section 3.15 |

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appendix 3

Outcomes of Consultation: Submissions from the Public

Section contents

3.15 Comment on policy, process and regulation provided through public submissions by public sector organisations

Background

Certain government departments and agencies made submissions to the Royal Commission through the public submission process. These organisations either had not sought or were not granted Interested Person status with the Commission.

The submissions by public sector organisations provided extensive information on the work of the organisations where they had been involved in genetic modification or biotechnology issues and on policy, processes, legislation and regulation relating to genetic modification. The Commission received such submissions through the public process from:

- Australia New Zealand Food Authority
- Department of Conservation
- Human Rights Commission
- Institute of Environmental Science and Research
- Ministry of Agriculture and Forestry
- Ministry of Consumer Affairs
- Ministry of Economic Development
- Ministry of Foreign Affairs and Trade
- Ministry of Health
- Te Puni Kokiri (Ministry of Maori Development).

A brief summary of information on public sector policy, process and regulation provided by each of these organisations is provided below, with reference to the relevant Warrant items where appropriate. (These submissions were received by the Commission before 1 December 2000 so this commentary does not reflect

recent developments in regulation and policy, eg strengthening of border control measures. For up-to-date details, contact the organisations directly.)

Full texts of all but one of these submissions are publicly available on the Commission website (http://www.gmcommission.govt.nz) until 30 June 2002. The submission from the Institute of Environmental Science and Research included some confidential sections that were not placed on the website: the public part is available.

Australia New Zealand Food Authority

The submission by the Australia New Zealand Food Authority (ANZFA) does not specifically respond to any of the Warrant items but rather is provided in two parts. The first part sets out the role of ANZFA, its establishment under the agreement between New Zealand and Australia establishing a system for the development of joint food standards (the Treaty) and the policy and processes to review and develop food standards and the regulations. The second part of the submission sets out the history and current practice for the regulation of genetically modified food in New Zealand and in Australia. The submission closes with ANZFA's position as a member of the international community involved in the investigation and regulation of genetically modified foods and some thoughts as to the future directions and implications for genetically modified foods.

ANZFA also supplied a set of attachments (obtainable from the ANZFA website, http://www.anzfa.govt.nz) ranging from the Australia New Zealand Food Authority Act 1991 and the Treaty mentioned above to specific applications and to international guidelines concerning genetically modified foods.

ANZFA is a statutory authority established by an Act of the Commonwealth Parliament of Australia with a bi-national function in the food standards area. It conducts scientific risk assessments and consults with community and stakeholders before making recommendations to the Australia New Zealand Food Standards Council (ANZFSC) concerning proposed amendments to the foods standards code.

As at September 2000, ANZFA had received 20 applications to approve genetically modified food commodities, two of which had been withdrawn after application and two of which (Roundup Ready soybeans and Ingard cotton) have been approved for inclusion in Standard A18: *Food Produced Using Gene Technology*.

The ANZFSC determined to amend Standard A18 requiring provisions for the labelling of all genetically modified foods on 28 July 2000. This standard becomes compulsory in 2001.

Also in 2001, ANZFA will be replaced by a new organisation, Foods Standards Australia New Zealand, which will have similar functions and responsibilities.

The ANZFA process for review and development of food standards

ANZFA's objectives in developing food regulations are set out in section 10 of the ANZFA Act and in Annexe A of the Treaty. These are:

- protection of public health and safety
- provision of adequate information to enable consumers to make informed choices
- prevention of misleading or deceptive conduct.

In making recommendations to ANZFSC, ANZFA must also have regard to:

- the need for standards to be based on risk analysis using best available scientific evidence
- the promotion of consistency between domestic and international food standards
- the desirability of an efficient and internationally competitive food industry
- the promotion of fair trading in food.

Applications for ANZFA's proposals for a food standard go through four steps:

- making a preliminary assessment
- making a full assessment report based on scientific risk assessment
- conducting an inquiry into any resultant draft standard or variation
- making a recommendation to ANZFSC.

ANZFA comments that the bi-national operation of ANZFA is unique. The joint code will provide the New Zealand and Australian food industries with a common set of regulations covering food manufacture. Essentially, the Treaty means that the Australian and New Zealand food industries are one and the same, with a market of 23 million people in total. ANZFA has two New Zealand members on its Board and a third New Zealand representative was appointed during the transition process to the new joint Australia New Zealand Food Standards Code.

There is a fully operational New Zealand office based in Wellington. Meetings are held in both Australia and New Zealand. Consultation takes place in non-government forums, meetings and workshops and there is special provision for consultation with Maori. Individual government agencies and the Officials Committee on Food Administration are also involved in ANZFA's consultation process. ANZFA must reach agreement with New Zealand on the outputs it must achieve each year and it reports directly and regularly to the New Zealand Minister of Health and Ministry of Health.

Regulation of genetically modified food

ANZFA's submission sets out in some detail the processes and the history of the regulation of genetically modified food in New Zealand. It also discusses the labelling of genetically modified food. In 1999-2000 KPMG was engaged by ANZFA to evaluate the cost implications of any labelling regime. The project was estimated to be NZ$43 million for one-off or set-up costs for the mandatory labelling of genetically modified foods based on a process of "due diligence" by industry and verifiable documentation. A similar amount was estimated for ongoing compliance costs.

International regulation of genetically modified foods

The ANZFA submission points out that requirements for the safety and labelling of genetically modified foods vary throughout the world. There is currently no formal global agreement on how food sourced from genetically modified organisms or containing genetically modified substances should be treated.

As members of the World Trade Organization (WTO), both Australia and New Zealand have notified it regarding the development of and amendments to Standard A18.

Australia and New Zealand also recognise the Codex Alimentarius Commission (CAC) as the appropriate body for setting international food standards, including those applying to genetically modified foods. CAC is currently considering safety and labelling issues relating to genetically modified foods. ANZFA has been an active participant in each of the Codex groups as an invited member of the Australian delegations. Although ANZFA does not speak for New Zealand at these meetings, it notes there has been close collaboration between New Zealand and Australian delegations at the group meetings. The Codex process for finalisation of international documents and standards relating to safety of foods derived from biotechnology is on a four-year time limit set to conclude in 2004. The Codex process for labelling standards for genetically modified foods may also take at least this long.

Future directions

In conclusion, ANZFA notes that future directions in the development of biotechnology will have significant impact on and present many challenges for regulatory authorities such as ANZFA. ANZFA identified some of these issues as including:

- continuing high levels of consumer and community interest in genetically modified foods and potential health impacts

- an increasing number of genetically modified foods with new properties which may provide benefits to consumers in taste, shelf-life and nutrition
- the development of genetically modified foods with therapeutic effects (ANZFA notes these will require careful consideration and will create challenges for food and therapeutic goods regulatory authorities in coordinating regulatory action)
- international developments of agreed protocols and arrangements for the regulation of genetically modified foods
- the need for careful monitoring and evaluation of potential and unforeseen health effects from both the current and future range of genetically modified foods available commercially.

Department of Conservation

The Department of Conservation (DOC) was established under the Conservation Act 1987 with responsibility for conservation management and advocacy and for the preservation and protection of indigenous flora and fauna. It is responsible for advising the Minister for Biosecurity on risks to indigenous flora and fauna and has a small operational biosecurity role under the Biosecurity Act 1993 (such as eradication and control of *Undaria* around Stewart Island and certain weed and pest control activities).

Points raised in the submission related to Warrant items (a), where, how and for what purpose ..., (c), risks and benefits, (f), intellectual property issues, (j), main areas of public interest and (n), statutory and regulatory processes.

Main areas of public interest: environmental matters

Exotic species have had dramatic effects on New Zealand's biodiversity. Invasive exotic pests are the greatest single threat to our remaining natural ecosystems, habitats and species. They damage habitats and ecosystem processes and pose high costs and threats to productive ecosystems.

The Department spends over half of its total budget on protecting natural heritage and most of this is spent on weed and animal pest control and threatened species protection work. Conventional pest and weed control is labour intensive and expensive. Despite a recent funding package for pest and weed control on public land, DOC is restricting pest control to priority areas and mostly is limited to "holding the line" until new pest control techniques are developed. The Department needs to explore new options, particularly as public attitudes are hardening towards use of pesticides and herbicides.

Conventional biological control (biocontrol) uses a natural enemy to control a pest or weed population. Examples include *Lochmaea suturalis* to control heather in Tongariro National Park, parasitoids for wasp control and *Procecidochares alani* to control mist flower. Biocontrol releases for new organisms are considered under the Hazardous Substances and New Organisms (HSNO) Act by the Environmental Risk Management Authority (ERMA).

DOC notes that it manages New Zealand's ecosystems and species on behalf of all New Zealanders and that any potential use of genetic technology for conservation purposes would have to be within the bounds of what the wider community sees as reasonable.

Risks and benefits

From a conservation perspective on requirements to be met before the release of new organisms, DOC advocated risk assessment on native species and ecosystems, minimum environmental standards and a precautionary approach.

There are many possible risks from introduction of new organisms into the environment. For example, there is a risk to native insects from bacterial endotoxins from Bt (*Bacillus thuringiensis*) incorporated into many genetically modified plants and of the toxins building up in the soil and killing soil insects.

Statutory and regulatory processes

The HSNO Act sets minimum standards. These are a statement of a level of risk considered unacceptable. Regardless of potential benefits, DOC would oppose any introduction of a genetically modified organism if these minimum standards were not met. Moreover, where there is uncertainty, the precautionary approach should be applied.

DOC has a statutory role to advise on new organisms considered for introduction and their impacts. Under s 53(4) of the HSNO Act, ERMA must notify DOC of applications for approval of new organisms and must have particular regard to the Department's views (s 58). DOC has requested significant changes in applications to field-test genetically modified organisms, for example, petunias and maize.

DOC notes that there is no scientific consensus as to the seriousness, or even existence, of potential harm from genetic modification technology. It therefore asks whether there is any advantage in postponing decisions on release of genetically modified organisms into the New Zealand environment until there is a larger body of information on their effects on the environment and on biodiversity. And it also raises the issue of whether case-by-case assessment adequately takes into account the cumulative and synergistic effects of multiple releases.

Where, how and for what purpose ...

The submission provides examples on DNA technology that helps to identify species and assist in conservation work, eg the differentiation of two species of brown kiwi, *Apteryx australis* and *Apteryx mantelli*, and how future application of genetically modified organisms could improve conservation work and pest control.

Intellectual property issues

DOC notes that New Zealand currently has no statutory management framework for bioprospecting. The Department has informally placed a moratorium on issuing permits to collect flora and fauna from public conservation lands for bioprospecting purposes. However, private landowners may allow this, except for animals protected under the Wildlife Act or conservation legislation.

The Department notes that the issue of ownership and access to benefits derived from New Zealand's biological and genetic resources has been raised by the WAI 262 claim to the Waitangi Tribunal.

Human Rights Commission

The functions of the New Zealand Human Rights Commission relate to the promotion and protection of human rights in accordance with various international covenants and conventions. The Human Rights Commission took a neutral stance on the risks or benefits associated with genetic modification. The focus was primarily on Warrant item (j), main areas of public interest: human health, with some commentary on legislation referring to Warrant item (n), statutory and regulatory processes.

The submission raised the following issues of significance or concern.

Attention to New Zealand's domestic and international human rights obligations should be part of considering strategic options on genetic modification. These are covered by:

- Universal Declaration of Human Rights 1948
- International Covenant on Economic, Social and Cultural Rights 1996.

The right to health is also included in:

- International Convention on the Elimination of All Forms of Racial Discrimination 1965
- Convention on the Elimination of All Forms of Discrimination against Women 1979
- Convention on the Rights of the Child 1989.

The Human Rights Commission suggests that the Human Rights Act 1993, which presently prohibits discrimination on 13 specific grounds, should also cover "genetic discrimination" (the discrimination against individuals on grounds of their genetic make-up). The submission notes the Council of Europe's 1997 Convention on Human Rights and Biomedicine (Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine), which sets out a series of principles and prohibitions such as:

- banning discrimination on genetic grounds
- allowing predictive genetic tests only for medical purposes
- allowing genetic modification technology only for preventive, diagnostic or therapeutic reasons and only where it does not change the genetic make-up of descendants
- banning use of *in vitro* fertilisation to choose the sex of a child (except to avoid serious hereditary conditions)
- regulation of medical research
- prohibiting creation of human embryos for research purposes and requiring adequate protection of embryos where countries allow in vitro research
- prohibiting profit from the use of any part of the human body
- requiring informed consent
- acknowledgement of patients' rights to be informed about their health or to reject that information
- banning removal of organs for transplant without consent, except for regenerative tissue from siblings
- public debate and consultation.

The Human Rights Commission also refers to the United Nations Educational, Scientific and Cultural Organization's Draft Universal Declaration on the Human Genome and Human Rights 1997 with its requirement that individuals should not be reduced to their genetic characteristics but respected for their uniqueness and diversity.

The submission also raises the issue of consumer choice. Consumers have the right to know of the presence of genetically modified organisms or genetically modified products, particularly in food. The right to such information is provided for by Article 19 of the International Covenant on Civil and Political Rights (ICCPR), a United Nations convention ratified by New Zealand in 1976. ICCPR enables complaints of breaches of the convention to be made by individuals to the United Nations Human Rights Committee.

Institute of Environmental Science and Research

The Institute of Environmental Science and Research (ESR) is a Crown Research Institute (CRI) that is neither sector- nor resource-based as are the other CRIs. It presents itself as an independent agency, not involved in genetically modifying products, plants or animals, with its focus as "protection of people and their environment through science". ESR provides scientific services in public health, environmental and forensic sciences with particular capabilities in molecular technology. The Institute says it has deliberately stood aside from any alignment in the genetic modification debate to safeguard its scientific independence. ESR agrees with the general scepticism displayed by New Zealanders about the self-interest in a science environment driven by the prevailing business model.

In its written submission through the public submission process, ESR dealt mainly with Warrant items (1), strategic options, (2) and (n), statutory and regulatory processes, (b), evidence and uncertainty, (c), risks and benefits, (h), global developments and (j), main areas of public interest.

The submission made the following introductory observations:

- Biotechnology is rapidly developing worldwide.
- The 'science' is ahead of society's acceptance of its use.
- Community perceptions of harm must be addressed. These perceptions will not be influenced solely by more scientific evidence.
- Assessment and quantification of risks must be from both biophysical and social science perspectives.
- A lack of basic research, eg on horizontal gene transfer (HGT) in ecosystems, hinders development of biotechnology industries.
- There is a disparity in government research purchased between the areas of development and environmental risk of genetic technology. Around one-third of the Public Good Science Fund ($100 million) is invested annually in molecular technology development but little or none in the area of potential environmental health effects of using genetic modification in plant and animal production systems.
- ESR's particular interest is in the development and validation of methods to detect genetically modified foods. There is a dearth of information from long-term feeding trials and ESR recommends that New Zealand should promote and participate in internationally coordinated and financed research trials of this kind.

Further points by Warrant item follow.

Strategic options

ESR sets out three options for New Zealand's genetic modification strategy:

- Develop and use genetic modification in all sectors and be at the forefront of developments to move from commodity-based to high value-added niche markets.
- Adopt an organic brand for primary production to add value to food-based products. Where genetic modification is used in sectors such as medicine and health, ensure informed choice about public use is possible.
- Develop a framework and guidelines for the coexistence of the first two options to maximise benefits and minimise risks.

ESR supports the third option.

Evidence and uncertainty

HGT is a natural phenomenon occurring on land and in aquatic environments by various means. Viable free DNA has been shown to persist in soil for several years and is therefore available for uptake by microorganisms.

There is increasing evidence that HGT can occur between genetically modified plants and microorganisms. The submission cites work on transfers of the hygromycin resistance gene from decaying modified brassica plants to the soil-borne fungus *Aspergillus niger* and the kanamycin resistance gene from modified sugar beet plants to the modified soil bacterium *Acinetobacter* BD314pFGΔnptII. It suggests that HGT is a rare event but its potential impact on soil ecosystems cannot be underestimated under supportive environmental pressures.

ESR notes potential ecotoxic effects. Large-scale commercial planting of genetically modified plants may affect soil 'health' directly by modifying microbial population diversity. Current research results on this have been extremely variable.

Risks and benefits

ESR believes that greater understanding of physical contamination processes such as HGT is needed to enable a more robust risk assessment. Thus continuing scientific research could offset the risk of loss of scientific capability offshore posed by the current delay on the release of genetically modified organisms, which ESR supports.

Global developments

It is important to maintain international links with overseas researchers to ensure standardisation of the methodologies used to assess effects of genetically modified organisms.

Main areas of public interest: human health

Acceptance of genetically modified medicines is because of public appreciation of the benefits and more confidence in the regulatory regimes in place to ensure safety. The food industry, in comparison, has fuelled public concern and distrust and caused the perception that commercial interests are valued more than public interests. This is reinforced by food scares concerning bovine spongiform encephalopathy (BSE).

Main areas of public interest: environmental matters

New Zealand has unique soils and ecosystems. Therefore, genetic modification impacts must be investigated here and not simply extrapolated from overseas data.

The submission suggests that we must improve our understanding of key adverse effects of genetically modified plants on the environment in order to be able to protect New Zealand's flora and fauna from the planned environmental release of genetically modified plants, animals or other organisms, for example, for biocontrol purposes.

Main areas of public interest: economic matters

New Zealand's economy is biologically based. To build wealth, New Zealand must develop strengths it already has in the productive sector and new wealth-creating enterprises and markets.

Some producers believe they have the 'right' to access new technology to develop new products and markets. Other producers believe organic production is the future market positioning for New Zealand and that they have the 'right' not to be contaminated by genetically modified organisms.

New Zealand must develop a 'coexistence' regime, which provides a regulatory process that gives people faith in its decision-making and the ability to exercise their democratic rights.

Ministry of Agriculture and Forestry

The Ministry of Agriculture and Forestry (MAF) in its written public submission to the Commission dealt particularly with Warrant items (1), (k) and (m), strategic options, issues and outcomes, (2) and (n), statutory and regulatory processes, (a), where, how and for what purpose ..., (c), risks and benefits, (h), global developments and (j), main areas of public interest.

MAF is the New Zealand contact point for the Codex Alimentarius Commission, which sets international food standards and the WTO's Committee on Sanitary and Phytosanitary Measures. In addition MAF's regulatory responsibilities include

biosecurity, food safety in animal and dairy products and a joint role with the Ministry of Health on the Codex Committee on Food Labelling.

Points made include the following observations, which span multiple Warrant items.

Statutory and regulatory processes

The submission notes that it is critical for New Zealand's primary producers that consumers have confidence in the safety of their products. Confidence in the integrity and reputation of New Zealand's regulatory processes underpin access to many overseas markets.

The current regulatory system provides mechanisms for weighing up risks and benefits of new technology. The submission comments on gaps and issues in the existing regulatory system:

- The legislation covering new organisms (HSNO Act) does not recognise the capacity for post-release controls under other legislation administered by MAF.
- Ethical approvals are not required for research on animal foetuses under half way through term.
- Stockfeeds that are genetically modified products may not require safety assessments because there is no risk factor specific to genetic modification that would trigger such an assessment.

Strategic issues, opportunities, global developments

Border control alone cannot guarantee that New Zealand could remain genetic modification-free.

New Zealand has to operate within the trading framework of the bilateral and multilateral agreements and commitments between it and its trading partners.

External consumer demands and regulatory requirements will be highly influential in the profitability of New Zealand's exports of agricultural and forestry products. There are likely to be opportunities in both genetic modification and non-genetic modification markets. New Zealand could be seriously disadvantaged if its producers were locked out of the future opportunities provided by either technology.

The extent to which genetic modification and non-genetic modification production can coexist must be critically examined. Any success in this area will depend on the extent to which consumers can be confident about the separation and integrity of non-genetic modification supplies.

Where, how and for what purpose ...

The submission comments that genetic modification has been mainly used as a research tool in New Zealand but genetically modified crops have been rapidly adopted in some overseas countries. It provides an account of some of these commercial applications.

Risks and benefits, statutory and regulatory processes

MAF takes a risk management approach rather than attempting complete elimination of risk. It comments that the impacts of genetic modification are unforeseeable.

Managing biosecurity at the border alone is a physical impossibility for genetic modification. Control at the border will continue to rely on importers obtaining appropriate approvals from ERMA before importing genetically modified organisms and for documentation to determine the genetic modification status of incoming goods.

Containment facilities and operators for genetically modified organisms are approved under the Biosecurity Act. Containment control is based on standards approved by ERMA under the HSNO Act and developed by MAF and ERMA based on the Australia/New Zealand standard AS/NZS 2243.3:1995. MAF inspects facilities to ensure they meet standards plus additional controls imposed by ERMA.

Strategy, risks and benefits, main areas of public interest, statutory and regulatory processes

Should New Zealand decide to prohibit the use of genetic modification in primary production, a definition of "non-genetic modification" is needed. That could range from a "due diligence" approach to avoid genetic modification inputs or mixing to an absolute genetic modification-free proven by audit trails and/or with testing for genetically modified material.

The definition would have to reflect what standards are realistically obtainable and enforceable.

The submission comments on environmental risks and benefits from the use of genetic modification.

Maori views are balanced between significant cultural concern over whakapapa and tapu issues and as significant stakeholders in agriculture and forestry where there may be potential economic benefits. MAF feels that Maori, like other New Zealanders, are still weighing the implications of genetic modification.

Regulatory systems based on perceptions of risk or ethical considerations:

- could have unintended consequences unless there were a clear societal consensus and decisions were made with regard to all known consequences
- would not be based on scientific assessments of risk or economic assessments of costs and benefits
- could create uncertainty for industry and consumers (as perceptions and values shift over time) and discourage investment
- could be seen as arbitrary trade barriers.

MAF is concerned to protect the integrity and reputation of New Zealand's regulatory processes, which are central to gaining and keeping access to export markets. New Zealand exports have recognition from overseas regulators often denied trading competitors (eg, a bilateral veterinary agreement with the European Union accords "equivalence" to New Zealand's regulatory system).

Future values of genetically modified or non-genetically modified products are dependent on consumer demands. There is no certainty as to their future value. Given this, the submission asks whether a choice of one production system precludes the other, or can both production systems coexist? It describes various methods for keeping genetically modified and non-genetically modified products separate.

Ministry of Consumer Affairs

The submission by the Ministry of Consumer Affairs (MCA) addressed Warrant items (c), risks and benefits, and (j), main areas of public interest: human health. It focused on consumer rights, in particular, consumer safety, choice, information and education. These rights must underpin any approach to genetic modification, particularly in relation to food.

Points made included the following observations.

Two key aspects are scope and effectiveness of consumer information on genetic modification. Without adequate information on issues, consumers cannot choose whether to purchase genetically modified foods based on their perceptions of risk or other considerations. Without adequate information through product labelling, consumers cannot distinguish genetically modified from non-genetically modified products.

The Australia New Zealand Food Standards Council (ANZFSC) has agreed to a proposed comprehensive labelling regime based on the presence of novel DNA, protein or altered characteristics. MCA raises the issue of process labelling as well

as presence labelling: thus supporting consumers' right to know if the food they purchase has been subject to gene technology at any stage in the production process, not solely that the end product has novel DNA or protein.

MCA is looking at an "information alert labelling framework", which may create incentives for producers to supply consumers with effective information about genetic modification. The framework would require a standardised alert label be placed on genetically modified products drawing consumer attention to the attributes of the product.

The Ministry recognises that any requirement for producers to "alert label" products must be balanced against compliance costs. Compliance costs in food labelling are an important consideration for a food-exporting nation.

Ministry of Economic Development

The Ministry of Economic Development (MED) is charged with ensuring that the policy decisions of government agencies are consistent with the Government's goals of sustainable development.

The submission from the Ministry touched on matters relating to Warrant items (c), risks and benefits, (d), international legal obligations, (e), liability issues, (f), intellectual property issues, (h), global developments, (i), opportunities, (j) (iii), main areas of public interest: economic matters, (k), strategic issues, (m), strategic outcomes and (n), adequacy of statutory and regulatory processes. Issues raised often spanned several Warrant items. Some of the points are summarised below.

Opportunities, economic matters and strategic outcomes

Genetic modification technology is already having an impact in sectors important to New Zealand's economy and export markets. Land-based industries, including forestry and wood products, are being affected and account for 11% of gross domestic product and 70% of exports.

New Zealand has a reputation for high-quality research in agricultural and horticultural industries. Research on genetically modified products is a potentially valuable source of intellectual property for sale in world markets. It also could enhance the export potential of New Zealand's agricultural products.

Opportunities for advancement from use of genetic modification include:

- reduced production costs from biological controls and disease-resistant genetically modified organisms
- increased returns from faster growth rates and high-yielding crops
- development of new raw materials and products.

Risks from avoidance of genetic modification research and development include:

- restricted industry development
- loss of potentially valuable intellectual property
- loss of research opportunities in New Zealand's areas of competitive advantage.

Alternatively there are may be opportunities in focusing on non-genetic modification or organic technology. The choice facing New Zealand could include a spectrum of options, including genetically modified and non-genetically modified products.

The Ministry notes that New Zealand has also been identified as having a comparative advantage in "pharming" (using genetically modified animals to produce pharmaceuticals) because of the absence of most major animal diseases.

Risks and benefits and strategic issues

Weighing risks and benefits will not necessarily lead to an "all or nothing" stance on genetic modification. Uncertainties abound, particularly around reversibility, environmental risk, the longer term preferences of key trading partners and the extent to which it may be possible to maximise the use of both genetic modification and non-genetic modification to maximise benefit to the New Zealand economy.

Considerations of the risks and benefits of use or non-use of genetic modification may include the following factors.

Benefits of use:

- increase in new intellectual capital
- retention/attraction of personnel
- attraction of foreign investment.

Risks of use:

- unknown degree of reversibility of effects
- inadequate safety procedures
- environmental damage
- cost of regulation
- loss of competition
- rejection of New Zealand products by genetically modified organism-averse markets.

Risks of non-use:

- limitation of innovation
- limitation of value-added products New Zealand can trade.

International legal obligations

Any decision on genetic modification has to factor in detailed specific legislation and the complex range of international agreements already in place.

MED is responsible for the Trans-Tasman Mutual Recognition (TTMR) Act 1997. Section 10(1) states that goods sold legally in Australia may be sold in New Zealand regardless of the different standards applying in each country. The mutual recognition principle applies to genetically modified foods but not to foods that contain a genetically modified organism.

Liability issues

Under the Consumer Guarantees Act 1993, goods must be of acceptable quality, measured from the standpoint of a reasonable consumer fully aware of the state and condition of the product, having regard to a range of factors such as the nature of the product, information available and provided and all other relevant circumstances. MED considers that Courts would be reluctant to deal with acceptable quality issues regarding genetically modified organisms and genetically modified products under this Act.

Limitation period difficulties under the Fair Trading Act 1986 should be rectified by the current proposal in the Business Law Reform Bill for extension to three years from discovery or reasonable discoverability.

Intellectual property issues

New Zealand has seven intellectual property rights statutes, two of which (Copyright Act 1994 and Layout Designs Act 1994) provide rights automatically, while the other five (Trade Marks Act 1953, Patents Act 1953, Designs Act 1953, Plant Variety Rights Act 1987 and Geographical Indications Act 1994 (pending)) grant or extend protection by way of registration systems. The Patents Act is currently under review.

On the international front, New Zealand is a member of, or party to, the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement), International Union for the Protection of New Varieties of Plants (UPOV) and World Intellectual Property Organization (WIPO).

MED considers that it is not appropriate to use intellectual property rights statutes as mechanisms for regulating ownership of, or access to, New Zealand's genetic resources. A distinction should be maintained between review of intellectual property laws and the regulation of material or activities generally labelled "intellectual property".

The submission noted that if plant material cannot be field-tested in New Zealand before the grant of a plant variety right, then, even if the Plant Variety Rights

Office were to issue a plant variety right using the results of field trials from another country, the right to grow the variety in New Zealand cannot be exercised in the absence of ERMA's consent for its release.

Treaty of Waitangi responsibilities

The Ministry noted particular Maori concerns with the review of New Zealand's intellectual property rights statutes commenced in the early 1990s. Consultation continues with Maori on the proposed recommendations.

Adequacy of statutory and regulatory processes

The submission notes that Regulatory Impact Statements, which must accompany all Cabinet papers, are an important part of the quality of the regulation process for new regulatory proposals. The Regulatory Impact Statement requirement was to be reviewed by 31 March 2001.

MED stresses the importance of adequate checks and balances in the system to ensure that regulations meet their objectives at the least cost to business.

Ministry of Foreign Affairs and Trade

The submission by the Ministry of Foreign Affairs and Trade was primarily related to Warrant items (d) and (l): international obligations and implications. It provided information on international agreements relevant to consideration of genetic modification, including the Biosafety Protocol to the Convention on Biological Diversity and the World Trade Organization (WTO) and its Agreement on Technical Barriers to Trade (TBT Agreement) and Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). It also discussed relevant agreements and arrangements under Closer Economic Relations (CER) with Australia and made reference to international consideration of human rights and bioethics of relevance to genetic modification.

Points made included the following observations on policy and international interactions.

International obligations and implications

When governments consider policy responses to genetic modification, these international agreements and arrangements must be taken into account. Rules in these agreements require that measures affecting the trade of products, including genetically modified products, are not arbitrary or indiscriminate, but rather are based on objective scientific and technical approaches. Most of these rules are generic, they are not technology specific, but their provisions are relevant to the policy challenges of genetic modification.

The international community has recently been discussing a number of specific policy issues arising from biotechnology. Many countries are still in the early stages of developing policy and regulatory responses to gene technology and there is no consensus yet on whether international agreements need more explicitly to incorporate genetic modification issues. The fluid nature of these issues means that the impacts on New Zealand foreign and trade policy of different approaches to gene technology are difficult to predict.

International bodies, of which New Zealand is a member, have been discussing issues such as:

- physical aspects of trade in biotechnology products, for example, trans-boundary movements and environmental impacts
- desirability of internationally agreed product and labelling standards
- adequacy of existing risk management approaches
- adequacy of existing international rules to deal with new technologies
- incorporation of consumer concerns into decision-making processes.

These issues traverse both domestic and international policy responses to the challenges of genetic modification, and their consideration at the international level is still in progress.

At the time of the adoption of the Universal Declaration on the Human Genome and Human Rights, New Zealand expressed concerns, especially that the Declaration did not cover the ownership of human genetic material, and the lack of time allowed for public, and particularly Maori, consultation. UNESCO's 1999 report on the implementation of the Declaration noted that New Zealand already had in place legislative measures to protect individuals' rights under its principles.

Countries have exhibited different attitudes to genetic modification, often based on the presence or absence of significant export interests in genetically modified crops and other products. The different approaches to labelling of genetically modified food, either voluntary or mandatory, and the issue of consistency of such schemes with the WTO's TBT Agreement are examples of the current absence of a common approach.

The submission raised the possibility that discussion and information sharing on genetic modification issues and challenges has the potential to enhance international understanding.

Ministry of Health

The extensive submission from the Ministry of Health (MOH) submission addressed four main areas where genetic modification affects, or may affect, its functions:

- medical products and consumer issues
- genetically modified foods in New Zealand
- environmental health
- Maori perspective of health and genetic modification.

Medical products and consumer issues

The Ministry has no position on genetic modification or genetically modified organisms. MOH does recognise that medicines derived from genetic modification are significant in the treatment of specific medical conditions. MOH believes that gene technologies, including genetic testing, screening and gene therapies, will begin to affect health care over the next five years with significant impact over the next 10 to 20 years.

MOH points out that New Zealand is a tiny part (less than 0.1%) of the international market for pharmaceuticals and has a strong interest in minimising any barriers to pharmaceutical manufacturers entering the market with the latest products. New Zealand and Australia are discussing the harmonisation of their regulatory frameworks for medicines.

Currently MOH is undertaking analysis on the implications of genetic modification for the range, costs, availability, benefits and risks in New Zealand's health system.

MOH identifies a number of consumer issues connected with genetic modification, such as privacy of health information, ethical consideration of research and treatment proposals, consumer information and protection of consumer rights.

MOH notes that currently there is no legal requirement to disclose the recombinant origin of a medicine. MOH reports that it is common practice to voluntarily provide genetic modification-related information and the MOH supports this practice.

Genetically modified foods in New Zealand

Food regulation in New Zealand is currently in a transitional phase with the introduction of a joint food code with Australia. There are mandatory standards that must be complied with and Standard A18: *Food Produced Using Gene Technology* regulates the sale and labelling of genetically modified foods. Only genetically modified foods approved by ANZFSC may be sold and the labelling requirements

have been extended to require all food that has any characteristics that have been modified as a result of recombinant DNA techniques to be labelled.

MOH believes the amended A18 is a comprehensive, workable and enforceable regime that will enhance consumer information and choice. Moreover, because it is aligned with that of the European Union, it will ease difficulties of sourcing non-genetically modified food and may lower trade barriers.

Environmental health

MOH has responsibility to identify and prevent harm from environmental risks to public health under a number of statutes, such as the Biosecurity Act and HSNO Act.

MOH notes that genetically modified organisms potentially could be both beneficial and a threat to public health. (The example given was of using genetically modified products to control exotic mosquitoes.)

Maori perspective of health and genetic modification

MOH recognises that genetic modification and related technologies raise particular concerns about adverse impacts on whakapapa, mauri and rangatiratanga. The collection and use of genetic material has the potential to breach tikanga Maori, causing cultural and spiritual offence. It also raises some complex issues around intellectual property rights. MOH also notes that appropriate use of genetic modification could lead to environmental and health benefits for Maori (as well as non-Maori). The submission gives the example of a whanau's involvement in a genetic research project into an inherited cancer affecting members over generations.

Te Puni Kokiri

The focus of the submission by Te Puni Kokiri (Ministry of Maori Development) was on Warrant item (g), responsibilities under the Treaty of Waitangi, and the implications under it in relation to genetic modification in New Zealand. It also dealt with the concerns and interests held by Maori about genetic modification (Warrant item (j), main areas of public interest) and identified five key strategic issues (Warrant item (k)). The submission did not purport to speak for Maori as a whole but to complement other government departments' submissions by focusing on Treaty issues and Maori perspectives on genetic modification.

Issues raised are summarised below.

Responsibilities under the Treaty of Waitangi

The Treaty partnership recognises the need for Maori to be involved in the design of policies and practices affecting them. Treaty principles might assist in identifying what the Crown's obligations under the Treaty of Waitangi are in regard to genetic modification, genetically modified organisms, and products. This would include the development of strategic options to enable New Zealand to address, now and in the future, genetic modification, genetically modified organisms, and products.

There are three fundamental principles that underlie the mutual obligations of the Treaty partners and from which more specific expressions of the Treaty principles can be derived:

- The Treaty partners are under a duty to act reasonably and in good faith in their dealings with one another.
- The Crown must make informed decisions by having proper regard to the Treaty when exercising its discretion and powers.
- The Crown has a duty to take positive action to redress past wrongs. This duty includes active protection of Maori in the use of their resources.

The submission sets out in some detail the application of the Treaty principles to government policy making as developed through court and Waitangi Tribunal cases. This is discussed under:

- good faith and partnership
- consultation
- obligation on Maori to act in good faith
- active protection
- right to development
- tino rangatiratanga ("the mana to control resources in accordance with custom")
- taonga
- need for compromise between Maori and the wider community.

Main areas of public interest: human health

The submission repeated comments made in an earlier submission to the Ministry of Health.

Health for Maori people places emphasis on taha wairua (spiritual), taha whanau (family), taha hinengaro (mental) and taha tinana (physical). This all-encompassing perspective of health and wellbeing contrasts with the traditional western model in which the physical aspects of health and sickness are emphasised. The labelling of genetically modified food is one aspect of the much larger issue of Maori health

and wellbeing, which is a link in the Maori belief system, an integral part of Maori culture.

The continuing disparities in standards of health between Maori and non-Maori highlight a strong need for Maori to be informed of the developments in the health sector. In 1990, the death rate for Maori men and women from cancer and heart disease was significantly higher than that of non-Maori. If genetically modified foods have even a small likelihood of causing an adverse influence on longer term Maori health, then this should be sufficient reason for ensuring that adequate measures are taken to inform Maori consumers of the ingredients of the foods they are eating. The choice to purchase rests with them. Without mandatory labelling it becomes an issue of government policy decisions.

Main areas of public interest: environmental matters

The role of Maori as tangata whenua means that any environmental impacts of genetic modification are of importance to them because it impacts on their links to the land and its natural and physical resources.

Main areas of public interest: economic matters

The submission accepted that there were possible economic gains from genetic modification but characterised them as supposition because the full impacts are not yet known.

Main areas of public interest: cultural and ethical concerns

In July 1999 Te Puni Kokiri commissioned the International Research Institute for Maori and Indigenous Education (IRI) at Auckland University to complete a report on Maori perspectives on genetic engineering. The key issues that this report identified as being important to Maori are:

- need for further discussion and debate
- incomplete knowledge of the risks of genetic engineering
- cultural and intellectual property
- links with other indigenous peoples
- whakapapa (genealogy)
- requirement for more information for Maori
- perception of genetic engineering as being market driven
- concerns for whenua (land)
- role of globalisation
- wairua (spirituality)
- potential for food monopoly

- need for collective decision-making
- mauri (life force)
- tapu (sacred)
- need for national body or Maori monitoring group.

Strategic issues

The submission raised five key strategic issues:

- Education and consultation are vital to ensure that people have the proper information to make informed decisions.
- Risk management is a key consideration in determining the risks and benefits of genetic modification.
- Ethical and cultural opinions on genetic modification are just as valid as scientific and economic assessments.
- Intellectual and cultural property rights are a key consideration for Maori in addressing genetic modification.
- The Treaty of Waitangi is a reference point for Maori consideration of these issues.