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]).