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3.

appendix 3

Outcomes of Consultation: Submissions from the Public

Section contents

3.3 Statutory and regulatory system

Background

The Warrant contains two items that relate to the statutory and regulatory framework and processes that are currently in place in New Zealand, namely Warrant item (2) and, under "Relevant matters", item (n).

Warrant item (2) called for information and comment 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 and comment 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

Both Warrant items invited submitters' comments on the current legislative, regulatory, policy and institutional arrangements. The first, item (2), invited comment on desirable changes and item (n) on their adequacy and, also, changes needed to achieve strategic outcomes (discussed in the previous section). Given the similarity of these Warrant items and the ways in which submitters raised issues around regulatory and legislative processes, their responses to these two Warrant items are combined into a single section of the report.

The few public submitters who commented on legislation and regulations tended to make general comments about the adequacy or inadequacy of current regulatory and legislative processes rather than link suggested changes to the strategic outcomes they identified as desirable. Thus, their comments generally related to how they perceived the current processes as operating and how they might be improved.

Outline of this section

This section of the report presents submitters' views about:

- the adequacy of the current legislative and regulatory system
- problems with the legislative and regulatory framework
- suggested improvements.

Adequacy of current statutory and regulatory system

As Table 3.4 shows, only 113 public submitters made any comment about the overall adequacy of the current legislative and regulatory framework, and most of their comments were of a general nature. When specific comments were made they were almost always with regard to food, referring to either labelling requirements or production controls. To some extent, their less specific comments may have reflected their general lack of familiarity with, or detailed knowledge of, current legislation and regulations and the decision-making processes. The most significant features of the current legislative and regulatory framework are the Hazardous Substances and New Organisms (HSNO) Act, which is the principal legislation affecting the use of genetic modification in New Zealand, and the Environmental Risk Management Authority (ERMA).

Table 3.4 Adequacy of current statutory framework and regulatory process (n = 113)

Adequacy of current framework/process	Number	%
Inadequate – complete renewal required	61	54.0
Needs major improvement to be made adequate	29	25.7
Adequate – no improvement required	10	8.8
Needs minor improvement to be made adequate	7	6.2
Adequate but could be improved	6	5.3

It needs to be noted that many submitters may not have felt a need to address the current legislative and regulatory framework as they were recommending a total ban on genetic modification, precluding the need for more detailed comment. Submitters were more likely to comment on general issues such as the perceived lack of attention given to ethical and cultural issues; the lack of independence of individuals and organisations responsible for administering regulations and approving applications; and the lack of guiding principles to inform these processes and ensure better decision-making.

Problems with current system

Some 292 public submitters commented on perceived problems with the current statutory framework and regulatory process. Few public submissions contained specific references to the current legislation (rarely was the HSNO Act referred to and submitters were more likely to refer to ANZFA than ERMA). Their greatest concerns related to insufficient regulation of genetic modification activity and little recognition of public views, including ethical, spiritual and cultural considerations. See Table 3.5. Some also expressed concern about lack of clarity around definitions used. Other than in submissions presented by Maori interests, Treaty of Waitangi and other Maori-related concerns were seldom raised.

In general, public submitters made no comment about characteristics of the legislation, such as its prescriptive rather than principles or outcomes basis and the absence of discretionary powers. Similarly, they made no comment about compliance costs and impacts on research investment. In fact, they were more likely to suggest that current legislation and low compliance costs enable or promote research rather than limit it.

Public submitters addressing the current regulatory framework were intent on freeing ERMA and ANZFA from what they saw as excessive levels of corporate control. They expressed a desire for regulatory bodies and decisions to be totally transparent and above suspicion. Most of these submitters felt that ANZFA and ERMA were currently biased towards corporations, and politicians overseeing the process could not be trusted to work on behalf of the general public instead of big business. The example most frequently cited was that of a recent court case in the United States in which it was shown that the FDA declared genetically modified foods to be safe against the recommendation of many of its own scientists. This perceived bias in the regulatory system was also felt to be rife in the political system as well, with politicians more concerned about big business than public safety. Given this lack of trust, a number of submitters felt that "... a referendum is

essential if our present leaders still proclaim themselves to be governing for the good of all the people of New Zealand."

Public submitters also raised issues around consistency with respect to the legislative frameworks of New Zealand and its international trading and other partners. They typically expressed a view that any inconsistency with international partners could be a virtue. They thought that New Zealand should take an independent stance, as with the case of nuclear power. Such independence, they argued, could give New Zealand moral, ethical and economic advantage.

Table 3.5 Problems with current statutory framework and regulatory process (n = 292)

Problems with framework/process	Number	%
Under-regulates GM	154	52.7
Potential to allow patenting of genetic material	76	26.0
Too little recognition of those opposed	39	13.4
GM inappropriate for ethical/spiritual/cultural reasons	34	11.6
Over-regulates GM	10	3.4
Fails to protect information and intellectual property	8	2.7
Barrier to GM research investment	5	1.7
Too high transaction costs for applicants	5	1.7
Includes irrelevant social/economic and ethical criteria	1	0.3
Inconsistent with international agreements	1	0.3
Inconsistent with trading partners	1	0.3
Other	6	2.1

Multiple response

Other identified problems with the regulatory process (but mentioned only once or twice) included:

- too much secrecy in the application process
- overly low transactions costs for applicants
- limits on consumer choice
- unnecessary bureaucracy
- no viable risk assessment strategy
- need for the debate on genetic modification to be separated into research, medical uses and field releases.

Suggested improvements

The public submitters who commented on legislative improvements (4259 in total) tended to focus on what the legislation should do. Few commented on what needed to be changed to make it more effective. This lack of specificity probably reflected the majority's lack of familiarity with the legislation. One of the strongest messages given by public submitters who commented on legislative improvements was their desire for the legislation to bar all genetic modification, genetically modified food or specific genetic modification uses (57.9%). Most of these wanted all genetic modification activities barred. The next strongest message, as Table 3.6 shows, was for more stringent food labelling requirements (46.3% of those who commented).

Most submitters demanding a stricter food-labelling regime were insistent that it be comprehensive, detailing any use of genetic modification anywhere in the production of that food. Many expressed dissatisfaction with the labelling regime proposed by ANZFA, one individual, for instance, writing that "... the new labelling laws announced by ANZFA (an organisation who has no non-industry consumer representation) have favoured the Biotech Industry and Grocery Manufacturers over the concerns and fears of the people who have to eat the food." Public submitters wondered why New Zealand has delayed the implementation of a labelling regime when other countries have had one in place for years.

Many submitters who preferred a total ban on genetically modified products also expressed resignation that they could not keep genetic modification out of New Zealand. They, therefore, insisted that, at the very least, a comprehensive labelling regime must be installed.

The improvements to decision-making processes around genetic modification suggested by public submitters were usually of a generic nature. Only 109

Table 3.6 Improvements to legislation (n = 4259)

Improvements to legislation	Number	%
Bar all GM or GM food/crops or specific uses	2469	57.9
More stringent labelling, particularly for GM food	1974	46.3
Increase prescription of procedures (fines, penalties and enforcement)	467	11.0
New organisational/institutional mechanisms required	192	4.5
Expand to include social, economic, and ethical considerations	153	3.6
Clarify principles, concepts and definitions	52	1.2
Improved protection of information and intellectual property	31	0.7
Allow greater procedural discretion	21	0.5
Provide appeal and review mechanisms, institutions and processes	21	0.5
Ban specific aspects of GM	19	0.4
Define liability	10	0.2
Increase consistency with key trading partners	7	0.2
Increase compatibility with international obligations	2	0.0
Other	94	2.2

The "Other" category included suggested improvements to HSNO Act and other legislation:

- amending to increase restrictions
- amending to decrease restrictions
- repealing the new organism sections
- retrospective application (re. Application A363 – Monsanto) after amendments
- introducing strictest labelling requirements, covering any amount of genetic modification
- removing any requirement for GM-labelling
- withdrawing from ANZFA and replacing it with a New Zealand body
- reviewing ANZFA assessment methods
- gaining independence from international organisations and free trade agreements
- repealing the Plant Variety Rights Act
- amending the Biosecurity Act to exclude GM-biotechnology
- following the EU stance on genetic modification.

Multiple response

submitters commented on ERMA. However, most of these argued for more attention to social and ethical considerations and increased independence. See Table 3.7 for details of suggested improvements to ERMA, Table 3.8 for improvements to decision-making processes.

For 310 submitters commenting on processes in general, their comments seemed to be directed at ideal types rather than responding to known shortcomings of current arrangements. The suggested establishment of an independent body was a case in point. A small number of submitters suggested the setting up of an independent, trustworthy organisation (defined as free from profit motive) that would monitor, assess, and audit genetic modification experiments, trials and genetically modified products to ensure their ethical, environmental and health safety. However, there were also specific suggestions for changes to, or extensions of, current legislation. For instance, in suggesting changes to the legislation to ban specific aspects of genetic modification, submitters variously identified terminator technology, antibiotic resistance marker genes, viable genetically modified organisms, genetic modification of animals, patenting, experiments, commercial uses and military uses as requiring total bans. Others suggested embedding liability clauses in legislation to:

- provide protection for non-genetic modification producers
- establish an indemnity scheme for health risks
- establish central (rather than regional) government responsibility for impacts
- require public liability insurance and/or bonds for environmental protection
- set a tax on genetically modified products.

Public submitters expressly asked for more principle-based processes. In particular, given their concerns about the shortcomings of risk assessment, the potential enormity of risks and the general lack of information about risks, they argued for a precautionary approach to any decision-making.

Table 3.7 Improvements to ERMA (n = 109)

Improvements to ERMA	Number	%
Expand capacity on social, economic and ethical considerations	50	45.9
Increased independence	30	27.5
Clarify assessment criteria and/or method	24	22.0
Separating process from corporate control	20	18.3
Increase enforcement – heavier fines, penalties for non-compliance	19	17.4
Increase discretion over procedures	13	11.9
Increase Maori representation	11	10.1
Reduce costs	6	5.5
Other	16	14.7

The "Other" category included the following specific suggestions about ERMA:

- legislating consideration of health, ecosystems, ethics, biodiversity, and public education, not only economic matters in risk assessment
- renewing, renaming, reorganising ERMA to focus on risk management
- more diverse membership on ERMA
- reduce time needed for approval.

Multiple response

Table 3.8 Improvements to process (n = 320)

Improvements to process	Number	%
Increase public consultation and participation	154	48.1
New organisational/instruction mechanisms required	113	35.3
Establish controls commensurate with risk	62	19.4
Case-by-case assessment	29	9.1
Increase consultation and participation of Maori	27	8.4
Provide appeal and review mechanisms	19	5.9
Establish an independent body	15	4.7
Delegate oversight of contained laboratory experiments	11	3.4
Improved protection of information and intellectual property	4	1.3
Industry undertakes regulation	3	0.9
Decrease public consultation and participation	3	0.9
Allow self-regulation through peer review processes	2	0.6
Delegate oversight of low-risk contained laboratory experiments	1	0.3
Other	12	3.8

The "Other" category included the following suggestions:

- adopting the Precautionary Principle
- directing government research funds to organic research and development
- introducing a Genetic Bill of Rights / Protection from Genetic Discrimination
- introducing a Code of Conduct
- establishing a Ministry of Organic Production
- establishing a Ministry for Genetic Modification.

Multiple response