groups. Most of these submitters favoured use of genetic modification technology: 10 were 'strongly for' and five 'tending to be for' genetic modification.

Several submitters cited lack of public understanding of the benefits of genetic modification as an issue. National Testing Centre [IP44] noted:

> … the public in New Zealand and other places are often ignorant of the facts of human biology and genetics … Time magazine (7 August 2000) quotes that in a recent poll, 35% of Europeans agreed with the statement "Ordinary tomatoes do not contain genes, while genetically modified tomatoes do."

New Zealand Life Sciences Network [IP24] had similar concerns. It commented that:

> Perceptions rather than facts heavily influence opinions about GM products. … Real public interest lies in being able to continue to do the research.

Lysosomal Diseases New Zealand [IP99] stressed "fear of the unknown" and the "absence of good information".

The public's right to know

Comments upholding consumers' right to know what products and what technology involved genetic modification had wide sectoral support, including that of biotechnology companies, industry associations and religious groupings. Typical of views presented were the following comments:

- "We believe consumers have the right to know what they are purchasing" (DuPont [IP1]). (DuPont also advocated "informed consumer choice through meaningful information and product assurances".)
- "Consumers have a right to know what they are buying when they go to the supermarket, and farmers have a right to know what they are planting in their fields" (Nelson GE Free Awareness Group [IP100], quoting from a press release of October 2000).

Under the general heading of "public education, consultation and choice", Monsanto [IP6] noted that it supported "the right of the general public to be consulted on important issues" and that "it is essential that the public is well informed and that an appropriate organisation is resourced to present issues". Monsanto maintained that "the individual must have sufficient information for freedom of choice".

The public's right to choose

Submitter comment on consumers' right to choose was noted by submitters such as Grocery Manufacturers Association [IP54] which argued: "It is essential that appropriate information about the GM status of food is available as consumers must have the right to choose what food they consume." Similarly, Quaker Spiritual Ecology Group, Religious Society of Friends [IP50] stated that "consumers have a right to choose the food they eat".

New Zealand Catholic Bishops' Conference [IP38] commented on safeguarding the rights of individuals to make choices, stating that mechanisms were available "to ensure that those who do not wish to eat GM food can avoid doing so, while not depriving others of their right to choose GM foods if they are considered to confer an advantage".

Although the issue of choice had wide application, most submitters commented on this matter in terms of foodstuffs. The opportunity to exercise choice in purchase of food through adequate product labelling is discussed in "Areas of public interest: human health".

The public's exercise of choice

Given the right to choose, the public then need to be given the opportunity to exercise that choice. This requires that adequate information be available for people to understand the issues (as discussed above) and, in the case of traded goods, that products be appropriately identified.

Issues of food safety elicited a very high level of response in all representations to the Commission. In terms of comment on exercise of choice, most offered in submissions from Interested Persons focused on the purchase of foodstuffs and adequate product labelling. This is discussed later (see "Areas of public interest: human health").

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3.16 Areas of public interest: human health issues

Introduction

The Warrant under item (j) (i) invited submissions on "human health (including biomedical, food safety, and consumer choice)". Health issues were a major concern for most of the 58 submitters commenting on areas of public interest. Most comment centred on the three areas specified in the Warrant: biomedical research, food safety and consumer choice.

Biomedical research

Biomedical research was a significant focus of many comments. There were three broad groupings in comments: those who supported biomedical research, those who had concerns about such research, and those who felt it was inconsistent to support genetic modification techniques in medicine but not support its application elsewhere.

Submitters who supported use of genetic modification technology in medicine mostly came from medical research organisations, universities and patient advocacy groups.

The stance of these submitters was encapsulated in the view expressed by New Zealand Biotechnology Association [IP47] that "every New Zealander should have access to the latest healthcare benefits available through genetic modification". New Zealand Life Sciences Network [IP24] also summed up the impression from many submissions with its comment that there was "greater comfort with medical applications than [with] food and agriculture".

Submitters often noted specific advantages of using this technology in medicine. For example, submitters such as University of Otago [IP19] saw the advantages of biomedical research as including:

- better understanding of genetics and the human genome sequence
- safer and more specific drugs
- more accurate prescribing

- better diagnoses of inherited disease
- more predictive tests for disease
- improved understanding of complex diseases.

Such advantages were also mentioned by University of Canterbury [IP7], Malaghan Institute of Medical Research [IP10], Researched Medicines Industry Association of New Zealand [IP55], and New Zealand Transgenic Animal Users [IP45]. Malaghan Institute [IP10] noted that genetic modification at the Institute did not pose a threat to human health or to the environment and that "this has been widely accepted by the public".

New Zealand Feed Manufacturers Association/Poultry Industry Association of New Zealand/Egg Producers Federation of New Zealand [IP35] also raised the possible benefit of animal organ transplants. Transgenic Animal Users [IP45] noted its view that:

> … the New Zealand public has relatively little appreciation of the importance of GM animals, particularly in medical research. Rather than a technology to be shunned or feared, GM animal research offers enormous hope in the battle against disease.

Patient support groups such as the Cystic Fibrosis Association of New Zealand [IP39] reinforced the importance of genetic modification technology in medical research. Cystic fibrosis sufferers saw genetic modification as their only hope. The Association noted: "… it is 'genetic irregularity' that causes conditions like Cystic Fibrosis. If there is no modification of the gene, then there is no benefit."

Other submitters expressed concerns about the use of genetic modification for health purposes. Most of these submitters voiced concern at unknown risks and side effects.

Qualified support for this technology came from Physicians and Scientists for Responsible Genetics New Zealand (PSRG) [IP107], which stated:

> Provided it can be guaranteed that there are not general side effects from use of GE by individuals seeking cures to medical problems of genetic origin, PSRG supports the use of genetic engineering in contained medical research and production.

Nelson GE Free Awareness Group [IP100] also had concerns. It maintained that "the biomedical uses of genetic engineering have not been proven and may well harbour tremendous risks of environmental pollution".

Another smaller group considered it was not practical to restrict genetic modification techniques to one particular application. Representative of this position were the comments from New Zealand Organisation for Rare Diseases

[IP98], which felt:

> It is not a practical option to say yes to [genetically modified] medicine and no to [genetically modified] food/crops, because the two are closely intertwined. Some medicines may be harvested from [genetically modified] crops, while some genetically modified foods may have nutriceutical value.

Food safety

Food safety was notable among the topics relating to genetic modification as a high-priority area for many submitters (and a major focus of all other forms of representation to the Commission). Typical of comments on its importance was the statement by Federated Farmers of New Zealand [IP34], which saw human health issues as being: "of considerable public interest, with genetically modified food high on the agenda of public concern".

Submitters were particularly polarised in their views on food safety.

Proponents of genetically modified foods noted the good "safety" record of genetically modified foods. They especially emphasised rigorous testing requirements. Specific comments noted about food safety included:

- Proteins produced in genetically modified crops typically had a long history of safe consumption (Monsanto New Zealand [IP6]).
- International agencies agreed that the food safety risks for foods from genetically modified crops were the same as those for food produced by conventional breeding methods (Monsanto [IP6]).
- The greatest risk of hazard from food was not the food itself but its handling and preparation (New Zealand Life Sciences Network [IP24]).
- There was no evidence that any food product derived from genetically modified organisms and currently on the market was unsafe for human consumption (Life Sciences Network [IP24]; similarly, Meat New Zealand [IP31], New Zealand Game Industry Board [IP33]).
- Genetically modified foods have undergone far greater testing than conventionally produced food (New Zealand Grocery Marketers Association [IP54]; similarly Life Sciences Network [IP24], Monsanto [IP6]).
- Anti-genetic modification campaigners used lack of public knowledge to create fear and the impression that genetically modified foods that had been approved were unsafe (Biotenz [IP25]).
- The current Australia New Zealand Food Authority (ANZFA) assessment system provided adequate coverage of food safety (Meat Industry Association of New Zealand (MIA) [IP32]).

Submitters concerned about using genetic modification techniques for food cited several reasons for their opposition to genetically modified foods. Most concerns centred on lack of information on downstream effects and the adequacy of "tests". Specific concerns cited included:

- There was a lack of independent testing of genetically modified foods (Safe Food Campaign [IP86]).
- There had been no testing for long-term health risks of genetically modified foods (GE Free New Zealand (RAGE) in Food and Environment [IP63]).
- The vague definitions of the concept of "substantial equivalence" and the generalness of its interpretation, of molecular and nutritional equivalence, meant that, in effect, substantial equivalence was an avoidance of safety testing (Safe Food Campaign [IP86]).
- The concept of substantial equivalence had been used to include genetically modified ingredients in food without adequate evaluation (Sustainable Futures Trust [IP51]).

Other submitters expressed concerns about the safety of the crop production systems for genetically modified foods. For example, Commonsense Organics [IP66] noted that the outcomes of genetic modification experiments were unknown and that if an unwanted result occurred "in the wild" it would be likely to be irreversible. It suggested that herbicide-resistant, genetically modified crops resulted in an increase in herbicide use, not a decrease. Commonsense Organics also commented that once genetically modified crops were permitted in New Zealand, the opportunity might be lost to provide organically certified foodstuffs as an alternative to genetically modified foods.

Submitters concerned about genetically modified foods often focused their arguments on testing procedures. For example, Rural Women New Zealand [IP52] noted that:

> … assessing the safety of GM foods is complicated by: firstly, practical difficulties posed by testing "whole" foods (whereas most food safety analytical tools have been developed for constituent parts — additives, residues and contaminants, ie, small volumes); and secondly, by the lack of labelling.

Consumer choice

Health issues, especially food safety, provided a catalyst for expression of several wider concerns of public interest. Paramount among these was the issue of consumer choice, with comment centring on the public's need for education on the issues of genetic modification, the public's right to know and right to choose

(discussed previously: see "Areas of public interest: an introduction"), as well as the public's opportunity to exercise that choice.

The opportunity for the public to exercise choice had two dimensions:

- the need for adequate information
- the appropriate labelling of foods.

The need for adequate information was discussed previously so discussion here focuses on food labelling.

Labelling of foods

Several submitters, mostly biotechnology companies and industry representatives, supported the widespread dissemination of information to the public and saw labelling as the means to afford consumers choice.

Grocery Manufacturers Association [IP54] said: "The current labelling regime provides meaningful information to consumers … The dissemination throughout the community of factual information that is scientifically substantiated and verified and devoid of vested interest influence is imperative."

MIA [IP32] also stressed the importance of food labelling to ensure consumer choice. It felt that "the requirement to label food resulting from GM technology allows consumers the opportunity to make choices, accepting or rejecting such food as they wish".

Likewise, Sustainable Futures Trust [IP51] supported "the unambiguous labelling of food", noting that until the risks were much better known and the public felt otherwise, all food that contained any genetically modified component should be unambiguously labelled and genetically modified ingredients subjected to the same testing procedures as pharmaceuticals.

New Zealand Jewish Community [IP80] also supported labelling to allow Jews 'informed choice'. It maintained that:

> The principle of 'informed choice' of food is central to the practical observance of food laws. Those who wish to choose kosher foods need to be properly informed by the labelling and certification on the food package. They can select, or not select, according to the information given. Full and accurate labelling of all foods does not impose Jewish observance of religious dietary laws on others; but without such labelling, Jews will not have 'informed choice'.

Submitters from environmental and consumer organisations, however, expressed concerns about the current labelling system and the efficacy of the ANZFA arrangements. Green Party of Aotearoa/New Zealand [IP83] saw the current labelling system as "inadequate and misleading". Safe Food Campaign [IP86]

agreed and "rejected" the ANZFA testing procedures as being safe on four grounds: lack of independent testing, limited allergenicity and toxicity tests, use of substantial equivalence as a method of testing and its vague definitions. Friends of the Earth (New Zealand) [IP78] also noted that claims that genetically modified foods were safe (based on the "substantial equivalence" argument) had "sidelined" health professionals and "elevated plant scientists to a position where they are considered to be experts on the safety of genetically modified foods".

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3.17 Areas of public interest: environmental matters

Introduction

Warrant item (j) placed the environment (including biodiversity, biosecurity issues and the health of ecosystems) as the second main area of public interest. The environment was a significant issue throughout many of the submissions with 35 submitters making substantial comment on environmental matters.

Submitters' views on the environment were fairly evenly distributed between those supporting and those opposing the use of genetic modification technology. Views expressed across all of submissions showed a fairly even distribution of opinion: 16 of the submitters making substantial comment on environmental issues supported and six generally opposed the use of genetic modification technology. More specifically, 11 submitters had concerns about genetic modification in relation to New Zealand's flora and fauna.

Supporters of genetic modification generally felt that any environmental risks posed by genetic modification could be managed. They also noted positive environmental benefits in using genetic modification to protect New Zealand's biodiversity.

Major concerns of those submitters who had reservations about the environmental impact of genetic modification were:

- "unknown" and "unpredictable" impacts on the ecosystem
- gene transfer.

Other specific concerns of submitters included:

- development of unexpected characteristics in genetically modified organisms
- development of new pathogenic viruses
- genetic erosion (ie, the loss in genetic diversity through the planting of crops of the same hybrids)
- development of genetically modified, herbicide-resistant weeds ("super-weeds")
- unintentional spread of genetically modified organisms throughout an environment

- potential degradation of air, water and soil quality
- reduction in the variety of food available to animals.

Effects on the ecosystem

Among those submitters generally opposing the use of genetic modification technology, the most frequently mentioned issue was concern about the unpredictable impacts of genetically modified organisms on the ecosystem as a whole. Many submitters noted that the interdependence of the components of an ecosystem was such that a small change could have far-reaching and irreversible deleterious effects.

Representative of these concerns were comments from Safe Food Campaign [IP86], which talked of the "unbalancing effects" that genetically modified organisms might have on an ecosystem. Canterbury Commercial Organics Group [IP65] expressed concern at the "downstream effect on the wider environment". Pacific Institute of Resource Management [IP84] said information was lacking on how genetically modified organisms would behave "in context" ("genomic, cellular, ecological and evolutionary"). Several submitters noted the need to recognise that the environment was a "complex system" with each element interdependent.

Environment and Conservation Organisations of New Zealand (ECO) [IP102] effectively summarised opinion on the issue in its comment that:

> Every part of an ecosystem interacts with other parts and even seemingly tiny changes can have huge effects on our biodiversity and health of our ecosystems. ECO is concerned that the use of genetically altered organisms could cause irreversible and damaging contamination of our environment with consequent loss of biodiversity.

Bio Dynamic Farming and Gardening Association in New Zealand [IP61] noted that New Zealand had the opportunity to wait until the outcomes were clear of what happened elsewhere as other countries released genetically modified organisms into their environments.

Interchurch Commission on Genetic Engineering [IP49] expressed concern about "the unintentional spread of GM plants or other organisms throughout the environment" and noted that this could affect the "credibility" of organic farmers. Interchurch Commission also raised concerns about "respect for God's creation" and the importance of "retaining integrity and biodiversity of species" in the environment.

Royal Forest and Bird Protection Society of New Zealand [IP79] noted the "responsibility of people to other living things" as expressed in the concept of

kaitiakitanga (guardianship). The Society said that "biodiversity is New Zealand's biological wealth" and that "the uniqueness of much of New Zealand's indigenous biodiversity means that responsibility for its continued existence is entirely ours".

Gene transfer

Gene transfer was the next most frequently mentioned cause of concern. This included both gene transfer by pollination (the natural spread of pollen via the wind, bees and birds) and horizontal gene transfer (the transfer of genes between organisms by means other than sexual reproduction).

Submitters expressed concerns about the potential impact on organic production, the transfer of engineered genes to related 'wild' species, the spread of viral pathogens, as well as development of genetically modified, herbicide-resistant crops, leading to the development of "super-weeds" and "super-bugs".

Gene transfer was raised as a potential issue of public interest in submissions from a number of sources including those of submitters who were generally regarded as supporters of genetic modification. Submitters who mentioned gene transfer (either by pollination or horizontal gene transfer) included: AgResearch [IP13], New Zealand Game Industry Board [IP33], Interchurch Commission on Genetic Engineering [IP49], Canterbury Commercial Organics Group [IP65] Environmental Risk Management Authority (ERMA) [IP76], Royal Society of New Zealand [IP77a (biological sciences)], Pacific Institute of Resource Management [IP84], Safe Food Campaign [IP86], New Zealand Cooperative Dairy Company [IP88], New Zealand Association of Scientists (NZAS) [IP92], Nelson GE Free Awareness Group [IP100], New Zealand Vegetable and Potato Growers' Federation/New Zealand Fruitgrowers' Federation/New Zealand Berryfruit Growers' Federation [IP75], Royal Forest and Bird Protection Society of New Zealand [IP79], Green Party of Aotearoa/New Zealand [IP83] and ECO [IP102].

Specific public interest issues raised by submitters about gene transfer are outlined below.

Pollen drift

NZAS [IP92] noted that "the main area of environmental concern appears to be one of pollen drift from GM plants and the associated problem of horizontal gene transfer". The Association argued that "the main issue is one of management". It further suggested that the "terminator" genetic modification technology "could be productively applied in areas where there may be a threat to native flora or where weedy characteristics pertain".

New bacteria and viruses

Noting that horizontal gene transfer was now recognised as a "phenomenon" that was "far from rare", Canterbury Commercial Organics Group [IP65] said that this suggested "that transfer of transformed genes to new host plants, bacteria or viruses" might produce "unplanned events … an unpredictable, potentially disastrous and irreversible phenomenon". Pesticide Action Network New Zealand [IP87] suggested that soil bacteria could take up genetic material from genetically modified organisms and that the use of virus-resistant genetically modified crops could result in "the appearance of new disease-causing viruses".

"Super-weeds"

The issue of transfer of engineered genes to related "wild" species, which could allow the plant or weed a competitive advantage through enhanced fitness or greater reproductive capacity (thereby creating "super-weeds"), was a significant concern of several submitters. Safe Food Campaign [IP86] registered particular concern about the creation of new weeds. It commented that the creation of new weeds by horizontal gene transfer was viewed as "genetic pollution". Noting that "techniques being utilised to reduce the possibility of genetic pollution are 'crippled' GM bacteria and viruses" (ie, "'crippled' laboratory strains of bacteria and viruses … that have been engineered not to survive release into the environment"), it warned that "if this technology fails, many critics [believe] that 'super weeds' will develop". Canterbury Commercial Organics Group [IP65] noted that such plants would have "the capacity to overwhelm a given ecosystem".

Transfer from plant material to animals

Game Industry Board [IP33] considered that "the evidence to date" indicated that "the risks of instability in new organisms, the risks of horizontal gene transfer from say plant material in the digestive tract of an animal to animal cellular DNA or the risks of pollen contamination from transgenic plants are both minimal and manageable".

Unpredictability

Pacific Institute of Resource Management [IP84] noted that "new evidence suggests that current knowledge of evolutionary theory is inadequate to predict the fate of recombinant organisms or recombinant genes". It further commented that "there is no way to extrapolate from one region or environment to another, differing environment … especially true when GMOs are transferred to ecosystems and climates which differ from those where they were first developed and used". As a consequence, the Institute recommended: "Unless there is sufficient scientific evidence that a GMO or its recombinant genes will not pose any environmental stress or health impact we should abide by the precautionary approach."

Irreversibility

ECO [IP102] raised concerns about "the possibility of new and virulent diseases through the use of the antibiotic marker genes and viruses used in the process of gene transfer and identification and from the actual organisms created through horizontal gene transfer". It argued that "once released these organisms cannot be recalled".

Cultural implications

Royal Society of New Zealand [IP77b (social sciences)] noted that "genetic manipulation may be seen to interfere with the integrity of species" and that "the mixing of genes between species is an affront to the mauri inherent in whakapapa". And Nga Wahine Tiaki o te Ao [IP64] stated:

> 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.

Management of risks

Supporters of genetic modification also commented on environmental issues. Submitters frequently refuted claims of risks to the ecosystem from genetically modified organisms, arguing that the risks could be assessed, managed and therefore minimised. University of Otago [IP19] claimed that there was "no evidence of risk to the environment, biodiversity, or ecosystems, despite 25 years of laboratory based GM research". Crop and Food Research [IP4] maintained that "potential environmental risks posed by genetically modified crops are very similar to those posed by crops that are not genetically modified". HortResearch [IP5] commented that New Zealand had "thorough, robust, and systematic risk management systems in place". Monsanto New Zealand [IP6] concurred, arguing that in New Zealand environmental effects were "thoroughly evaluated".

Several submitters noted that effective management could reduce risk. New Zealand Biotechnology Association [IP47] saw the potential risks to the environment from genetically modified crops as "not due to the nature of the technology that derived the product" but, rather, "due to the way in which that product is used". NZAS [IP92] argued that the risks of both pollination from genetically modified plants and horizontal gene transfer could be managed effectively. NZAS noted that many plants used for food production did not have weedy characteristics and had no wild relatives in New Zealand; ie, selective breeding for food purposes had essentially "ring-fenced" most crop plants.

New Zealand Transgenic Animal Users [IP45] said that the "biosecurity risks of GM animals are very low, and little different to those from non-GM animals" and added that "regulatory systems in place are adequate to manage these risks".

Environmental benefits

Some 33 submitters felt that genetic modification could provide opportunities for environmental benefits: 16 submitters felt that genetic modification was acceptable if used for environmental protection. Several submitters noted substantial benefits to be gained from the use of genetic modification in environmental management, including preservation of biodiversity and improving biosecurity, as well as bioremediation. The benefit for pest control, particularly control of possums, was frequently mentioned. Supporters of genetic modification not only saw the risks to the ecosystem as "low" and "manageable" but also believed that genetic modification offered ecological advantages.

Introduction of genetic modification meant that "agriculture will be revolutionised", according to New Zealand Life Sciences Network [IP24], with benefits of reduced use of harmful chemicals.

AgResearch [IP13] saw environmental benefits in greenhouse gas reductions (by reducing methane production from ruminant animals through modification of rumen microorganisms) and reduced nitrate pollution of groundwater (by using improved legumes to supply nitrogen rather than inorganic fertilisers). Genetic modification technology was also of similar benefit to the environment by restoring the "nitrogen balance in the soil" and the ability to "bioremediate harmful pollutants in the environment" (Life Sciences Network [IP24]). It offered "tools for control and eradication of diseases of special concern to our biosecurity". (New Zealand Veterinary Association [IP28]).

Several submitters argued that conservation of indigenous flora and fauna would be enhanced. University of Canterbury [IP7] advanced the benefits of genetic modification to biodiversity arguing that: "Routine GE is an essential tool in analysing and monitoring biodiversity and ecology. Conservation of indigenous flora and fauna depends on this fundamental research." University of Otago [IP19] noted that much of the research aimed at protecting the diversity and health of ecosystems was based on the use of genetic information, including fingerprinting of endangered species. "Terminator" genetic modification technology could also be productively applied where there might be a threat to native flora (NZAS [IP92]).

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3.18 Areas of public interest: economic matters

Introduction

The Warrant under item (j) (iii) invited submissions on "economic matters (including research and innovation, business development, primary production, and exports)".

Most submitters commenting on this item were involved in the production sector. Most were strongly in favour of using genetic modification. The principal sector focus for the 58 submitters making substantial comment on areas of public interest was the economic/production sector (33 submitters). A majority (31 submitters) were assessed to be 'strongly in favour' of genetic modification, with a further seven 'tending to support' the use of genetic modification.

Economic information dominated much of the material in written submissions from all Interested Persons, with 53 submitters making substantial comment on economic issues. Some of this information was included in response to Warrant item (j) (main areas of public interest), but much of the economic material was included in other areas, especially Warrant item (l) (strategic options available to New Zealand) and also under Warrant item (i) (opportunities from the use or avoidance of genetic modification) as described previously in the relevant sections. Witness briefs also contained considerable economic argument that is not discussed in this report.

Most submitters saw the 'public interest' in economic matters in terms of the economic benefits that biotechnology would bring to New Zealand's production sector (including primary and secondary production, and research and development). Improved performance in this sector was seen as the key source of economic benefit for the country as a whole. Those submitters opposing the widespread use of genetic modification technology generally raised issues of economic benefits arising from avoidance of the technology, such benefits deriving from fostering New Zealand's "clean green" image and organic production. They also expressed concerns about moral constraints on the pursuit of economic advantage.

Economic advantage from use of genetic modification

The key issues raised by submitters who saw economic benefits for New Zealand in the use of genetic modification technology were generally grouped around two themes:

- benefits in terms of business development
- opportunities from research and development.

Business development

Business development opportunities available through the use of genetic modification technology were frequently evidenced as a source of economic advantage to New Zealand, particularly by submitters from biotechnology companies and organisations with affiliations to the production sector. Typical of such comments were those of Wrightson [IP3], which listed the economic advantages of "improved yields, increased productivity and improved product quality" from the use of biotechnology.

Genesis Research and Development [IP11] highlighted encouraging "wealth creation", maintaining a "competitive economy" and attracting "foreign investment" as key reasons for choosing genetic modification technologies. This view was shared by New Zealand Biotechnology Association [IP47], which considered that genetic modification had the potential "to lift New Zealand's economic performance and quality of life".

Industry representatives noted several industry-specific benefits as economic matters of public interest. Production areas for such benefits included trees, food and fibre. For example, New Zealand Cooperative Dairy Company [IP88] cited "reducing the cost of milk production" and "reducing farm inputs" as potential benefits from using genetic modification. Monsanto New Zealand [IP6] saw future benefits in "healthier food" and "nutraceuticals in food". AgResearch [IP13] saw opportunities for economic benefits in food production with "high value niche opportunities in export markets". New Zealand Forest Industries Council [IP9] noted several "economic opportunities" including the potential to "improve the health of our forests and … improve the management of insect and other pests", as well as "by growing trees that require the use of less and fewer herbicides". Carter Holt Harvey/Fletcher Challenge Forests [IP17] specifically mentioned the potential benefits of improvement in wood yield and improvement in wood quality.

New Zealand Veterinary Association [IP28] argued that without the use of genetic modification technology to control and eradicate animal diseases New Zealand's "chances of success" would be "severely limited". New Zealand Game Industry Board [IP33] advanced economic net benefits through "gains from increased parasite host resistance", "potentially lower agricultural inputs" and "improved nutritive value of food". New Zealand Feed Manufacturers Association/Poultry Industry Association of New Zealand/Egg Producers Federation of New Zealand [IP35] cited general economic benefits arguing that the "economic benefits resulting from GE technologies will be significant, with a reduction in cost inputs". In manufacturing, Federation of Maori Authorities [IP69] identified "wealth created by food and fibre industries" as an economic advantage.

Research and innovation

Opportunities for New Zealand to advance its production capacity through the use of knowledge-based technology were frequently referenced by submitters. (See also discussion of Warrant item (i), "Opportunities from the use or avoidance of genetic modification".)

Research and development using genetic modification was seen as a "the key strategic option for the New Zealand dairy industry" (Cooperative Dairy Company [IP88]). In the research sector, economic benefits were noted for New Zealand "as a producer of pharmaceuticals, nutraceuticals, medical and veterinary treatments" using genetic modification technology (New Zealand Biotechnology Association [IP47]). Researched Medicines Industry Association of New Zealand [IP55] emphasised how biotechnology would "boost New Zealand's knowledge-based economy".

Submitters noted several industry-specific economic benefits, especially benefits from innovative research using genetic modification techniques. They saw particular advantages to be gained from the development of new and innovative products, as well as the potential for providing new management tools. For example, AgResearch [IP13] saw economic advantages from the development of "novel pesticides". Carter Holt Harvey/Fletcher Challenge Forests [IP17] saw economic benefits from the opportunity "to diversify into end products" such as "new pharmaceuticals and liquid fuels — products currently outside the range of forest companies". Feed Manufacturers Association/Poultry Industry Association/ Egg Producers Federation [IP35] saw "the ability to produce a consistent product is of significant advantage to the Intensive Livestock Industry where it is traditionally difficult to produce the same product every season".

Research institutions (especially in the health sector) and biotechnology companies (such as Genesis [IP11]) also noted the general economic benefits of immediate job creation, follow-on employment effects and a highly skilled workforce.

But the greatest economic benefit seen by many submitters (from the research sector and primary and secondary production sectors) was to be gained "from the continued development of biotechnology and the full range of its tools" (New Zealand Life Sciences Network [IP24]). Again, "our best economic interests … reside in the continuing development of a strong and vibrant innovative culture in the field of GM" (New Zealand Association of Scientists [IP92]). These views were typical of the submitters' opinion that defined progress in terms of new paradigms. While increased yields, increased productivity and improved product quality were important, submitters noted that even more important was the new technology itself whose full potential had yet to be realised.

Economic advantage from avoidance of genetic modification

The key issues raised by submitters who did not see economic benefits for New Zealand in the use of genetic modification technology were generally grouped around two themes:

- the negative impact of use of genetic modification, especially on New Zealand's "clean green" image
- the positive impacts of "GE-free" production, especially organic produce.

These submitters also raised issues of moral constraints on the pursuit of economic advantage.

Negative impact on "clean green" image

Several submitters had concerns about the risks of any commercial release of genetically modified crops to New Zealand's "clean green" image. Typical of such concerns were the comments from New Zealand Vegetable and Potato Growers' Federation/New Zealand Fruitgrowers' Federation/New Zealand Berryfruit Growers' Federation [IP75], which noted:

> … there is potential for the first commercial releases of GM crops in New Zealand to have an impact on the marketing leverage of our exporters using New Zealand's "clean green image". We are not implying that GM is necessarily "un-clean and non-green" however consumer perception currently links these issues. "Clean and green" is a real marketing

> tool and the market reality is that it may be affected by association with GM crops in New Zealand.

Submitters' views on the compatibility of organic production and genetically modified crops are discussed more fully in relation to Warrant item (i), "Opportunities from the use or avoidance of genetic modification".

Positive impacts of "GE-free" production, especially organics

Submitters who saw economic advantage from avoidance of genetic modification perceived economic benefits to be gained from New Zealand adopting a "clean and green" environment. They saw benefits in the positive advocacy of a "GE free" environment. Several advanced the economic benefits of organic production. Representative of this standpoint were the comments from Environmental and Conservation Organisations of New Zealand [IP102], which noted '"growing demand, world wide, for organic food, GE Free food". Nelson GE Free Awareness Group [IP100] also noted that "clean green exports of GE Free primary produce and organics … will guarantee premiums for New Zealand [primary producers]" (These arguments are covered in more detail in discussion of Warrant item (i), "Opportunities from the use or avoidance of genetic modification".)

Moral constraints on pursuit of economic advantage

Submitters not favouring genetic modification often stressed the importance of totally different paradigms and values. For example, Te Runanga o Ngai Tahu [IP41] asked: "… are we to be manipulated by economics, rather than ethics and value systems that have served us well … ?" Royal Forest and Bird Protection Society, Nelson/Tasman Branch [IP43] raised similar concerns in its comment that: "Economic matters must never override the ethical responsibility and guardianship … [New Zealanders] have in respect to the natural environment … Decisions on GM activity must not be economically driven." Friends of the Earth (New Zealand) [IP78] commented that issues with very large environmental and sociopolitical risks were often ignored because they were "difficult to monetise" and that "as a rule, profits are privatised and costs are socialised".

section 3.19 |

appendix 2

Outcomes of Consultation: Submissions from Interested Persons

Section contents

3.19 Areas of public interest: cultural and ethical concerns

Introduction

Warrant item (j) (iv) deals with "cultural and ethical concerns" in relation to genetic modification. Some submitters suggested that specific reference should also have been made to spiritual concerns and included comment on such matters.

The terms, "ethical", "spiritual" and "cultural" were not generally defined or distinguished by submitters. Submitters commented according to their cultural background and ethical values.

Submitters with backgrounds in the economic/production sectors, Maori sector and religious groups sector were the prime sources of comments on general cultural and ethical matters, with religious groups providing comments in particular on ethical and spiritual concerns and, to a lesser extent, on Maori cultural concerns.

As explained in the section "Areas of public interest: an introduction", comment on areas of public interest extended beyond specific responses to Warrant item (j). This was particularly so for cultural, ethical and spiritual concerns, so issues discussed below are drawn from throughout all submissions.

Most submissions on cultural concerns (27 submitters) commented on Maori cultural issues. In addition, cultural and religious beliefs and practices were raised by New Zealand Jewish Community [IP80] and referred to by some submitters from the agricultural/production sector.

Ethical concerns were the subject of substantial comments in 20 submissions, and spiritual concerns were discussed in four submissions. There was a considerable overlap between ethical and spiritual issues, making it difficult at times to discern a distinction between the two.

Eleven submitters believed that social, economic and ethical considerations should be dealt with in legislation.

Overall, submitters seemed to cluster around the following approaches to the

concepts:

- Cultural concerns: the framework of values, beliefs and practices within which a community of individuals operates. Submitters referred to specific Maori concepts, for instance whakapapa, in discussing cultural concerns.
- Ethical concerns: what is the right or good thing to do, and what is the process for deciding this? Several church submitters referred, for example, to "goodness", the "good of all", as the test for developing "GM" policies.
- Spiritual concerns: respect for the sacred nature of creation and acknowledgement of the spiritual beliefs of indigenous peoples.

Nature of concerns

Cultural concerns included:

- the need to respect and accommodate different cultural beliefs and practices
- no single cultural framework should predominate.

Ethical and spiritual concerns:

- raised the need for a new approach to the current regulatory/legislative framework
- called for greater public education about issues of genetic modification
- identified, in many instances, concepts and principles that should be taken into account.

Key themes

Overall, the themes that emerged included:

- choice: a choice not to use or participate in genetic modification technology
- respect: a need to acknowledge values and take them into account in processes and decisions involving genetic modification
- impact: a need for awareness of long-term risks, for instance, ecological damage to the environment.

Significance of issues

A common starting point in submissions was a reference to the significance of the issues raised by this item. There was a view that genetic modification gave rise to questions ("areas of uncertainty") and "profound cultural and ethical implications" (Rural Women New Zealand [IP52]). Sustainable Futures Trust [IP51] commented: "The GM debate is not really about the technology itself, nor wholly about ethics. It is about finding meaning in life and of our role within it." The Trust further

observed that molecular biology might be able to tell us "what we are and how we function, but it will tell us nothing about who we are and why we are".

Religious groups saw the big ethical issue as power. Interchurch Commission on Genetic Engineering [IP49] summed up their concerns in saying that:

> Like most sophisticated technologies, this one promises both potential blessings and curses, both power for good and power for evil. And the key word here is power, for genetic engineering is in large measure a question of the ethics of using and abusing power.

Anglican Church in Aotearoa New Zealand and Polynesia [IP42] warned of "the arrogance of people towards the intricate and subtle relationships which sustain life on the planet".

Matters of general concern raised in submissions included:

- the nature of the public debate on genetic modification
- need for more public awareness
- long-term impacts.

From the religious groups sector there was a view that the genetic modification debate had primarily occurred at "a pragmatic level" related to safety and economic matters, with little elucidation or definition of ethics.

New Zealand Catholic Bishops' Conference [IP38] was not concerned that the technology of genetic modification might conflict with ethical values. The concern was the ethics of the uses to which it might be put.

A related concern was the need for greater public awareness and education about genetic modification generally. The statement was made that much public and media comment was not well informed This issue was raised under other Warrant items elsewhere in this report and is further discussed in the introduction to Warrant item (j).

An additional concern was anxiety about the unknown results of genetic modification. Again, this issue is discussed further in relation to Warrant item (b) ("Evidence and uncertainty").

Cultural concerns

Twenty-three submissions commented on Maori cultural matters and four on other cultural issues.

The Maori submissions were concerned with respecting Maori cultural values. The non-Maori submitters were also generally concerned that Maori cultural values should be acknowledged and respected.

On other cultural matters, the focus was on informed choice. It was important that consumers should be able to comply with cultural/religious tenets: for example, by being able to select foodstuffs that had no genetically modified ingredients.

Maori cultural concerns

Two submissions from Maori representative organisations, and a further 21 other submissions made substantial comments under this item on cultural concerns. The non-Maori submitters included Church groups, industry networks, consumer groups, and two government bodies.

As a general rule, most Maori submitters commented throughout their submissions (rather than under this item) on the cultural implications of genetic modification technology. Several made detailed comments under Warrant item (g) (see section "Responsibilities under the Treaty of Waitangi").

The points made in the two Maori submissions under this item included:

- the need to respect Maori ethical and cultural values
- Maori participation in decision-making.

There was concern that Maori ethical and cultural principles should not be diminished or demeaned "in acquiescence to scientific experiments". It was suggested that Maori in the main were opposed to the transfer of human genetic material into other species, and that "opposition is ethically and morally bound up with the value system of Maori as tangata whenua". Maori Congress [IP103] referred to a number of Maori concepts, including mauri, mana, rangatiratanga and ira tangata, and indicated that these formed a "paradigm for sustainable utilisation and enhancement of taonga".

Reference was made to the close relationship Maori have with the land and taonga. It was suggested this be taken into account in the biotechnology debate via consultation and Maori participation in decision-making.

In a comment representative of the views in the Maori submissions, the actual relationship between Maori and the land was described elsewhere by the WAI 262 claimants, Ngati Wai, Ngati Kuri, Te Rarawa [IP89]:

> Maori, like other indigenous peoples, have a unique relationship with their natural world. Maori view themselves as part of the natural world and therefore understand the importance of protecting these taonga. The people, the land, the sea, the forest and all living creations are all members of the same family.

Non-Maori submitters also expressed concern about respecting Maori values in the debate on genetic modification. Religious groups acknowledged a different

relationship between Maori and the natural world from that "found in many Western cultures".

Environmental Risk Management Authority (ERMA) [IP76] noted an incompatibility between genetic modification and concepts of tikanga (whakapapa, kaitiakitanga) and the principles of the Treaty (active protection, acting in good faith), but expressed the view that "these concerns are not necessarily widespread and may not be generally held by Maori".

Other cultural concerns

The need for informed choice for consumers (also discussed in relation to Warrant item (j) (i), "Areas of public interest: human health") was a theme in submissions referring to other cultural issues.

New Zealand Jewish Community [IP80] referred to Jewish cultural customs, although the focus of their submission was on religious beliefs and practices. In light of Judaism's strict rules governing the handling of animals, foods and medicines, the submission stressed the importance of "informed choice" for consumers, particularly in relation to food labelling.

On cultural issues in general, Federated Farmers of New Zealand [IP34] indicated that the agricultural sector had responded to a wide range of cultural beliefs and practices; for instance, halal and kosher requirements for killing stock. Federated Farmers supported a general policy of "choice" in accommodating cultural requirements, and was "opposed to the notion that the cultural rights of one group in society should over-ride the rights of other members of the same society to the extent that they confer a right of veto". New Zealand Life Sciences Network [IP24] and New Zealand Wool Board [IP30] raised similar views.

Ethical concerns

Submissions on ethical issues came from the religious groups sector and the economic/production sector. Themes involving ethical issues included:

- fundamental ethical concepts
- governing principles
- need for a governing ethical regulatory framework.

Submitters from religious groups raised the need for clarity in the terminology used, with a distinction being made between ethical and moral issues in relation to genetic modification. One submitter (Catholic Bishops' Conference [IP38]) indicated that different uses of the term "ethical" tended to confuse rather than to enlighten, and suggested that definitions of "ethical" and "moral" were required.

The Conference noted that "ethics" comes from "ethos" meaning principles or mores or values. Ethical values were seen as flowing from our nature as human beings living in a community, and reflected "fundamental codes of being and behaviour". Morality was held to include ethics, but also to encompass "the added perspective of a faith tradition".

Some religious groups saw ethical concerns as including people's right to offer "informed consent" on matters of genetic modification. "Ethical concerns include the need for autonomy and the rights of all to give or withhold informed consent regarding GM" (Interchurch Commission [IP49]).

Underlying concepts

Reverence for life

Submissions from the religious groups sector referred to "the interdependence and interconnectedness of life", and emphasised a responsibility to live with a reverence for life (Quaker Spiritual Ecology Group, Religious Society of Friends [IP50]). The Group expressed dismay at the perceived rush to patent life forms and genes, and "bio-prospecting for profit". Other submitters from this sector expressed concern about "enhancement" of human characteristics to make a "perfect" being (described by some as production of "designer" babies) and the use of embryos for research purposes.

ERMA [IP76] noted that ethical issues raised in applications that it had assessed expressed a fear that approval of genetic modification would be the start of a "slippery slope" which would trigger "big picture ethical issues" such as the unnatural creation of unnatural hybrid species, cloning to produce genetically selected children, and "scientists playing God".

Ecological integrity

Some submitters raised concerns over permanent ecological damage to the environment for future generations.

Interchurch Commission [IP49] referred to:

> … a strong sense of stewardship of the earth and a concern therefore that in careless manipulation of the flora and fauna of New Zealand we may inflict permanent and unpredicted damage on our environment.

Other religious groups were concerned that the long term impacts of different forms of genetic manipulation had consequences for future generations, despite the beneficial effects. There was a suggestion that "genetic modification interferes with the creative, intelligent process of life itself" (Quaker Spiritual Ecology Group [IP50]).

Governing principles

The following general principles emerged from the submissions as a basis for guidance in dealing with ethical issues:

- non-maleficence (no harm)
- public participation
- public ownership of genetic information
- informed choice
- wider public good prevailing over profit.

There was an emphasis in the submissions from the religious groups sector on education, public information and discussion about genetic modification issues, and that ethical criteria should outweigh commercial considerations.

Public Questions Committee (Methodist, Presbyterian, Churches of Christ, Quaker) [IP93] repeatedly emphasised that "goodness" must be the "primary criterion in the development of GM policies". Good actions were those that aimed for "the welfare of all New Zealanders, other people, the environment and biosphere". Similar views were raised by Catholic Bishops' Conference [IP38].

New Zealand Wool Board [IP30] suggested the adoption of a "utilitarian ethical framework". The Board commented that a utilitarian approach to public policy is:

> ... the moral framework that holds that the morally correct course of action gives due weight to the interests of all people equally. An interest can be defined as something that a person wants, or a means to it.

Many of the above principles are further discussed elsewhere in this report (for example, in relation to Warrant item (k) on "Strategic issues" and Warrant item (c) on "Risks and benefits").

Institutional frameworks for ethics

Submissions on this topic came from a variety of sectors including farming, government agencies, biotechnology companies, producer boards, religious organisations and Maori groups. There was a divergence of views, ranging from submitters who believed that the current framework was adequate to those who saw a need to construct an ethical framework. In broad terms, the range of positions was:

- current system works: no change required
- current system generally satisfactory: minor improvements would help
- system inadequate or non-existent: framework required.

Ethics committees

Life Sciences Network [IP24], Federated Farmers [IP34] and Aventis CropScience [IP14] commented that New Zealand already had a well-established ethical framework (eg, medical ethics and animal ethics committees) and already considered ethical questions arising from research. Federated Farmers [IP34] stated: "GM technology does not introduce any new ethical questions that have not already been considered in such a framework."

Legislation

For some submitters, the Hazardous Substances and New Organisms Act 1996 (HSNO Act) provided a generally workable framework. One large company from the forestry sector suggested that cultural and ethical concerns could be dealt with on a case-by-case basis by adopting the consultation processes indirectly provided for under the Act (Carter Holt Harvey/Fletcher Challenge Forests [IP17], in an accompanying witness brief).

ERMA [IP76] in discussing the "strengths and weaknesses" of the HSNO Act made a similar point: "A strength of the Act is that it provides a framework which conforms strongly with ethical principles." Ethics was defined as "taking full account of the interests of all those affected when deciding what to do". ERMA acknowledged some weaknesses with the Act, but overall was of the view that:

> … the current legislative and decision-making arrangement has strong merit compared to other arrangements, provided some important elements of the framework can be tidied up …

Matters to be tidied up included: clarifying HSNO coverage of human cell use, providing for a clear interface with other legislation and implementation agencies, providing more discretion over public notification, provisions governing the ability to set policies or make determinations giving guidance on dealing with applications under the Act, and other matters. (These are discussed in more detail in relation to Warrant items (2) and (n) on "Statutory and regulatory processes".)

New approach

In contrast, Parliamentary Commissioner for the Environment [IP70] concluded that New Zealand had no purposeful framework to assess the risks and benefits of genetic science. The Commissioner went on to suggest that "a wide range of views and value sets" would need to be acknowledged and "given space" in the debates and decision-making processes. A series of principles proposed for these processes in an accompanying witness brief included:

- accessibility for all interested persons and groups
- provision of wide ranging information

- transparency of information and openness of discussion
- recognition of the Treaty of Waitangi and provision for fulfilment of kaitiaki responsibilities for tangata whenua
- accepting the precautionary principle.

Auckland Uniservices [IP23], Rural Women [IP52] and several submissions from religious groups also commented on the need for guidelines. Some submitters suggested that a case-by-case assessment of GM applications was insufficient, with Catholic Bishops' Conference [IP38] indicating that cultural concerns, in particular, were better handled at the level of a framework of principles rather than on a case-by-case basis as at present.

Anglican Church [IP42] suggested the establishment of an Ethics Council "bound to utilise guidelines or principles which may be adopted from the recommendations of the Royal Commission" and free from any political interference.

Taking an alternative approach, WAI 262 claimants [IP89] referred the Commission to the principles and the Code of Ethics developed by the International Society of Ethnobiologists. This Code of Ethics sets out guiding principles such as "active participation", "full disclosure" and "prior informed consent and veto" in accessing plant and genetic resources and benefit sharing.

Spiritual issues

Several submitters from religious groups raised the importance of a separate and distinct section to consider 'spiritual' concerns.

The broad themes which emerged were:

- respect for the sacredness of life and creation
- acknowledgment of the spiritual views of indigenous peoples.

Respect for creation

Interchurch Commission [IP49] saw "spiritual concerns" as distinct from "ethical and cultural concerns". Spiritual concerns included a sense of humility, expressed in terms of the query "Do we have the 'right' to manipulate 'God's world' in this way?"

Public Questions Committee [IP93]) noted that every aspect of genetic modification had a spiritual, cultural and ethical dimension, and considered that there should have been "a separate section [in the submission form] to assist those

interested parties for whom spiritual values are of fundamental importance to their world view".

Anglican Church [IP42] discussed its beliefs and explained that "all human beings are spiritual beings" and "all are the children of God and made in God's image".

Quaker Spiritual Ecology Group [IP50] also commenced its submission with a reference to the Quakers' spiritual traditions, including the importance of respecting life. In relation to genetic modification, its concerns were based on the "spiritual and ecological understanding that all life is sacred, and that all life forms are interdependent and interconnected." The Group suggested that genetic modification intervened in these processes with unpredictable results.

Beliefs of indigenous peoples

Anglican Church [IP42] indicated that it encouraged a view of the biosphere as a place of "discovery and awe rather than a realm for further exploitation, ownership and profit", and referred, with approval, to the spiritual traditions of indigenous peoples that provided an alternative way of looking at creation rather than the 'usual Western approach of dominance'.

ERMA [IP76] noted that Maori spiritual concerns had been raised in applications to the Authority, and also that "the same point" had been made by some submitters who claimed that genetic modification is forbidden according to Christian scripture (largely Old Testament) and therefore contrary to their spiritual beliefs. ERMA concluded (by a majority) that:

> … the issue is essentially jurisprudential, i.e. the extent to which spiritual beliefs should be upheld in the interpretation of the law — and that the Treaty of Waitangi does not require the rest of New Zealand society to accept Maori (or Christian) spiritual beliefs as the determinant of how the HSNO Act should be implemented.

At the time of this analysis of submissions, ERMA's decision was under appeal to the High Court.

4.1 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.

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

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

antigen

A usually protein or carbohydrate substance (as a toxin or enzyme) capable of stimulating an immune response.

Merriam-Webster's Collegiate Dictionary

bacteriophage

see **phage**

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.

biodynamic

Of or relating to a system of farming that uses only organic materials for fertilising and soil conditioning.

Merriam-Webster's Collegiate Dictionary

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. Secondarily, 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 unauthorised and uncompensated taking of biological resources.

World Foundation for Environment and Development

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

(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

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

also **PC1 containment**: [*Australia/New Zealand*] PC1 containment applies to microorganisms with low community and individual risk, which are unlikely to cause human, animal or plant disease. Special containment is not necessary, open bench work is permissible, with standard laboratory practices.

University of Technology, Sydney

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

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 the anther of the flower of one plant to the flowers of a different plant.

Garden Web

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

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

ecosystem

The complex of a community of organisms and its environment functioning as an ecological unit.

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

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 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 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 occurance 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

Note: for purposes of the Commission, the term "genetic modification" is defined in the Warrant establishing the Commission (see Appendix 1, page 159).

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 specifies, 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

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

horizontal gene transfer

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)

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

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.

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.

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 nineties phenomenon. [Note: "Nutraceutical" and "nutriceutical" are frequently used interchangeably.]

ScienceNet

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 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

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

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

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

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

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

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4.2 Glossary of Maori terms

Maori term	**English equivalent in context**
Aotearoa	New Zealand
atua	divinity, god
hapu	clan
harakeke	New Zealand flax, *Phormium tenax*
ira tangata	human element of life
iwi	kin group, public, communities
kaitiaki	guardian, guardianship
kaitiakitanga	guardianship
korero	communicate
mana	authority, control
matauranga	knowledge
mauri	life principle, principle
Nga Kaihautu Tikanga Taiao	Maori advisory group of ERMA
Pakeha	European, non-Maori
rangatiratanga	independence, dominion
Runanga	councils, boards
taiao	environment, world view
tangata whenua	local people, native people
taonga	assets, belongings
tapu	inviolable
tikanga	culture, cultural, customs
tino rangatiratanga	independence
whakapapa	genealogy, heredity
wairua	spirit
whanau	family
whanui	community

4.3 Abbreviations

Abbreviation	Meaning
ANZFA	Australia New Zealand Food Authority
ACVM Act	Agricultural Compounds and Veterinary Medicines Act
ANZCERTA	Australia New Zealand Closer Economic Relations Trade Agreement
APEC	Asia-Pacific Economic Cooperation
BSE	bovine spongiform encephalopathy
CAC	Codex Alimentarius Commission
CBD	Convention on Biological Diversity
CER	Closer Economic Relations [with Australia] (CER includes ANZCERTA)
CRESA	Centre for Research Evaluation and Social Assessment
CRI	Crown research institute
DNA	deoxyribonucleic acid
ERMA	Environmental Risk Management Authority
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration
G-CSF	granulocyte-colony stimulating factor
GATT	General Agreement on Tariffs and Trade
GE	genetic engineering
GM	genetic modification
GMAC	Genetic Modifications Approval Committee
GMO	genetically modified organism
GST	Goods and Services Tax
GTAC	Genetic Technology Advisory Committee
HCV	hepatitis C virus
HIV	human immunodeficiency virus
HSNO Act	Hazardous Substances and New Organisms Act
IBSC	Institutional Biological Safety Committee
IP	(a) Interested Person

IP	(b) intellectual property
IPM	Integrated Pest Management
IPPC	International Plant Protection Convention
IPR	intellectual property right
ISE	International Society of Ethnobiologists
LMO	living modified organism
MAF	Ministry of Agriculture and Forestry
NIP	non-interested persons
OECD	Organisation for Economic Co-operation and Development
OIE	Office International des Épizooties
OSH	Occupational Safety and Health Service
PKU	phenylketonuria
PVR	Plant Variety Rights
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
TRIPS Agreement	Agreement on Trade-Related Aspects of Intellectual Property Rights
TTMRA	Trans-Tasman Mutual Recognition Arrangement
UN	United Nations
UNEP	United Nations Environment Programme
UNESCO	United Nations Educational, Scientific and Cultural Organization
UPOV	Union Internationale pour la Protection des Obtentions Végétale
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

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