Genetically Modified Organisms

Exploration of Issues and Policy Options

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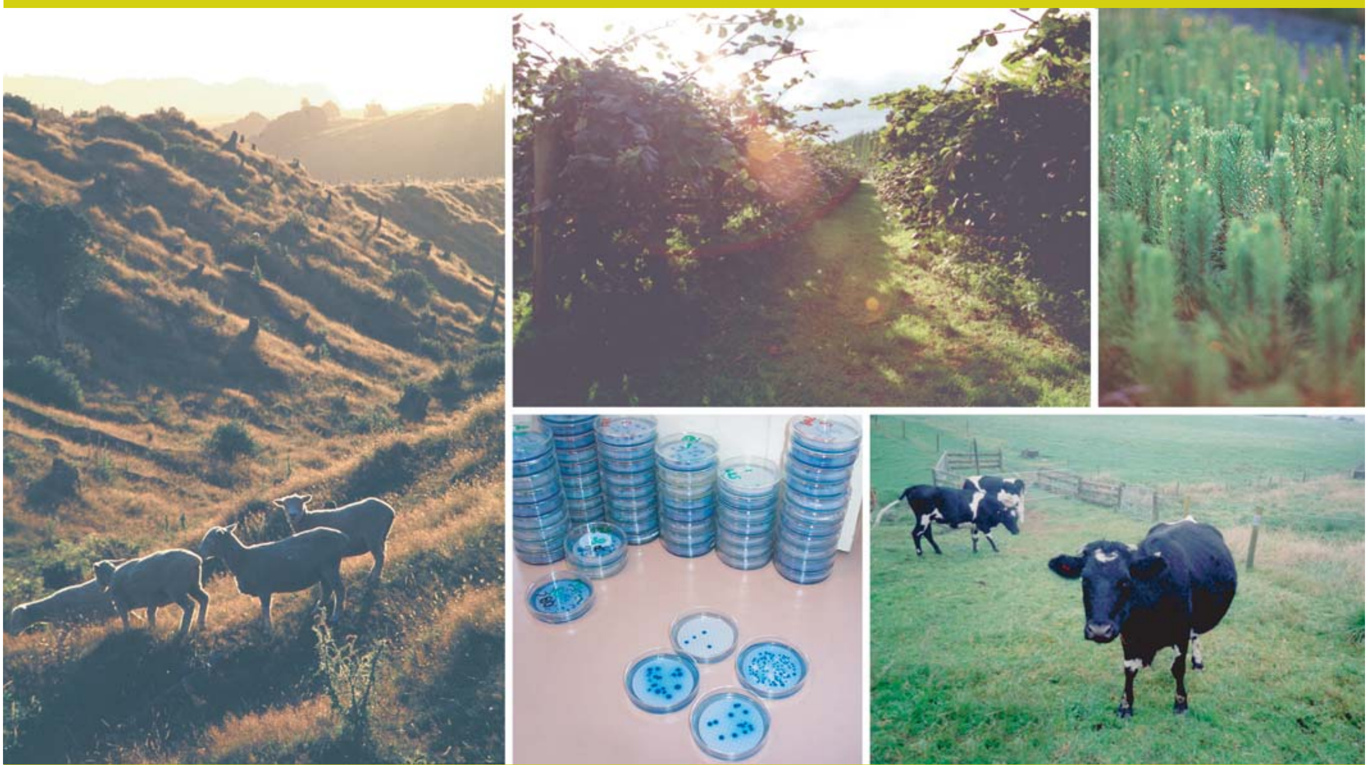

Environment Bay of Plenty
Resource Policy Publication 2003/01
February 2003

5 Quay Street
P O Box 364
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NEW ZEALAND

ISSN 1175 - 8546

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Executive Summary

This report was prepared at the request of the Bay of Plenty Regional Council, in response to concerns regarding genetically modified organisms (GMOs).

A Royal Commission on Genetic Modification was held in 2000-2001. After extensive consultation and deliberation, the Royal Commission concluded that New Zealand should 'preserve opportunities', developing and using GMOs as well as maintaining existing methods of production.

A moratorium on the commercial release of GMOs in New Zealand is in place until October 2003.

GMOs have a wide range of potential applications, particularly in agriculture and medicine. Some have the potential to deliver environmental benefits, including reductions in the use of pesticides. Increased yields from crops, stock and forestry could result in decreased land clearing worldwide. Animal pest control and improved pulp and paper effluent quality are other examples of benefits.

However, concerns have been expressed about the potential for GMOs to have adverse environmental effects. These could include adverse effects on non-target species or ecosystems, contamination of neighbouring non-GM crops and establishment of weed populations.

In addition, concerns have been expressed about the potential for GM in agriculture to have adverse effects on New Zealand's economy. In North America, price falls for key crops and a reduced demand from European and Asian markets have been attributed to consumer resistance to GM food. Some New Zealand analysts fear that use of GMOs in agriculture would result in a similarly reduced demand for New Zealand produce.

Many people also have a deep unease about GMOs and their potential effects, both environmental, ethical, cultural and spiritual. For many tangata whenua, the existence and use of GMOs has serious implications for key elements of Maori life, including whakapapa and mauri. Many other cultural groups and individuals in New Zealand also have serious misgivings about the use of this technology.

GMOs are regulated in New Zealand by the Environmental Risk Management Authority (ERMA), under the Hazardous Substances and New Organisms Act 1996 (HSNO). GMO importation and development applications undergo close scrutiny by ERMA. An application will not be approved unless ERMA is satisfied that the GMO does not pose any significant risk. All approvals are subject to appropriate conditions of containment, which are enforced by the Ministry of Agriculture and Forestry.

The potential role of local government in the regulation of GMOs is uncertain. At present, local government has no role. Some local councils have declared themselves to be GE-free, but this is a purely symbolic declaration with no legislative backing. The Ministry for the Environment appears to hold the view that as GMOs are regulated under specialist legislation (HSNO), there is no place for regulation by local government under the RMA.

However, the situation is not clear cut. A recent discussion paper on proposed changes to HSNO suggested regional councils as possible enforcement agencies for conditional release of GMOs. Letters from the Ministry for the Environment suggest that it may be theoretically possible (although not desirable) for a council to address environmental risks associated with GMOs in their area under the RMA. A thorough section 32 analysis would be needed to demonstrate why this was necessary, given the need to obtain HSNO approval prior to release of a GMO. Given that specific legislation exists for regulating GMOs (the HSNO Act), a council would need to show that there were outstanding risks remaining that required additional regulation under the RMA. This would probably be a lengthy and expensive process, with an uncertain outcome. It would be likely to reach the Environment Court, given the range of interests involved and the uncertainty of the legal position.

Most other regional councils in New Zealand appear to be taking little action on this issue, with the exception of unitary authorities. However a number are maintaining a watching brief and expressed interest in being kept informed of Environment Bay of Plenty’s progress. Local Government New Zealand and MfE have also shown interest in the preparation of this report and some ongoing dialogue is expected.

Ultimately, a policy decision will need to be taken by Council on this issue. Council could resolve that management of GMOs is a central government issue which regional councils do not need to be involved with. Alternatively, Council could request a legal opinion on the role of the RMA in regulating GMOs and assess options for involvement. In either case, it is recommended that Environment Bay of Plenty continue to conduct a dialogue with Local Government New Zealand and MfE to clarify whether the RMA and local government have a role in regulation of GMOs.

Table of Contents

Chapter 1: Introduction

This report was prepared at the request of the Bay of Plenty Regional Council. Council requested the development of a regional policy perspective on genetically modified organisms (GMOs).

The request followed consideration of the Hazardous Substances and New Organisms (Genetically Modified Organisms) Amendment Bill by a Strategic Policy sub-committee in early 2002. Amongst other things, the Bill[1] put in place a moratorium on release of GMOs until October 2003. Council requested 'the development of policy to contribute a regional perspective and collective regional council perspective to the development of the central government policy that will be required by the end of the proposed moratorium'[2].

It is recognised that central government regulatory structures exist for the approval of GMOs, particularly the Hazardous Substances and New Organisms 1996 (HSNO) and the Environmental Risk Management Authority (ERMA). However, questions arose for Environment Bay of Plenty regarding (i) the potential role of local government in regulating GMOs and (ii) whether there was a need to make representations to central government regarding GMOs. In addition, a recent discussion paper by the Ministry for the Environment (MfE) on further proposed amendments to the HSNO Act suggested regional councils as a possible enforcement agency for conditional release of GMOs[3]. Finally, the increasing profile and importance of this issue make it important for Council to consider what policy position, if any, they may wish to adopt with regard to this issue.

In order to make such decisions, it was considered necessary to provide background information on the regulatory, scientific and cultural dimensions of the issue. Clearly this is an enormous topic and one of great complexity. The coverage in this report cannot be considered exhaustive. It is intended merely to provide an overview of some of the issues so that the implications of potential policy choices can be considered. There is a vast range of information on this field and readers are referred to consult other sources for a more in-depth coverage of issues. In particular, the report of the Royal Commission of Inquiry into Genetic Modification[4] is an excellent source of information.

A diversity of views exists on the risks and benefits associated with GMOs. This report aims to remain as impartial as possible and to present information on both the potential advantages and disadvantages of genetic modification, based on information currently available.

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[1] Subsequently passed as the Hazardous Substances and New Organisms (Genetically Modified Organisms) Amendment Act 2002

[2] Environment Bay of Plenty Council minutes, 12 February 2002, page 3/1/6.

[3] September 2002. Ministry for the Environment. Public discussion paper: *Improving the Operation of the HSNO Act for New Organisms. Including Proposals in Response to Recommendations of the Royal Commission on Genetic Modification.*

[4] Referred to throughout this document as 'the Royal Commission'.

1.1 What is Genetic Modification?

In simple terms, genetic modification means artificially changing the genetic material of an organism. Genes may be moved from one organism to another, or existing genes may be changed. The terms ‘genetic modification’ (GM) and ‘genetic engineering’ (GE) are interchangeable.

Genetic modification is defined by the Royal Commission as:

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

Genes can be moved between species (for example between humans and sheep), and between different levels of biological organisation (for example between plants and microorganisms).

Genetic modification differs from traditional selective breeding in that genes or other genetic elements can be inserted into completely unrelated organisms (for example, from a tuatara to a bacterium). In selective breeding, changes of the traits of organisms does occur, but does so through normal mating processes. Modification of existing traits does result, and is in fact the intention of selective breeding (e.g. increasing yields of crops), but genes from new species are not introduced.

Basic terminology

Gene: a unit of hereditary information. A gene is a section of a DNA molecule that specifies the production of a particular protein. (About Biotechnology. Definition used in Report of the Royal Commission on Genetic Modification.)

DNA: deoxyribonucleic acid. A self-replicating material present in nearly all living organisms, especially in chromosomes, as the carrier of genetic information and the determiner of protein synthesis, usually occurring as a molecular double helix in which a phosphate group alternates with a deoxyribose sugar linked to a base. (The New Shorter Oxford English Dictionary.)

A transgenic organism is one which contains genes or other genetic material from another species. A transgene is a gene which is transferred to another organism.

The following excerpt from the report of the Royal Commission on Genetic Modification may assist in understanding what genetic modification is, and how it differs from selective breeding, cloning and other techniques.

What is genetic modification?[5]

For centuries farmers have used selective breeding to improve both crops and stock by breeding from the plants or animals that had the qualities they wanted to bring out and strengthen. This was the only way they had to develop animals and crops that were more productive and resistant to disease, and could cope better with extremes of climate.

Today, scientists can find individual genes that control particular characteristics, separate them out, change them, and transfer them directly into the cells of an animal, plant, bacterium or virus. Because the DNA code is known and is common to all life, it is also possible to produce synthetic genes. This technology is called genetic modification or genetic engineering.

There are three major differences between selective breeding and genetic modification:

- In genetic modification, scientists take individual genes from one plant or animal and put them into the DNA of the cells of another. They may also make changes to (modify) an existing gene.
- Genetic modification provides a way of giving a plant or animal new, inheritable qualities that is much faster than traditional breeding methods; these qualities may themselves be entirely new.
- Genes can be transferred in ways that are not found in nature, between different species and even between animals and plants.

[5] Source: Royal Commission on Genetic Modification 2001.

Chapter 2: Regulatory Framework

The importation, development, trial and release of GMOs is regulated under the Hazardous Substances and New Organisms Act 1996 (HSNO) by the Environmental Risk Management Authority (ERMA). ERMA is a central government authority established under HSNO.

The purpose of HSNO is *'to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms'.* ERMA has the principal responsibility for implementing the HSNO Act.

The Act operates mainly by requiring applications for introduction and development of new organisms. Management is achieved either by declining applications or by setting controls for applications that are approved.

2.1 ERMA

The principal role of ERMA is to make decisions on applications to introduce new organisms and hazardous substances to New Zealand. With regard to GMOs, ERMA is responsible for approving:

- Importation of GMOs into containment;
- Development of GMOs;
- Conducting contained field trials. (The purpose of field testing is to test the product in the environment in similar conditions to those that it will be released under);
- Releasing any contained or imported GMOs. (Note: No GMOs have yet been approved for commercial release in New Zealand. There is currently a moratorium on the release of GMOs; this expires in October 2003.)

The Authority consists of up to eight members appointed by the Minister for the Environment. ERMA New Zealand is the operational arm of ERMA, and is lead by a Chief Executive appointed by the Authority. ERMA New Zealand is based in Wellington and has approximately 60 staff. The authority has a Maori Advisory Committee, Nga Kaihautu Tikanga Taiao (Nga Kaihautu). Nga Kaihautu's main role is to advise the authority on Maori issues relevant to applications made under the Act.

2.2 HSNO Amendment Act (2002) and Moratorium

The Hazardous Substances and New Organisms (Genetically Modified Organisms) Act, enacted in May 2002, provides for tighter mandatory controls on field trials of GMOs. It also sets in place a moratorium on the release of GMOs to the environment, until October 2003.

The moratorium was put in place in order to allow time to put in place actions recommended by the Royal Commission on Genetic Modification. This includes establishment of research programmes, a Bioethics Council, and further amendments to HSNO.

The Act prevents ERMA from considering or approving applications to import or release genetically modified organisms, for a two-year period beginning on 29 October 2001. There are exceptions to the restriction for genetically modified organisms used for medical and veterinary medical purposes.

The Act also introduced requirements for controls on field trials of genetically modified organisms. Prior to the Amendment Act, such controls were not mandatory. The amendment also introduces requirements for ERMA to consider the safety and ecological effects of any field test of a genetically modified plant or animal, and to consider alternatives to undertaking field trials.

The Amendment also requires ERMA to specify inspection and monitoring of containment facilities during field tests, and after field testing to ensure that all heritable material is removed and destroyed. ERMA may also require inspection of the site prior to field testing.

The Act was passed by Parliament in May 2002.

2.3 Possible future amendments to HSNO

A discussion paper on changes to the HSNO Act, including consideration of a conditional release category, was circulated by the Ministry for the Environment (MfE) in the last quarter of 2002. Environment Bay of Plenty made a submission on this paper. Submissions have been analysed and will be presented to government by 31 January 2003. It is anticipated that a bill will then be drafted for introduction to parliament, probably in the first quarter of 2003. This will then be referred to a select committee, under the usual parliamentary process, which will call for submissions and hold hearings on the bill.

2.4 ERMA review

In August 2002, the Environment Minister Marion Hobbs announced a review of ERMA. The purpose of the review is to ensure that ERMA is able to fulfil its requirements under HSNO, so that the Act is implemented properly. This review is currently underway.

2.5 Applications for Approval

A GMO cannot be imported to New Zealand, developed or field trialled without approval by ERMA. Applications are assessed on a case-by-case basis. The application will be approved if, after considering all the potential effects of the organism, the benefits of the application are considered to outweigh the risks and costs. The Authority must also be satisfied that the organism can be adequately contained.

Applicants must present a substantial body of evidence supporting their application to demonstrate that it complies with the requirements specified in the Act.

ERMA makes its decision by considering the adverse effects of the application after controls have been applied. Risks, costs and benefits of the application are weighed up in order to make a decision. ERMA may also vary the controls applied to the work.

ERMA must decline an application if it is likely to cause any significant risk, namely:

- Displacing native species within their natural habitat;
- Causing deterioration of natural habitats;
- Adversely affecting human health and safety;
- Adversely affecting New Zealand's inherent genetic diversity;
- Causing disease.

ERMA must have also regard to:

- The ability of the organism to establish an undesirable self-sustaining population, and
- The ease with which the organism could be eradicated if it did so.

2.5.1 Approval Process

Considerable detailed information needs to be provided in order for ERMA to be able to make a determination on an application. For a field test, these requirements include:

- Location and duration of the field trial and associated facilities;
- Details of the target ecosystem;
- Full trial design and experimental plan;
- Capability of the test organism to disperse and survive;
- Specific potential effects being tested;
- Methods of disposal of the organism from the test site;
- Information on any likely inseparable organisms (e.g. viruses).

Information must be provided on all possible adverse effects of the organism on the environment, in particular:

- Environmental and ecosystem effects;

- Public health;
- Relationship of Maori with taonga;
- The ability of the organism to escape from containment.

The application should identify and assess risks, costs and benefits. In particular, the applicant must provide information on the potential impacts of escape of the organism. For field trials, applications must also provide information on consideration of alternative methods to achieve the research outcomes.

2.5.2 Public Notification

Generally, applications for organisms that can affect the environment are publicly notified. ERMA has the discretion to notify applications to import or develop new organisms in containment if there is likely to be particular public interest. A hearing will be held if the parties request one, or if ERMA thinks it is necessary. Applications to field trial a GMO must be publicly notified.

2.6 Containment

All approvals are subject to work taking place in appropriate conditions of containment. Applicants must provide information on how the organism will be contained, and the controls that will be used to manage risks.

Containment approvals can be specific to an organisation or a location, depending on the controls placed on the approval. For example Landcare has an approval to import into containment a specified number of Hawaiian plants as long as they are imported to the Lincoln Landcare site. Development approvals are approval-holder specific. Section 25(3) of the HSNO Act potentially allows containment approvals to be used by a number of people. However, the specialised controls required for approval usually mean that this is impractical.

Containment requirements are set by the decision-making committee, to prevent any risks to human health or the environment.

Matters which may be included in containment controls include:

- Requirements for treatment of air, water, waste or any other materials leaving a facility boundary;
- Facility construction standards, including providing for treatment and decontamination;
- Access restrictions and security standards;
- ‘Chain of command’ for transport and identification of all biological material.

Controls imposed as part of an approval can include:

- The length of approval given for the trial;
- The size of the trial
- Requirements to remove heritable material at the end of the trial
- Reporting requirements throughout the trial.

Containment does not necessarily have to be in a laboratory, provided the organism is restricted to a secure location or facility to prevent escape. For example, the recent approval for GM cattle development by AgResearch specified a series of fences and other security measures for an outdoor containment facility. For field trials of flowering plants or trees, the controls specified are likely to include removal of any reproductive structures prior to maturity, to prevent the release of pollen or seed.

Containment facilities must comply with controls attached to the approval by ERMA. Containment facilities are registered by the Ministry of Agriculture and Forestry (MAF) under the Biosecurity Act. Facilities must be constructed and operated in accordance with relevant MAF and Australian/New Zealand standards. The level of physical containment required for any given trial is specified in the ERMA approval, and defined in an Australian/New Zealand standard[6]. (E.g. for flowering plants, appropriate screening is to be provided to separate them from other plants and to prevent pollen and/or seed being dispersed beyond the specified area within the containment facility.)

The standards also contain specifications for disposal of biological waste, including plant material.

Contingency plans must be in place in case of accidental release of GMOs, or emergencies (e.g. fire).

Containment standards are jointly developed by MAF and ERMA. Containment facilities and operators are approved by MAF under the Biosecurity Act. MAF Biosecurity Officers audit containment facilities to ensure that containment standards, and any controls set by ERMA, are complied with. MAF Biosecurity and ERMA have an operational agreement under which this work is carried out.

External audit of containment facilities by MAF Biosecurity occurs at least annually. Premises are subject to audit at any time, particularly if previous instances of non-compliance have been found (MAF Biosecurity Authority 2000).

2.7 Application Fees

ERMA operates on a cost-recovery basis. Applicants must pay an up-front fee for processing of their application ($3000 for importation or development in containment, $5000 for a field test). They are also likely to have to pay additional charges (usually on an hourly basis) depending on the complexity of the application and the amount of time taken to process it. Extra costs will be incurred if a hearing is held, or if specialist external consultants need to be hired by ERMA to advise on the application.

[6] AS/NZS 2243.3

Applying for approval can be a costly process. Charges for field tests are likely to be considerably greater than indicated by the up-front fee. Costs of between $10,000 and $103,000 have been charged for field trial applications, depending on the complexity of the proposal and the number of submissions it attracts. In addition to the application fees, it will usually cost an institution considerable sums of money to prepare the necessary documentation and supporting evidence. The costs of compliance can be even higher (for example upgrading a laboratory to the required containment standard and ensuring ongoing compliance with containment standards). Forest Research estimates that it cost $450 000, and took two years, to obtain approval from ERMA for a field trial.

2.8 Institutional Biological Safety Committees

ERMA is able to delegate decision-making powers for low risk GMOs to institutions which have set up Institutional Biological Safety Committees (IBSCs). Most of these institutions are universities or Crown Research Institutes (CRIs). IBSCs can make decisions on the development of low risk GMOs in laboratory and research situations, within contained facilities.

The definition of ‘low risk’ genetic modification is highly technical and is set out in HSNO regulations[7]. In general terms, low-risk experiments are those which do not use disease-causing or toxin-forming[8] organisms (unless using an approved host/vector). Experiments must be carried out in appropriate containment facilities, as specified in the regulations. (Note: The low-risk regulations have been redrafted to improve their usability, and are currently awaiting consideration by Parliament.)

IBSCs are required to demonstrate that they have followed the provisions of the HSNO Act, and the ERMA New Zealand Methodology.

Members of IBSCs include:

- Chairperson
- Biological Safety Officer
- Engineering expert
- A layperson not associated with the institution, who is able to consider community interests
- Microbiologist
- Molecular biologist and/or geneticist or ecologist
- Maori representative.

It has recently become mandatory for each IBSC to include a tangata whenua representative. That tangata whenua representative should be from the hapu or iwi with mana whenua for that area.

[7] Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 1998.
[8] Toxins for vertebrates.

Approvals for development in containment are specific to an institution. If another institution wanted to do the same work, the application would need to be assessed by their own IBSC, or by ERMA. If an approval is given by an IBSC, it must set the relevant level of containment.

If an institution does not have an IBSC, its low risk applications are considered by ERMA.

2.9 Role of the Ministry for the Environment

The Minister for the Environment has two roles under the HSNO Act. The first is to appoint members to the Authority. The second is to call in applications which are of such significance that they require Ministerial decision. No such call-ins have yet occurred.

Regular meetings occur between ERMA and MfE staff, and the Chairperson and Minister respectively.

The Ministry for the Environment (MfE) also has a role in developing policy and changes to legislation, particularly the HSNO Act. MfE currently has the task of coordinating the work responding to the recommendations of the Royal Commission across Government.

2.10 Ministry of Agriculture and Forestry (MAF)

Enforcement of new organisms requirements is undertaken by MAF under the Biosecurity Act. MAF enforces HSNO containment requirements for GMOs, under a Memorandum of Understanding between ERMA and MAF. MAF has enforcement powers under the Biosecurity Act 1993. MAF also manages border control and quarantine issues for new organisms.

Chapter 3: Royal Commission on Genetic Modification

The Royal Commission on Genetic Modification was established in 2000. The Commission was established by the Government in response to public concerns regarding genetic modification[9]. A voluntary moratorium on release of GMOs was agreed between the government and industry and research groups for the duration of the Commission.

The Commission was directed to report on strategic options available to New Zealand regarding genetic modification. They were also asked to report on any regulatory changes required regarding genetic modification. Other matters which the Commission was authorised to investigate include risks and benefits, liability, the global context, human health, environmental issues, economic aspects and cultural and ethical concerns.

The Commission received over 10,000 written submissions from a wide range of stakeholders. Public meetings, hearings and hui were held by the Commission around New Zealand over a course of 9 months. The nationwide consultation process included 15 public meetings, 28 Maori consultation workshops and 11 regional and national hui. The Commission's consultation process also included a Youth Forum and public opinion telephone survey. Formal hearings were held in Wellington, Auckland and Christchurch over a 12-week period. These hearings involved over 100 Interested Persons (having an interest in the inquiry apart from that of the public generally) and nearly 300 witnesses, many from overseas.

Interested Persons included horticultural and agricultural producer associations, non-government organisations, biotechnology research institutes, horticultural, agricultural and forest research organisations, organic producers, iwi and religious organisations.

The Commission's report was presented to the Governor-General in July 2001. Its overall conclusion was that New Zealand should 'keep its options open' and preserve opportunities. The Commission found there to be positive and useful aspects of genetic modification which could be important to New Zealand in the future. However, the Commission also considered that it should be used "only in ways that are carefully managed".

The Commission considered a completely GE-free New Zealand to be impractical. They considered this would be impractical to enforce, would not allow current, let alone future, medical uses, and would have an adverse effect on the economy. They also did not consider that the economic advantages currently enjoyed by GM-free or organic produce would persist in the long term to an extent sufficient to compensate for the detrimental economic effects of not allowing genetic modification.

However, the Commission also rejected the option of unrestricted use of GM technology. They considered that to do so would involve "*taking unacceptable risks with human and*

[9] A petition of 92,000 signatures calling for a Royal Commission on genetic modification and a moratorium on field trials was presented to Parliament by the Green Party in October 1999.

environmental health and with our cultural heritage. It would also compromise consumer choice and our export market options."

The Commission considered it to be vital for New Zealand to have a strong research base in order to be able to *"pursue all possible opportunities"* as part of the knowledge economy. Continuation of GM research was therefore supported.

Banning the importation of GM food was not considered to be realistic. The Commission also considered that this would restrict future consumer choices and benefits (e.g. foods with potential nutrition, price or health benefits).

The Commission considered that the regulatory framework provided by HSNO was appropriate. However, recommendations were made to make the system more robust.

The Commission recommended that research be undertaken into environmental, socioeconomic, ethical and agricultural issues identified during the Inquiry. Further information on some of this research is given in chapter 5 of this report.

Other recommendations of the Commission included:

- Establishment of a Bioethics Council (Toi te Taiao). Its purpose is to advise and promote dialogue on cultural, ethical and spiritual issues associated with biotechnology.

- Amend HSNO to include cultural, ethical and spiritual grounds for Ministerial call-in of applications. (Currently under consideration by Government following circulation of the recent MfE discussion paper.)

- Investigation of liability associated with GM. (See chapter 7.)

- The establishment of a Parliamentary Commissioner on Biotechnology. The Government chose not to implement this recommendation.

- Development of a Biotechnology Strategy to ensure that New Zealand stays up to date with developments in biotechnology, and that risks and benefits are balanced.

- An additional level of approval under HSNO: 'conditional release'. A discussion paper including consideration of conditional release was released in September 2002. (Environment Bay of Plenty made a submission on this paper, expressing concerns about the workability of such a category.)

- Economic analysis of risks and opportunities associated with both GM and non-GM technologies (programmed to be done by end of February 2003).

The Government has been working through these recommendations and has a programme for implementation. Many of these recommendations are already in the process of being implemented.

Chapter 4: Potential Uses of GMOs

GMOs have a wide range of potential applications and benefits. These include producing crops or animal products with enhanced nutritional or medical benefits, improving the properties of crops and plantation forest trees, built-in pest and disease resistance in crop species, and animal pest control.

A brief outline of some of the major potential benefits from development and use of GMOs follows. This should not be considered exhaustive.

It should be noted that, as with many emerging new technologies, a number of potential benefits are claimed for GMOs. Some of these have been demonstrated, but many are yet to be proven (particularly at field or commercial level).

4.1 GMOs in New Zealand

Currently, no GMO crops are commercially grown in New Zealand. Much of the GM work conducted in New Zealand to date has been for research or teaching purposes. Examples include research work using GM mice to study disease, and studies with GM plants to improve understanding of the basic mechanisms controlling plant growth and development.

The first contained field trials of GMOs in New Zealand occurred in 1988. Since then, over 50 contained field trials have been approved. These have mostly been small scale trials. Crops have included pasture plants, fruit, vegetables and arable crops. Trials in goats, sheep, cattle and radiata pine have also been undertaken. Modifications tested included resistance to herbicides, diseases and insects, and improvements in crop performance.

4.2 Medicine

Medical applications are one of the main potential benefits of GMOs. This report does not discuss medical applications in detail. Its focus is applications with a much greater potential for environmental risks or benefits, which are of greater relevance to Environment Bay of Plenty's functions. However, it is recognised that GM techniques offer potential new therapies for a range of conditions, including those for which there are currently no effective treatments. The potential health benefits of these technologies must be considered when developing policy on GMOs.

Existing and potential uses of GM in medicine include:

- diagnostic procedures;

- formulation of medical products, particularly recombinant proteins;
- novel approaches to the treatment of cancer, infectious diseases and autoimmune diseases;
- vaccines;
- the potential for food to be a means of delivering pharmaceuticals or vaccines (e.g. in milk);
- gene therapy (for inheritable genetic diseases, cancer).

One of the major medical benefits of genetic modification is the production of recombinant proteins for medical use. GMOs can be used to produce human proteins to treat people with particular diseases (for example, insulin for diabetics). GM is used to insert genes coding for the human form of these proteins into the DNA of other species, which then produce the desired protein. In New Zealand, approximately 32,000 people with diabetes use insulin produced by genetic modification (Royal Commission 2001). Use of recombinant insulin has been approved in New Zealand since 1983.

Recombinant proteins can be produced in greater quantities from GM processes, compared with extraction from other animals or human blood. They also have the advantages of preventing immune reactions to the non-human proteins which would be used otherwise (e.g. pig insulin), and being free of the risk of contamination by pathogens from other sources, either animal or human (e.g. HIV, mad cow disease).

Genetic modification techniques are also widely used in medical research, including the study of disease processes. Genetic modification also offers the promise of treatment for people with rare genetic disorders, new diagnostic tools, and vaccines.

Case study – medical research with GMOs in New Zealand

Transgenic sheep and alpha-1 antitrypsin
PPL Therapeutics obtained approval to develop a flock of GM sheep in New Zealand for production of human alpha-1 antitrypsin (AAT). This is a protein used in the treatment of cystic fibrosis and emphysema

Currently, AAT is produced from human blood, but quantities are not sufficient to meet the need. Methods such as bacterial or yeast fermentation or cell culture cannot produce sufficiently large quantities of AAT to be commercially viable.

GM sheep have been modified to contain a human gene which codes for the production of human AAT. Flocks of transgenic sheep in Scotland are currently producing human AAT which is being used in clinical trials in Europe. More sheep are required to produce sufficient milk to meet future demand; hence this trial. New Zealand was chosen for the trial because of its skill and experience in raising sheep, and freedom from diseases such as scrapie and bovine spongiform encephalopathy (mad cow disease).

The flock of GM sheep is currently being expanded, ready for milk production. Currently the milk is shipped to Scotland for extraction of AAT.

4.2.1 Nutriceuticals

'Nutriceuticals' are touted by some GM researchers as the 'next wave' of GM products. Nutriceuticals are foodstuffs produced from crops or animals which have been genetically modified to increase levels of key nutrients, such as vitamins.

Closely related is the concept of 'functional foods', foodstuffs which are intended to be part of a normal diet but are modified to include substances with additional health benefits. Examples of potential modifications with health benefits include tomatoes with higher antioxidant activities and garlic with higher levels of cholesterol-lowering substances.

In submissions to the Royal Commission on Genetic Modification, a number of producer boards and companies highlighted the potential benefits of developing nutriceuticals and functional foods. These submitters included the New Zealand Dairy Board, Foundation for Research, Science and Technology, the New Zealand Arable Food Industry Council, the New Zealand Feed Manufacturers and the New Zealand Grocery Marketers Association.

Some researchers and producers believe that the availability of nutriceuticals with desirable properties and obvious benefits could overcome some of the current consumer resistance to GM produce. People may see more benefits for themselves from these products, compared with benefits from current first generation GM products, which are largely perceived to be only for large companies or producers (Saunders and Cagatay 2001).

4.3 Agriculture

GM crops were first grown commercially in the US in 1996. Today, 99% of the world's GM crops are grown in four countries: the US, Canada, Argentina and China (Soil Association 2002). The four main GM crops grown are soya, cotton, maize and oilseed rape. The majority of these crops have been genetically modified to express one of just two traits: (i) resistance to herbicides (e.g. Roundup™), or (ii) expression of the Bt toxin, to make the crop insect resistant.

There is an immense range of potential applications of GMOs in agriculture. The potential benefits of GM in agriculture include:

- resistance to pests and disease;
- decreased usage of pesticides;
- increased yields from crops;
- improved nutritional value.

Genetic modification can lead to crop or livestock improvements more quickly than conventional breeding techniques.

4.3.1 Disease and Pest Resistance

Genetically modifying crops for resistance to pests and diseases is a major area of research. Crops have been modified for resistance to viruses, and work on resistance to bacteria, fungi and nematodes is underway.

Plants with built-in insect and disease resistance could have environmental benefits in reducing the use of pesticides. This in turn would result in decreased worker exposure to pesticides, and reduced contamination of soil and water.

As well as reducing the use of pesticides, GM crops modified for disease or pest resistance could have great benefits in increasing yields. For example, if GM for resistance to the African cassava mosaic virus is successful in the field, cassava yields could increase ten-fold (Powell 1999).

In New Zealand, research into pest and disease resistance has included:

- Tamarillos: resistance to a virus which causes black spotting, decreases yields and shortens tree life;
- Potatoes: resistance to the potato tuber moth, blight, potato cyst nematode;
- Peas: resistance to alfalfa mosaic virus
- Brassicas: virus resistance, aphid resistance;
- White clover, rye grass: insect resistance (e.g. grass grub, porina moth larvae).

Bt toxin

Many pest-resistance modifications to date have been for expression of the Bt insecticidal toxin. Bt (*Bacillus thuringiensis)* is a bacteria that creates its own insecticide (the 'Bt toxin'). 'Bt plants' are genetically modified to express the Bt toxin (insecticide) in their leaves and/or pollen, so that browsing insects are killed. The modification was undertaken in order to improve crop yields and reduce the use of pesticides. Bt is one of the most common traits that has been incorporated into GM plants.

Concerns have been raised that widespread use of GM Bt plants could lead to resistance to Bt toxins in insect population, thereby ultimately resulting in the loss of this tool. This is of particular concern to organic farmers, for whom non-GM Bt (applied as a compound) is one of the few pesticides they can use without losing organic certification.

In the US, growers of GM Bt plants are required to adhere to management strategies to avoid the development of insect resistance (Teulon and Losey 2002). This is achieved by interplanting of non-GM plants (refuges) amongst GM crops expressing Bt. However, the effectiveness of these strategies depends on a number of factors[10], requires significant development and maintenance, and is not guaranteed (Teulon and Losey 2002).

There have been some reports that Bt crops have not lived up to expectations in field use (Glare et al. 2001). Failures of Bt cotton and herbicide resistant crops in the US and Australia have been reported (Hilder and Boulter 1999), although conclusive information is not available.

Other proteins with insecticide properties have also been worked with or are under investigation.

In China, a range of crops have been genetically modified for resistance to disease and pests. In fact, 90% of GMO field trials in China are of crops modified for resistance to pests or disease (New Scientist 2002c) Cotton modified to express Bt has been on sale since 1997, and is grown by 2 million Chinese farmers. It is

[10] These factors include the size of the refuge areas, the concentration of Bt expressed by the GM plants, the genetics of the insect pest population, the extent of insect movement between refuge and non-refuge areas, and the number of pest species present. (Teulon and Losey 2002).

reported that use of pesticides and production costs have decreased markedly for farmers growing Bt cotton (New Scientist 2002b). Rice modified for resistance to major pests has also been released, along with tomatoes and capsicums. Other crops are in development, including potatoes, peanuts, cabbage, maize, melons and chillies.

Concerns have been expressed in general about the development of resistance to insecticidal toxins produced by GM plants. However, it is predicted that future GM developments will target more than one aspect of pest resistance (New Scientist 2002c). This is theorised to prevent the development of 'resistant superbugs' and is a growing area of research.

In addition to reducing pesticide use, GM plants could have other direct environmental benefits, by reducing the need to plough under weeds after harvesting or before planting ('no-till agriculture'). This could lead to reductions in loss of topsoil, and therefore be of great benefit to both the environment and agriculture (Glare et al. 2001; New Scientist 2002c and 2002d).

4.3.2 Herbicide Resistance

Herbicide resistance is probably one of the best known types of genetic modification. Herbicide resistant crops can be sprayed to control weeds without harming the crop. There are some claims that herbicide use may be reduced on herbicide resistance crops, as farmers can achieve the desired weed control with a single spraying of herbicide once crops are planted and weeds emerging. Others state that while the total amount of herbicide used is not reduced, using herbicide-resistant crops allows farmers to use less toxic herbicides, such as Roundup™ (New Scientist 2002d). On the other hand, some cite evidence that use of herbicides is actually increased in herbicide-resistant crops, presumably because farmers can spray without damaging their crop, and so use more herbicide than is necessary (Benbrook 2001)[11].

4.3.3 Increased Crop Yields

GM could potentially increase the yield of crops and other resources (food crops, forestry) so that larger amounts and quality of food can be increased without increasing the area of land under cultivation. This could have obvious environmental benefits by reducing the amount of land needing to be cleared to yield food, timber, fibre and other resources to meet human needs. Much of this work is still in the research stage, although there have been reports of some increases in yields from GM crops compared with wild relatives (Glare et al. 2001). Some work has also been done in animals. For example, investigations have been undertaken using GM to increase wool production in sheep at Lincoln University (Royal Commission 2001).

4.3.4 Tolerance of Adverse Conditions

Genetic modification is being used to improve the tolerance of a number of crops to adverse environmental conditions. These include:

- salt tolerance;

[11] See page 41 for more detail.

- drought resistance;
- reduced susceptibility to frost;
- tolerance to elevated levels of metals in soil.

4.3.5 **'Biofertilisers'**

Research on genetically modifying crops to fix nitrogen is underway (Glare et al. 2001). Enhancement of the natural nitrogen-fixing abilities of some bacteria is also being researched (ibid).

4.3.6 **Environmental Benefits**

Many of these potential agricultural benefits could also have benefits for the environment. For example, increasing energy yields from pasture grasses could potentially reduce methane and ammonia production from stock, as well as increasing milk and wool yields. Improving uptake of nutrients by crops could result in decreased requirement for fertiliser, with consequent environmental benefits (e.g. improved water quality due to decreased nutrient runoff).

Incorporation of herbicide resistance, insect resistance and disease resistance into GM plants could all have potential benefits in terms of reducing pesticide use in agriculture. However, there is some dispute over the extent to which this has occurred (see section 6.4).

4.3.7 **Improved shelf life and 'cosmetic' enhancements**

Improved storage properties, colour, flavour and texture have been developed through genetic modification in some crops, including tomatoes (Tucker 1993).

4.3.8 **Decreased Allergenicity**

It is possible that allergens could be removed from foods by genetic modification of the source crops. For example, work in rice has shown a marked decrease in allergen content (Glare et al. 2001).

This approach is also being used with non-food allergens, including grasses and trees. GM experiments with rye grass (a common cause of hay fever) have shown promise in markedly decreasing the levels of allergens present in the grass (Glare et al. 2001, New Zealand Herald 25 November 2002).

4.4 **Aquaculture**

GM has been undertaken in fish, in particular to increase growth rates. Insertion of DNA coding for growth hormone has resulted in transgenic salmon and trout which grow substantially bigger than their wild-type relatives (cited in Muir and Howard 2001).

4.5 Forestry

Potential benefits of GM in forestry include:

- Improving timber yield and quality. This could have environmental benefits worldwide. If the number of trees needed to produce a certain amount of wood fibre was decreased, due to higher yield from trees, then less land would be required to grow plantation forests. Producing faster-growing trees could have similar benefits in reducing the amount of land area needing to be in forestry over the long term.

- Improved wood quality.

- Modifying pine trees so that they do not produce pollen. This has two potential benefits. (i) Infertile trees produce more wood than those that produce pollen; (ii) decreased pine pollen allergies for human populations near plantation pine forests.

- Trees optimised for paper production, reducing both energy requirements and pollution during the paper production process.

- Improvements in pest management (e.g. disease resistant trees).

- Potential increased rate of uptake of carbon dioxide, with benefits for greenhouse gas mitigation.

Forest Research in Rotorua has been conducting trials with GM *Pinus radiata* and Norway spruce. Genetic modification has been undertaken for herbicide resistance, reproductive development and wood quality. The majority of work being undertaken uses trees grown in greenhouses. Where trees are grown in the field, ERMA has imposed strict conditions requiring the removal of any reproductive structures, in order to prevent uncontrolled spread of GM pines.

Work currently being undertaken by Forest Research aims to decrease the amount of lignin in pine trees, in order to decrease the quantities of chemicals needing to be used in wood pulp bleaching, thereby improving effluent quality. This has potential environmental as well as economic benefits for the pulp and paper industry. The aim is to reduce the amount of lignin produced by just a small amount (e.g. 2-3%). This will not affect the structure and function of the tree, but would make a large difference to the amount of chemicals needed in the bleach process.

Eucalyptus

Also in the Bay of Plenty, Trees and Technology work as part of an international collaboration in forestry biotechnology, ArborGen, with partners in both New Zealand and the United States. Trees and Technology are undertaking GM research work with eucalyptus species. Their aim is to produce trees which grow faster and have better wood properties. As with other forestry GM work, this has potential environmental benefits, both in decreasing the amount of space needed to grow trees, and in increasing the extractability of fibre for pulp and paper making. The latter has benefits in terms of reducing the amount of bleaching needed, with flow on benefits for water quality, and in decreasing the energy needed in the pulp and paper manufacturing process.

Currently all GM work done by Trees and Technology occurs in the laboratory and in glasshouses, both operating in containment conditions. Field trials are not currently underway, mostly because of regulatory difficulties and the expense of applying for approval. There are concerns that the current regulatory environment is stifling research opportunities, and that New Zealand is losing its competitive advantage in this field because of the barriers to field research.[12]

4.6 Less Polluting Technologies and Other Environmental Benefits

GMOs have the potential to yield environmental benefits in a range of areas, from agriculture to industry. Some of these potential benefits have been outlined above (e.g. reduced pesticide use, decreased lignin levels in pine).

GM offers the potential to produce products which are currently derived from finite petrochemical resources, from biological sources. This has the potential to not only produce products from a renewable resource but also to use less polluting technologies. Examples include:

- production of nylon from glucose rather than hydrocarbon, using a GMO to create a key ingredient;
- development of biodegradable plastics and polymers (Glare et al. 2001).

4.7 Animal Pest Control

There are hopes that GMOs could offer a solution to some of the serious animal pest issues in New Zealand, including possum control.

Landcare Research is using molecular techniques as an approach to possum control. The aim of the research is to sterilise possums by immunising female possums against possum sperm and eggs. This would prevent fertilisation and therefore the production of young.

Landcare Research are carrying out this work together with an Australian research institution (the Australian Marsupial CRC). Possum egg and sperm proteins have been cloned and used to immunise possums. The GM and manufacture of the proteins is done in Australia; immunisation of the possums is done in New Zealand in containment. Results to date have shown infertility in immunised possums.

It is expected that delivery of the ‘fertility vaccine’ would be by edible plants (e.g. carrots) expressing the protein, or a GM parasite specific to possums (e.g. intestinal worm). In 2000, ERMA approved the importation into containment of GM carrots and potatoes expressing possum contraceptive antigens by Landcare Research. (Glare et al. 2001). The intention was to determine whether possums showed an immune response sufficient to affect their fertility.

Landcare Research are also working with Massey University on GM of a gut bacteria specific to mustelids, for the control of stoats. Australian researchers are also working with a New Zealand research team to develop an immunocontraceptive virus for stoats.

[12] Trees and Technology staff comment that they are effectively competing for work with similar laboratories based in the US. Despite undertaking work of high quality, and having cheaper labour and resource costs in New Zealand than internationally, Trees and Technology are losing research funding every year. They consider that the current regulatory regime has discouraged multinationals tendering for work in New Zealand and has directly contributed to the New Zealand partners providing services to the ArborGen consortium losing over NZ$1 million per annum in research funding.

Case study: rabbit control in Australia

Rabbits are a serious pest in Australia and resource and land managers alike struggle to control them. Australian researchers have genetically modified a highly infectious rabbit virus to make rabbits sterile. The myxoma gene (which causes myxomatosis) has been engineered to include a gene coding for a protein on the rabbit egg surface. Females infected with the virus will form antibodies against the egg protein. This means that when they produce their own eggs, their bodies will mount an immune response against the egg. This will make it impossible for the rabbits to conceive. This is known as immunocontraception.

The myxoma virus has changed over time since it was first introduced. Strains that are not lethal to rabbits have evolved through natural selection. Researchers hypothesise that the virus will infect the rabbits without killing them, and make them infertile. This is considered to be a much more humane approach than current methods which include poisoning, shooting and introducing new diseases.

Trials using the modified virus showed high success rates – over 70% of infected females did not bear any young. The researchers say that if success was similar in wild rabbit populations, it would reduce rabbit numbers substantially so that they were only a minor pest.

Critics, however, are concerned that the virus could spread to native species, making them infertile. There are also concerns about accidental release to other countries, where rabbits are not a pest but part of native ecosystems.

The researchers state that spread to native species is not a concern, as the myxoma virus has not spread to other species in the 50 years it has been in Australia. They also say that the modified virus is no more likely to spread to other species than the original strains (New Scientist 2002).

4.8 Economic Benefits

Many submitters to the Royal Commission gave evidence on the potential economic benefits of genetic modification. Many of these benefits were stated to flow from further development of existing primary industries. The New Zealand Dairy Board stated that GM technology would allow improvements of farm productivity and the production of new products, particularly nutriceuticals. Evidence was also given about New Zealand's current research competitiveness in the area of animal research.

The importance of research to New Zealand's future economic development was stated by a number of submitters to the Royal Commission. The flow-on benefits of research to other parts of the economy were also noted, including development of a highly skilled workforce, attraction of foreign investment and generation of intellectual property.

Chapter 5: Potential Risks

Concerns have been expressed about the potential risks of GMOs by scientists, ethicists, non-governmental organisations, tangata whenua and many other sectors of the community. Concerns range from effects on ecosystems to effects on spiritual and cultural values.

The risks discussed below will be primarily those which are held for the natural environment and agricultural systems, as these are considered to be of particular relevance for Environment Bay of Plenty.

5.1 Mechanisms of Impact

GMOs could have adverse effects on natural or cultivated environments by:

(i) adversely affecting non-target organisms;

(ii) outcrossing (transferring genes to non-GM relatives);

(iii) development of weedy/invasive strains;

(iv) unanticipated effects of GM on DNA function.

5.2 New Zealand Research on Potential Impacts of GMOs

The Royal Commission on Genetic Modification identified priorities for research investment into a number of areas, including the environmental impacts of GM plants. The Commission also noted that while international research in this area is ongoing, there is a need for New Zealand research in order to investigate potential effects on indigenous species and ecosystems.

Research into the potential environmental impacts of GMOs is now being undertaken by a number of Crown Research Institutes (CRIs) in New Zealand, in response to these recommendations. Many of these studies are being undertaken jointly between CRIs, sharing the research and results. This allows for cross-fertilisation of ideas, and for interconnections to be identified. The research is funded by public good science funding from the Foundation for Research, Science and Technology (FRST). Research projects are mentioned throughout this chapter with relationship to relevant topics.

5.3 Ecological Effects

Concerns have been expressed about the wider ecological impacts of GMOs. There are concerns that insufficient attention has been paid to potential wider impacts, as much research has focused on limited effects (e.g. effects on one species, over a short time period, rather than on ecosystem structure and/or non-target species).

As an example, in its submission to the Royal Commission, the Department of Conservation raised concerns about the potential impacts of Bt on New Zealand's indigenous ecology, including:

- Risks to native insects;
- Potential hybridisation and consequent threats to native species;
- Adverse effects on ecological processes in indigenous ecosystems;
- Hybridisation of GM plants with weeds in the conservation estate.

Another potential impact is competition of GMOs with native species. This could have adverse effects on native species if the GMO (introduced intentionally or accidentally) was more fit.

Some scientists consider that ecological risks are minimal because GMOs typically have reduced viability compared with their natural counterparts. However, researchers who modelled the effect of release of growth-enhanced GM fish concluded that GMOs may pose an environmental risk even if their viability is lower than non-GM fish (Muir and Howard 2001). This may occur if the GMO has an advantage over non-modified species as a result of the genetic modification, which is sufficient to overcome the reduced viability. The researchers concluded this is likely when GM is undertaken for growth rate and body size, as these are important determinants of survival and reproductive success. If the advantage is sufficiently strong, the GMOs could be so successful that they reduce the numbers of native competing species and, in extreme cases, lead to the extinction of those species (Muir and Howard 1999).

However, the success of a GMO in competing with other species will vary greatly between species depending on the nature of the modification and environmental conditions, including the presence of predators and other competitors. The researchers noted that the environmental risk posed by GMOs is likely to vary from case to case, and "*whether or not the spread of a transgenic organism constitutes a serious environmental threat remains an open question"* (2001). Nevertheless, they conclude that given the serious adverse environmental effects already experienced with introduction of exotic non-GM species, "*we need to proceed with caution before introducing transgenic organisms into nature".*

Irreversibility

The irreversibility of potential effects is of great concern to some scientists and members of the community. The fact that GMOs are living organisms underlines the concerns about the potential uncontrollability and irreversibility of adverse effects; the common analogy is that of a genie in a bottle. As the well-known ecologist David Suzuki said in his evidence to the Royal Commission, *"once these new life forms have become established in our surroundings, they can replicate, change and spread, so there may be no turning back"* (Royal Commission 2001).

New Zealand's numerous adverse experiences with introduced plant and animal pests underscore the concerns about the potential irreversibility of adverse effects on native ecosystems and species. The need for application of the precautionary principle is stressed by those with these concerns.

5.3.1 Non-target Effects

Concerns have been expressed about the potential effects of GMOs on non-target species. Such effects are harder to study than direct effects.

For example, some GM crops are modified to produce high levels of the insecticidal protein chitinase. At the Royal Commission, concerns were expressed about the potential effects of high levels of chitinase in the soil (much higher than those that occur in nature) on non-target fungi.

(a) Soil ecology

Soil is a complex and poorly understood ecosystem. A number of scientists have expressed concerns about the unpredictability of the effects of GM on soil ecosystems. The Royal Commission recommended that *"ERMA require research on environmental impacts on soil and ecosystems before release of genetically modified crops is approved".*

GM plants can have effects on soil ecosystems, including changes in decomposition. Unexpected changes in plant composition as a result of GM have been observed in several studies (Glare et al. 2001). These changes in turn can have effects on soil ecosystems. For example, changes in the amounts of carbon, nitrogen and phosphorus in plants have been found as unintentional effects of GM (Glare et al. 2001). These changes can have effects on decomposition of plant litter, as the proportions and availability of nutrients have effects on the soil organisms needed to break down organic matter in soil. At least one study has found changes in soil chemistry, including pH and activity of soil enzymes, which appear to result from the unintentional changes to the plant resulting from GM (Donegan et al. 1999).

In New Zealand, AgResearch is investigating how long plant DNA persists in soil. For example, does an antimicrobial gene from a plant persist in soil and slow decomposition processes? This is obviously important work in terms of investigating GM contamination concerns.

If insecticidal toxins produced by GM plants persist in the soil, this could have effects on soil organisms and ecology, particularly if they affect non-target insect larvae living in soil. The effects of GM crops on soil organisms vary between studies. For example, changes in population structure have been observed in nematodes feeding on litter from GM plants, presumably as a result of changes in nutrient composition of the plants (Donegan et al. 1997). However, studies to date have not shown adverse effects of Bt toxin on earthworms, although data is limited.

(b) Effects on insects

Some GM plants are modified to target insect pests, in order to prevent them feeding on the plant (for example, by producing an insecticidal toxin). Concerns have been expressed about whether these GM plants could affect other components of the ecosystem apart from the pest they have been designed to target.

Bees

Concerns have been expressed about the effects of GM plants on bees. Bees could be particularly susceptible to adverse effects of GM plants, as they rely on pollen as a food source (Royal Commission 2001).

A substantial amount of research on the effects of GM plants on bees has been conducted. Many studies have found no adverse effects of GM plants on bees. Overseas, researchers have investigated the foraging behaviour of small colonies of bees near flowering GM plants. No significant effects of GM plants on behaviour were found (Grallien et al. 1995). The effects of Bt-corn pollen on bees have also been investigated. Tests using purified Bt toxins have shown no toxicity to bees. However, some studies using another protein to confer insect resistance in some GM plants have shown that one type of these proteins may also affect similar enzymes in the bee gut. At high concentrations, this may decrease bee lifespans (Glare et al. 2001).

A recent review suggested that the impacts of GM plants on bees will vary from case to case, depending on the gene concerned and its expression in the parts of plants used by bees (Glare et 2001).

In addition to non-target effects of GM plants on bees, concerns have been expressed about the potential effect of GM crops on New Zealand's honey industry, and the potential role of bees as pollinators that could transport GM plant pollen large distances from the crop (Royal Commission 2001).

Research in bees

HortResearch, a CRI, is investigating the potential effects of GM plants on bees. GM plants could affect bees if (i) GM causes the plant to produce a novel protein in pollen (or nectar, resin etc), and (ii) the novel protein has an effect on the bees (e.g. slowing development, reducing survival, altering behaviour). GM plants could also affect bees if the modification results in a change to plants that make them less attractive to bees (e.g. not producing flowers, or changing flower development or nectar production).

To investigate these potential effects, HortResearch are (i) looking for novel proteins in the pollen and nectar of GM plants; and (ii) feeding proteins expressed by GM plants to bees in the lab to investigate whether this affects their development, survival and feeding.

For many transgenic plants, levels of proteins produced by GM are different in different parts of the plant. For example, many transgenic Bt plants express very low levels of Bt toxin in pollen, but higher levels in leaves. This means that insects feeding on the leaves will die, but those feeding on pollen (e.g. bees) will be unaffected.

Butterflies

Concerns about the effects on monarch butterflies of pollen from GM corn modified to express the Bt toxin were expressed internationally in 1999. Researchers fed GM Bt corn pollen spread on milkweed leaves to monarch larvae in the laboratory and compared outcomes with those in larvae fed milkweed leaves without pollen. The larvae fed Bt pollen had significantly poorer survival than controls that were not fed pollen. (Losey et al. 1999).

A second study was conducted using potted Bt corn and non-GM corn plants in the field. This study also found significantly greater mortality in larvae feeding on leaves dusted with Bt corn pollen. The US EPA, however, concluded that the evidence was not sufficient to cause 'undue concern of widespread risks to monarch butterflies at this time' (Glare et al. 2001). This conclusion is understood to be based on the fact that Monarch butterfly breeding occurs outside the time when corn pollen is produced. Thus, caterpillars would not be present at the same time as the pollen. In addition, other studies have found that corn pollen does not move far from the field (Royal Commission 2001). Thus, despite the potential for toxicity, there is very little risk of exposure of Monarch larvae to Bt corn pollen.

Another study found no difference in field populations of black swallowtail butterflies at sites with GM and non-GM corn (Wraight et al. 2001). However, mortality was higher in larvae fed leaves dusted with pollen from a particular strain of GM plant which expressed much higher levels of Bt toxin than another GM strain.

A review of butterfly studies concluded that more testing was needed to limit or remove the risk to butterflies and other non-target insects, particularly given the diversity of reactions of different butterfly species and the varying levels of Bt expressed in the pollen of GM plants (Pimental and Raven 2000).

Effects on native insects?

New Zealand researchers and ERMA are aware of the importance of assessing potential impacts of GMOs on endemic insects. ERMA requires researchers proposing to undertake field trials of GM plants to provide information on impacts on non-target insects Each application is assessed on a case by case basis, specific to the area where the crop is to be grown. Assessment of potential risks is undertaken based on knowledge of the type of protein that will be expressed by the GM plant, and its mode of action, in order to determine potential effects on non-target species. It is recognised that there is a need for more information on potential effects on endemic species.

Effects on food chains – New Zealand research

Food chain, or tritrophic, studies aim to investigate how GM plants affect the natural predators which prey on the insect pests.

HortResearch, a CRI, is undertaking research into the potential food chain effects of GM plants. These studies investigate the effects of GM plants on natural predators of pest insects. These predators have an important role in keeping insect pest numbers low. The concern which tritrophic studies seek to investigate is whether the GM plants, by reducing the numbers of insect pests, could have adverse effects on the natural predator species. They also investigate whether the GM plants themselves have any direct effects on the natural predator. For example, if the insect pest has ingested a toxin/protein (e.g. protease inhibitor) from a GM plant, this toxin could affect the predator. However, this will only occur if the toxin/protein is also toxic to the predator, and the predator consumes enough to be harmed.

The HortResearch research focuses on a native New Zealand beetle which is an insect predator. The beetle preys on caterpillars, which are feeding on an insect-resistant GM plant (tobacco). So far, the study has found no effect on growth or survival of beetles feeding on prey that had eaten only the GM-resistant tobacco. The researchers speculate that this may be because of the dilution of levels of insect-resistance protein at different levels of the food chain (i.e. between the plant, caterpillar and beetle).

(c) **Aquatic systems and birds**

Few effects on aquatic systems have been studied, nor have tritrophic effects on birds or reptiles (Glare et al. 2001). No published studies of the impacts of GM plants on New Zealand's native birds are available. However, some work has been done overseas in other bird species. A study done for EPA registration purposes in the US found no adverse effects of Bt-corn, cotton or potatoes on native quail (Glare et al. 2001). Farm-scale studies are currently underway in the UK to investigate the effects of GM crops on invertebrate diversity in farmland. This should also allow assessment of potential effects on birds feeding on field invertebrates (Glare et al. 2001).

5.3.2 Outcrossing and Gene Flow

Concerns have been raised in recent years about outcrossing or gene flow - the potential for genes to move from a GMO to a wild relative. A trait that is desirable in a GM crop plant (e.g. drought tolerance or herbicide tolerance) could be transferred to a wild relative via a plant's pollen. The offspring of these plants might then become difficult to control in the environment (e.g. herbicide tolerant weeds).

It should be noted that the risk of outcrossing is different for animals and plants. Plants are more readily able to disperse pollen or seeds via wind, insects and birds, and therefore have a greater potential for spread. Outcrossing is a particular concern for plants, because of the relative ease of cross-pollination, compared with the need for sexual reproduction for outcrossing to occur between animals. In addition, containment of animals (at least in the agricultural setting in which most GM animals are anticipated to be used) is generally far easier than it is for plants.

Fish represent an intermediate risk in terms of escape potential. There are concerns about potential escape from hatcheries, particularly of eggs given their small size.

The risk of a GM plant outcrossing to other plants (cultivated or in the wild) depends to a large extent on how closely related it is to other plants. If no wild or cultivated relatives are nearby, the escape of pollen is unlikely to have consequences as there will be no species for it to hybridise with.

Pollen

The distance that pollen can travel is one of the main reasons for concern about the risk of outcrossing and the difficulty of preventing it. Although the majority of pollen is deposited close to its source, a fraction does travel very long distances.

The distance pollen can travel varies between plant species. Pollen from oilseed rape (canola) can travel up to 4 km (Eastham and Sweet 2002). Sugar beet pollen dispersal has been recorded at distances of more than 1 km at relatively high frequencies. Maize cross-pollination has been recorded at distances of up to 800m, and it is predicted it could travel further under suitable atmospheric conditions.

Experiments conducted by the Canadian agriculture ministry's Saskatoon Research Centre found that pollen can travel at least 800 metres (New Scientist 2001).

> ***"Stray pollen and seed from genetically modified oilseed rape, or canola, is now so widespread in Canada that it is difficult to grow conventional or organic strains without them being contaminated." (New Scientist 2001).***

Recent research in Australia found that pollen from GM oilseed rape contaminated fields up to 3 kilometres away, and that there was no obvious drop-off with distance (Rieger et al. 2002). Although the frequency of cross-pollination between GM and non-GM canola was low, it did occur over a considerable distance. The pattern of distribution of GM-contaminated canola was variable across fields, rather than falling off with distance in an exponential manner as has been shown in smaller studies. This may be because of the role of both insects and wind, and the large size of the source fields, contributing to the apparent randomness of the pollination pattern. The authors suggested that insect behaviour may be of particular importance in explaining the apparently random distribution of pollination events.

Importantly, this study concluded that *"laboratory and small-scale experiments may not necessarily predict pollination under commercial conditions"*.

Pollen can be transported even longer distances by bees. At the Royal Commission, evidence was cited of bees in the UK transporting GM pollen up to 4.5km from a field trial to their hives. The National Beekeepers Association of New Zealand gave evidence to the Commission that bees flew distances of 6.5km to gather nectar and pollen and would fly up to 13.7km to a food source if nothing was available closer. Another research source found that most honey bee colonies foraged up to 2km from their hives, indicating the potential to transfer pollen and fertilise crops over some distance (Royal Commission 2001).

Mexican maize

A widely cited study reported the presence of transgenic DNA in non-GM maize grown in remote areas of Mexico, which had apparently been contaminated by cross-pollination with GM strains (Quist and Chapela 2001). The authors found insertion of transgenic DNA at a number of different points in the wild maize genome, and concluded this has resulted from multiple separate events, probably as a result of pollination by GM plants. However, these findings have been widely disputed and criticised by other scientists. In particular, the methodology used in the study has been criticised, as it can generate false positives (New Scientist 2002f). The researchers concede that there were some flaws in the study, but stand by their findings. Other researchers in Mexico have also found transgenic DNA in non-GM maize crops in Mexico, which is thought to have appeared either by pollination, deliberate planting (despite a moratorium) or spilling of GM seed in fields (New Scientist 2002g).

New Zealand Research

Landcare Research is undertaking a risk assessment of the potential for gene flow to occur via pollen and plants from GMOs to indigenous species. The aim of the risk assessment is to protect indigenous ecosystems and agriculture.

The study will commence with categorisation of potential risk groups. Groups identified as being of higher risk will be investigated more closely. The ultimate aim is to determine what are the high risk conditions for gene transfer, and whether plants persist in the field. The project will run for six years.

Issues to be investigated include:

- the potential for dispersion of GM crops via pollen, including the distance travelled by pollen;
- the potential for hybridisation of GM crops with wild relatives.

5.3.3 **Invasiveness**

Invasiveness is the capacity of an organism to become a pest species and spread through ecosystems (Glare et al. 2001). Invasiveness of GM plants could occur either by establishment of self-sustaining populations of GM plants, or crossing of transgenes into wild populations (e.g. by cross pollination).

It should be noted that the ability of a gene to transfer into wild populations is not sufficient to ensure that the gene will persist in the wild in its new host. To do so, it will have to confer a selective advantage on its new ‘host’ – in other words, plants with the transgene will need to do better than those without. Numbers of plants with the transgene will then increase through natural selection.

The ability of a transgenic species to survive (and, more than that, thrive) in the wild will therefore obviously vary greatly between habitats, depending on the type of plant (or other species), the properties conferred by the transgene, and the environmental pressures on the organism. For outcrossing, the risk will depend in large part on the presence of wild or cultivated relatives nearby. If there are no related plants for a gene to transfer to (e.g. via pollination), then transfer will not be able to take place.

Invasiveness is a property of interaction between a species and an ecosystem. The potential for invasiveness cannot therefore be assessed by analysing the traits of the plant alone. Persistence and capacity for invasiveness needs to be assessed on a case-by-case basis.

A transgenic plant will also need to be able to survive in the wild (i.e. without cultivation) in order to persist and become invasive. Many researchers state that it is highly unlikely that GM crops will become established in the wild because commercial crops generally need high levels of inputs and tending to survive (e.g. fertiliser, pest control). A 10-year British study of four GM crop species grown in natural habitats found that GM plants were no more persistent or invasive than their non-GM counterparts (Crawley et al. 2001). GM oilseed rape, potato, maize and sugar beet, genetically modified for either herbicide tolerance or insect resistance, were grown in 12 different natural habitats in Britain. There were no significant differences in recruitment between GM and non-GM plants for any of the sites. Populations of all crops, both conventional and GM, decreased at all sites after the first year because of competition from native species. GM lines did not persist for significantly longer than non-GM lines.

However, it should be noted that none of the crops had been genetically modified for traits that were expected to increase plant fitness in natural habitats. The authors state that results could be different for plants that had been modified to increase resistance against adverse environmental conditions (e.g. pest resistance). “*The ecological impact of plants with GM traits such as drought tolerance or pest resistance that might be expected to enhance performance under field conditions will need to be assessed experimentally when such plants are developed”* (Crawley et al. 2001).

A field study of rape plants producing the insecticidal toxin Bt showed increased survival of these plants compared with controls in the presence of herbivorous insects, and increased reproductive success of the GM plants (Stewart et al. 1997). The authors concluded that “*where suitable habitat is available, there was a likelihood of enhanced ecological risk associated with the release of certain transgene/crop combinations such as insecticidal rape”* (Glare et al. 2001).

Weediness

In addition to the potential establishment of 'escape' populations, GM could introduce weedy characteristics to wild populations, thereby enhancing their survival. They could also enhance the resistance of existing weed populations to control methods (particularly herbicides). As noted above, use of GM to introduce characteristics such as pest resistance or drought resistance could increase the ability of a plant to survive in the wild, making it more likely to persist in the environment, particularly in adverse conditions. Through natural selection, such plants could then increase in number.

A review concluded that *"genes were likely to escape from most if not all . . . transgenic crops"* (Hancock et al. 1996). Movement of genes from GM to non-GM plants by pollination has been demonstrated in a number of field trials. (Glare et al. 2001).

Recently, a study has demonstrated for the first time that weeds can become stronger and fitter by cross-breeding with genetically modified crops. Wild sunflowers (considered a weed by many US farmers) became hardier and produced 50% more seeds when they were crossed with GM sunflowers resistant to a moth larvae which feeds on the sunflower seeds (New Scientist 2002e).

A recent French study in sugar beet found that gene flow between non-GM beet and beet weeds growing in the same field occurred at a much higher rate that previously thought (Desplanque et al 2002). The scientists concluded that *"the eventual formation of transgenic weed beets is not only possible, but even probable, whatever the scenario adopted".*

New Zealand Research

Crop and Food Research are undertaking a number of research projects on the potential impacts of GM crops. The research is particularly focused on the stability of transgenes in the environment and through the food chain. The research will run over the next six years. The research is similar to that being conducted at Landcare Research, but focuses on field research rather than risk assessment. The aim of this work is to determine potential impacts on New Zealand fauna.

Issues being investigated include:

- The invasiveness of GM crops;
- Gene flow and gene transfer from GM crops;
- The potential for transfer of genes from GMOs to New Zealand flora, both native and introduced.

5.4 Effects of Insertion into DNA

There are concerns that because insertion of DNA into host genomes is effectively random (i.e. the site of insertion generally cannot be controlled), unexpected outcomes may result. Possible effects include production of unexpected toxins and instability of inserted genes. It is also possible that transgenes may move within the genome, with unanticipated effects (Royal Commission 2001). Some of these concerns are linked to the lack of understanding about the mechanisms of DNA function, and the consequent potential for unexpected outcomes (Glare et al. 2001).

Scientists hope that new GM techniques being developed will increase control over where genes are placed within the genome, decreasing the risk of unpredictable effects of gene expression and genome instability (Royal Commission 2001).

New diseases

Concerns have also been expressed about the development of new diseases through GM. This is mostly because of the use of viruses as vectors for insertion of DNA during the creation of GMOs, and the use of fragments of virus DNA within new GMO DNA constructs. Other proposed mechanisms by which new diseases could arise include: (i) as the result of inserted 'promoters' activating sequences of the GMO genome or dormant viruses; and (ii) recombination of inserted DNA, particularly virus fragments, with other viruses (dormant or otherwise).

Research work is underway in plants to find ways of introducing transgenes with a reduced chance of transfer to wild/unmodified relatives (Glare et al. 2001). Concerns include the potential for production of new viruses (Glare et al. 2001). Experiments have shown that this is possible, but there is a lack of evidence of this occurring in the field. A 6-year study of 65,000 transgenic potatoes producing a virus protein found no evidence of new viruses developing despite exposure to field infections of viruses (Thomas et al 1998).

"Whether such virus recombination is more likely in transgenic plants than between wild-type viruses, or that the resulting new virus would be more fit than wild-type viruses, is unknown" (Glare et al. 2001).

Other studies have shown development of recombinant viruses from viral genes in transgenic plants (Glare et al. 2001), including synthesis of insect virus proteins in plant cells. A recent literature review by New Zealand scientists stated that this "*suggests non-target studies need to be broadened"* (Glare et al. 2001).

5.5 Horizontal Gene Transfer

Horizontal gene transfer (HGT) is the transfer of genes (or other genetic material) from one species to another. This is a process that occurs naturally, although it is far more common in bacteria than in more complex organisms. Concerns have been expressed that HGT is a potential mechanism for transgenes to spread into the wider environment, with potential adverse consequences for species and ecosystems.

HGT has been shown to occur naturally in the environment. Most HGT occurs between bacteria. For example, it has been estimated that up to 16% of the genome of some bacteria has been acquired through HGT (Ochman 2000). It has been suggested that even some of the human genome could have been acquired through HGT in early stages of evolution[13].

HGT can occur in soil and is also likely to occur in the digestive systems of invertebrates living in soil, including earthworms, nematodes and insect larvae.

However, little is known about HGT from GMOs. Most research on the phenomenon of HGT has occurred in non-GMOs. Only a few laboratories

[13] For example, it has been suggested that 223 genes may have entered the human genome by HGT throughout human evolution (International Human Genome Sequencing Consortium, cited in Salzberg et al. 2001). However, other analyses have concluded the presence of these genes in the human genome and not in other species were more likely to be explained by other factors.

worldwide are working on HGT as a potential environmental risk, including some in New Zealand.

In addition, most study has been done in laboratories. Some field studies have been done, but so far they have not detected evidence of HGT from GMOs (Glare et al. 2001). However, it must be noted that HGT could be difficult to detect in the field because of the impossibility of sampling all of the large volumes of soil and massive numbers of soil bacteria in which HGT could have occurred (e.g. from GM crops to soil bacteria).

In vitro studies have shown that DNA released in soil can survive by binding to mineral surfaces, and that DNA bound to clay is still able to be taken up and incorporated into bacterial DNA (Nielsen and Townsend 2001). The length of time over which DNA would survive and remain viable in the field (and therefore be available to be taken up by another organism) is unknown, however.

Laboratory studies have shown that HGT can occur between bacteria and plants, but at very low frequencies and only under highly optimised conditions (Glare et al. 2001). It is not clear whether HGT can occur within the human digestive system, although concerns about this possibility have been expressed (Glare et al. 2001). Transfer of DNA to bacteria in the mammalian gut does appear to be possible. However, it should be noted that DNA has always been part of the human diet. It is not clear whether GMOs present additional risks in terms of gene transfer.

Unpublished research claims to have demonstrated horizontal gene transfer in bee gut (Royal Commission 2001). German television reported that a researcher, Professor Katz, had found that a herbicide resistance gene from GM rapeseed had transferred to bacteria and fungi in the gut of honeybees. The research has not been published in a peer-reviewed journal and critics claim that the results are far from conclusive. Another researcher is to attempt to repeat the experiments.

Concerns have been expressed that HGT could occur more frequently from inserted transgenes in GMOs than from native DNA. This is because of the type of DNA often used in genetic modification. Much of the DNA used in GM is of bacterial origin, which is much more likely to transfer into other bacteria than the plant or animal DNA of the transgenic organism. The modifications to transgenic DNA also mean it has an increased likelihood of transferring DNA.

However, for HGT to successfully introduce a new gene into the genome of an organism, a number of conditions must be met. Firstly, the DNA to be transferred must be able to survive in the environment (e.g. soil, digestive system, water). Secondly, the DNA must be taken up by bacteria (or other organism) and incorporated into its genome. The DNA must then be able to be expressed by the bacteria. Finally, it is not sufficient for the gene to be incorporated into the host organism. In order for the incorporation to persist, it must be stable within the host genome so that it can be passed onto the next generation. It must also confer a selective advantage upon its new host to persist into the next generations.

The frequency of gene transfer is usually very low. However, some scientists working in this area state that the frequency of transfer is of minor importance. What is important is whether the transferred gene confers a selective advantage on organisms that have incorporated it. If so, the frequency of that gene's occurrence will increase in future generations.

New Zealand Research

A number of research organisations in New Zealand are cooperating to undertake work on HGT, as recommended by the Royal Commission.

Landcare Research are undertaking basic research on horizontal gene transfer between distantly related bacteria.

AgResearch has also done research on horizontal gene transfer between soil bacteria. An important part of the work was demonstrating plasmid transfer between soil bacteria in the field. (Previous work has only demonstrated transfer in the lab.) This is important as it shows the potential for transfer of genes to occur in field conditions. The field experiment also showed that rates of conjugation were greatly increased within grass grub larvae in the soil.

AgResearch are also studying the potential for gene transfer from GM plants to bacteria living in insects feeding on the GM plants. This work is being done in conjunction with HortResearch.

Forest Research, together with other CRIs, is also involved in HGT research. They are looking at the potential for HGT from GM trees to other organisms. Forest Research will use the GM trees they already have planted in field trials to determine whether HGT has occurred to soil microorganisms. Research is also being undertaken in conjunction with AgResearch, looking at the effects of pine needles from GM trees on insects feeding on the needles. This latter project will investigate food chain effects.

At the University of Canterbury, researchers are investigating horizontal gene transfer between bacteria, and between bacteria and higher organisms (including mammals). They are also developing models that predict when, why, where and how often genes are transferred. This work has produced new insights into the mechanisms of gene transfer. ESR scientists are investigating the potential effects of GM crops on soil microbial communities in GM crop field trials currently underway in New Zealand. HGT of novel genes from GM plants to soil bacteria is also being investigated. The emphasis of this research is to find practical ways of minimising adverse effects of GMOs on biodiversity.

AgResearch in Lincoln are researching the potential effects of genes from GM plants on non-target soil organisms. This is important work, as soil ecology is one of the major areas of interest for GM impacts researchers, in terms of potential pathways for transgenes to enter non-GM organisms. Theoretically, transfer of transgenes to soil organisms could have major impacts on soil ecology and thus food chains, agriculture and other ecosystems. There has been relatively little research in this area so this is considered an important project. Some overseas studies have shown effects on soil biota (especially microorganisms) but the effects have usually been transient. Soil ecosystems are complex and incompletely understood. There are many interrelationships between soil organisms and their environment. This makes it difficult to predict potential effects of HGT of transgenes on soil ecosystems. The team wish to focus on the ecological significance of results, and effects at an ecosystem level, rather than studying components in isolation.

A key question is whether there will be sufficient information on horizontal gene transfer from GMOs before the moratorium expires in October 2003. Much of the research is programmed to run for up to six years, obviously well beyond the life of the moratorium. It is therefore highly unlikely that the necessary information for assessing risks will be available before the moratorium is lifted.

5.6 Human Health

Concerns have been expressed about the potential human health risks of GMOs. Detailed consideration of human health impacts is beyond the scope of this report. In brief, concerns include:

- Presence of toxins, or other compounds with potential health impacts, in GM food;
- Presence of allergens in GM food;
- Transfer of antibiotic resistance genes in the gut, leading to development of new antibiotic-resistant strains of human pathogens.

Concerns have been expressed about the lack of long-term studies on the health effects of GM foods (Antoniou et al. 2000). The lack of time over which GM foods have been available means that only limited information on human exposure is available.

Allergies

Tests for potential allergenicity of proteins in common transgenic crops have found no differences between GM and conventional crops tested (Glare et al. 2001). However, it is possible that transgenic crops could yield allergens that are different to known allergens; these would be more difficult to detect. Concerns have been expressed about the ability of food safety testing to recognise new, previously unknown, allergens (Royal Commission 2001). A recent review found only one instance of an allergenic substance being expressed in a novel (transgenic) plant. However, this study was important as it showed that a food allergen (in this case, from brazil nuts) could be transferred to another food by genetic modification (Nordlee et al, 1996).

The following two well publicised cases illustrate potential health concerns. Neither of these cases has shown adverse human health effects, but they are often cited as examples of potential health risks.

Starlink corn

In the US, Starlink corn, genetically modified to produce an insecticidal protein, was mistakenly sold in human foodstuffs despite being only approved for use in animal feed. There were concerns that people could be allergic to the insecticidal protein. No evidence of adverse health effects were found; however, testing did find there was a medium probability of the protein causing allergies (Royal Commission 2001).

Rats and GM potatoes

A study feeding GM potatoes to rats allegedly found that the GM potatoes depressed the rat immune systems and caused changes in their intestines. The researchers who undertook the study concluded that the effects were due to the genetic modification of the potato. However, this study has been widely criticised by other scientists, who have found that the methods used were unorthodox and the research was incomplete (Royal Commission 2001). In particular, it seems that the changes in the rats' digestive system may have been due to the fact that they were being fed a diet of raw potato. Raw potato will induce changes in the gastrointestinal system due to malnutrition and adverse reactions to the raw potato itself (Royal Commission 2001).

5.7 Conclusions

There is potential for a wide range of adverse effects associated with GMOs. Evidence for these risks ranges from limited laboratory data to large scale farm field trials. Some risks remain theoretical while for others there is evidence that some concerns may be valid. It must be remembered that conclusions are specific to each study, and it is difficult (and dangerous) to extrapolate from one study in a single species to statements about the effect of GMOs in general.

It is therefore not possible to make a blanket statement about the risks of GMOs. These vary considerably between GMOs depending on the species of organism, the nature of the modification and the environment in which it is grown. The risk of adverse effects of GMOs therefore needs to be assessed on a case by case basis.

Considerable research on the possible adverse effects of GMOs is underway, including in New Zealand. Much of the New Zealand research will not yield results for another five years. It is tempting to advocate that there be no full releases of GMOs until results of this result is available. However, this could unnecessarily stifle all GM research, not just in those areas which are suspected to present a higher risk.

Chapter 6: Agriculture and Economics - Concerns

This chapter briefly discusses some of the concerns which have been expressed regarding potential adverse effects of GMOs on agriculture and economics. Of particular concern is the potential for GM crops to contaminate non-GM crops.

The main potential sources of GM contamination of non-GM crops at farm level are:

- seed impurities;
- spread of pollen or seed by wind, insects and machines;
- persistence of GM plants over winter or from spread seeds;
- mixing of crops after harvest.

The Royal Commission concluded that all forms of agricultural production should continue to be viable in New Zealand (GM, conventional, organic, integrated pest management (IPM)). The Commission concluded that GM had a role to play in giving NZ a range of production systems. However, some question whether this wide range of production systems is possible if GMOs are used in agriculture. The potential for contamination of organic produce is the most obvious example of a detrimental effect on other agricultural sectors. The risks of contamination of conventionally grown non-GM crops by GMOs must also be considered.

6.1 North American experiences with GM crops

A recent report on experiences with GM crops in North America suggests the GMOs could adversely affect producer returns (Soil Association 2002). The report states that many conventional farmers in North America growing non-GM crops have had their crop inadvertently contaminated by GMOs. Consequently, they have been unable to achieve their previous price premiums for non-GM products on the European or Japanese markets. This report was funded by Greenpeace and some of its information is from anecdotal sources. It may therefore be viewed with scepticism in some quarters. However, the indications of commercial losses from introduction of GMOs, both for organic and conventional non-GM farmers, merit closer inspection.

The Soil Association report states that just two years after the introduction of GM rape, almost all of the European market for Canadian rape had been lost. The report implies that this loss of market share is connected to the introduction of GM technology into that industry.

Canada used to export large amounts of organic canola (rape). Organic industry sources state that this market has now been completely lost (BIO-GRO New Zealand, pers comm. 2002). Similar examples are cited for Canadian honey and

US maize (Soil Association 2002). In Saskatchewan, an organisation of Canadian organic farmers are taking a class action against the GM seed producers, Monsanto and Aventis, on behalf of all Canadian certified organic grain farmers, because of the economic losses resulting from GM contamination of their crops (Saskatchewan Organic Directorate 2002).

Literature research indicates that yields of GM crops in the US have been below expectations (Soil Association 2002). Many farmers have chosen to plant GM crops because of publicised increased yields (Duffy and Ernst 1999). However, studies and reviews by universities and the US Department of Agriculture have found that yield for GM crops are, for the most part, 5 to 10% lower than those for conventional crops (Soil Association 2002). For example, a study comparing GM with non-GM soybeans from sister cultivars found a 5% decrease in yield in Roundup™-resistant GM soybeans (Elmore et al. 2001). The exception is Bt maize, where increases in yield of approximately 2.5% have been found.

6.2 Compliance with Control Measures

A range of control measures for growing of GM crops have been proposed to prevent contamination of other crops, particularly by pollen movement. Such measures are currently being explored by MAF and MfE in order to set in place regimes for co-existence of GM- and non-GM agriculture, consistent with the recommendations of the Royal Commission. However, there are serious questions about how effective and workable such control measures are.

One question of particular concern is whether growers will comply with controls, or if there will be lapses (which could owe as much to oversight and human error as to negligence). Recent examples include field trials in Hawaii in which companies did not take the precautions specified by the EPA to prevent contamination. In particular, one company failed to plant a windbreak of trees and a buffer of hybrid corn to prevent pollen spread. Another planted GM crops too close to other crops (New Scientist 2002h). In another incident, in Scotland, seed was unintentionally mixed so that that the herbicide-resistant GM seeds approved for planting were mixed with GM seeds that contained genes for antibiotic resistance, which were not approved for planting. Such experiences suggest that stringent government regulations and guidelines may not be enough to ensure that transgenes do not spread in the field.

Buffer zones? How practical a choice are these?

The distance over which pollen can travel (see section 5.3.2), and the role of wind and insects in its spread, makes pollen movement difficult to control. While planted buffers may decrease the risk of contamination of nearby crops, it unlikely that they will completely eliminate it.

For example, a ‘buffer zone' of hemp plants was found to be ineffective in preventing pollen movement beyond the area of containment in a study of transgenic sugar beet (Saeglitz et all 2000). Transgenic plants were found up to 200m beyond the buffer zone, and non-GM plants up to 200m away were round to have transgenic offspring.

Federated Farmers spokespersons in New Zealand dispute the relevance of some studies of pollen-mediated GM contamination to New Zealand, as the studies have used crops which are not widely grown here (NZ Herald 23 September 2002). However, the biological principles should not be ignored.

In Australia, the NSW Agriculture Minister has stated that buffer zones are 'unrealistic' and have not been shown to work in practice (Brookers 25 June 2002).

6.3 Seed

The discovery in 2002 of the presence of GM contamination in maize seed that had been imported for planting in New Zealand the previous year raised alarm about seed purity and the ability to maintain GM-free status. However, it should be noted that the importation occurred before the introduction of seed testing requirements by MAF in 2002 (incidentally, before the contamination event was discovered).

An independent review of the management of this incident was released in late 2002. The review recommended consideration of possible changes or clarifications of the roles and responsibilities of ERMA and MAF, including possible legislative changes.

It is virtually impossible to guarantee that New Zealand can stay completely free of GMOs without closing the border to seed imports, according to Dr Tony Conner of Crop and Food Research (NZ Herald 10 August 2002). Dr Conner stated that GM was now so widespread that 'the concept of 100 percent GE-free' is 'almost certainly unachievable'.

However, opponents of GM say that since 99% of all GM production occurs in just 4 countries[14], it should be possible to obtain GE-free seed. Green Party co-leader Jeanette Fitzsimons suggests that New Zealand ban imports of seeds from North America and instead band together with other non-GM countries to trade seed.

6.4 Herbicide Use

Crops have been genetically modified to be resistant to Roundup™ (glyphosate) and Liberty™ (glufosinate ammonium). This allows the use of these herbicides on growing GM crops. The herbicide kills the weeds but not the crops.

It was originally predicted that use of herbicide-resistant crops would reduce the amount of herbicide used, because only a single application would be needed to control weeds. It was hoped that this would reduce weed control costs and pesticide application rates. According to some sources, the use of GM crops in the USA has resulted in reduced production costs for farmers and decreased pesticide application (New Scientist 2002i). US data show that the use of herbicide-resistant crops has lead to glyphosate being used instead of more toxic and persistent pesticides (Heimlich et al. 2000). For example, for soybeans it is estimated that 5.4 million pounds of glyphosate was used instead of 7.4 million pounds of other more toxic herbicides over 1996-1998.

However, there are conflicting reports on whether GM crops result in decreased application of pesticides. Some cite evidence that Roundup use has actually increased in the United States on Roundup-ready crops compared with conventional crops (Benbrook 2001). This is thought to be because farmers are able to apply the herbicide to herbicide-tolerant crops throughout the growing period. The most effective time for control is late in crop development, by which stage many weeds have already grown and thereby decreased crop yields. Farmers there are applying herbicides several times through the life of the crop in order to achieve weed control.

[14] USA, Canada, Argentina, China (see page 17).

Herbicide resistance has also begun to emerge in weeds, along with 'volunteer'/escapee GM herbicide resistant plants. As Roundup™ cannot be used to control these resistant escapees, other (more toxic) pesticides must be used instead. In addition, different weed species that are less susceptible to Roundup have begun to emerge. These weeds require different herbicides, which may be more toxic.

A review of the use of pesticides in GM crops states that the amount of herbicide applied to herbicide-tolerant crops (e.g. Roundup Ready strains) is slightly greater than that applied to conventional crops (Benbrook 2001). It also found that herbicide use on Roundup-Ready™ soybeans is gradually increasing as a result of changes in weed species composition, late season weed escapes, and resistance to Roundup in some weeds (Benbrook 2001).

There are also concerns that the development of herbicide-resistant crops perpetuates dependence on chemicals rather than on more sustainable agriculture, including integrated pest management (IPM). As the Soil Association report states:

> ***'While [herbicide tolerant] crops are . . . a very easy and attractive option for farmers, they set agriculture back on a more chemical dependent path.'***

Notably, the Royal Commission considered that GM crops containing herbicide resistance genes should not be approved for release until there is clear evidence that (i) there is no trend indicating either increased use or increased toxicity of herbicides, and (ii) there is no increase in weedy outcrossing involving herbicide resistance genes.

6.5 Pest Resistance

A recent review conducted by a New Zealand scientist found that the benefits of transgenic crops will vary depending on the type of crops, insect pests, environmental conditions and alternative pest management tools GM technology is compared against (especially IPM; Teulon and Losey 2002).

> ***"Insecticide use on Bt-cotton still remains high in some areas, sometimes as high as on conventional cotton, due to the requirement to control other insects not affected by the Bt toxin . . . Where there is a complex of pests, transgenic crops do not eliminate the need for farmers to remain vigilant in monitoring insect pests and in some cases may not affect insecticide use patterns" (Teulon and Losey 2002).***

Teulon and Losey also note that the benefits of GM plants may not be as great when compared with other management systems (e.g. IPM). IPM systems have been shown to dramatically reduce pesticide use (e.g. by 90% in apples, 63% in kiwifruit). Comparing the amount of pesticides used in GM crops with pesticide usage in conventional agriculture may give an incomplete picture.

> ***"The costs and benefits of IPM and transgenic crops should be critically appraised, especially in New Zealand where there has been a strong history of successful implementation of IPM programmes" (Teulon and Losey 2002).***

Teulon and Losey also note the potential for Bt-transgenic plants to lead to insect resistance to Bt and thereby lose Bt as an insecticidal tool. This could have adverse consequences for organic farmers, as Bt (applied as a biopesticide compound, not expressed by the plant) is one of the few approved pesticides which can be used by organic farmers. Transgenic Bt plants have a greater risk of inducing Bt resistance because:

- one toxin only is expressed (rather than a mixture as in Bt biopesticide);
- the toxin is expressed in all parts of the plant and throughout the growing cycle, resulting in constant exposure (rather than occasional application of Bt as needed);
- Bt genes have been substantially modified for expression in plants, so the concentrations in plants are often much higher than in the Bt biopesticide.

The potential to disrupt or lose the beneficial predators and parasitoids which are crucial to IPM is possibly an even greater risk with insect resistant GM plants.

> ***"In contrast to some expectations, it is likely that systems based on Bt-plants will require more, not less, management input than conventional crops" (Teulon and Losey 2000).***

6.6 Potential Effects on Organic Farming

Organic farming is based on working with natural biological systems using ecologically based practices (e.g. biological pest management). It involves growing crops and livestock without the use of synthetic chemicals. Organic farming standards do not allow the use of GMOs, or contamination with GMOs.

Worldwide, there is a large and growing market for organic produce. The world market for organic produce was estimated to be worth nearly NZ$45 billion in 2000 (Soil Association 2002). The US organic market is growing at over 20% per year.

Organic farmers have serious concerns about the potential impacts of GM crops on organic farms. New Zealand's annual exports of organic produce are worth $100 million from BIO-GRO certified farmers alone (BIO-GRO, pers comm. 2002). The majority of New Zealand's organic produce is exported, most to the United States, European Union and Japan.

None of the three organic certification schemes in New Zealand permits any GM contamination of crops.

Currently there is no requirement for New Zealand growers to test their produce for GM contamination, as until recently there were not thought to be any GM crops grown in New Zealand which could have contaminated the organic crops. However, the recent discoveries of GM-contaminated seed and crops in New Zealand mean that certifiers are now reviewing the requirements for GM testing.

A report prepared for the Ministry for the Environment by Crop and Food Research on co-existence of GM and non-GM crops states that 'contamination from either pollen or seed from GM sources cannot be entirely eliminated' (Christey and Woodfield 2001). The entire report appears to admit that a level of GM contamination of non-GM crops is inevitable if release of GM crops is to occur. It implies that organic farmers should therefore modify their standards to allow a certain low level of GM contamination.

A European Commission study found that coexistence of organic and GM crops in a region would be 'virtually impossible', even with significant changes to current farming practice (for a 0.1% threshold of contamination; Bock et al 2002). For a 0.3% threshold of seed contamination and 1% threshold[15] for GM contamination of food-feed, co-existence of GM and non-GM crops might '*technically be possible but economically difficult because of the costs and complexities of changes associated'* (Bock et al. 2002). Interestingly, the study also found there to be little difference in the degree of GM contamination of non-GM crops between higher (50%) and lower (10%) proportions of GM crop share.

During the Royal Commission, it was suggested by some submitters that organic farmers should modify their stance and permit some GM contamination (e.g. up to 1%). MAF stated that 'if organics standards allow the possibility of accidental contamination, then coexistence is possible. If standards demand zero tolerance for accidental contamination, then coexistence is not possible'.

Organic farmers reject the suggestion that they should accept a degree of GM contamination of their produce (BIO-GRO, pers comm. 2002). It is understood that they wish to retain their GM-free stance and associated market advantage.

General concerns about multinationals in agriculture

A number of concerns about GMOs in agriculture relate to the potential for control of food resources (e.g. seed) by multinational corporations. It should be remembered that concerns about multinational control of agricultural production are not new, and are not restricted to GMOs; similar issues are associated with pesticide use and other agricultural chemicals.

However, it should also be noted that GM crops with the potential to improve yields, enhance nutritional status or thrive in suboptimal environmental conditions – all of which could be of great benefit to developing countries – are unlikely to be affordable for poor farmers in developing countries, who are in greatest need of such improvements.

6.7 Potential Economic Effects

An economic analysis by Lincoln University Commerce Division found that "*the preferred option for NZ would be to delay the commercial release of GM food until the extent of the negative consumer attitude can be seen and the producer benefits become more apparent. This would enable NZ to position itself as being GM-free and obtain current price premiums and preferential market prices"* (Saunders and Cagatay 2001.)[16]

> ***"Evidence of producer benefits from growing GM products is mixed, with some reports of increases in producer returns. However, there has been a definite shift in consumer preferences away from GM food. This is seen both in the development of price premiums for GM-free food; trade diversion away from GM sources to GM-free sources, particularly in the Japanese market; and the positioning of key retail outlets in Europe as GM-free" (Saunders and Cagatay 2001).***

Internationally, there is strong demand for non-GM produce, both organic and commercially produced. This is particularly so in Europe and Japan. All of

[15] These are the thresholds for labelling food in the EU as containing GM.

[16] It should be noted that this assessment applied to currently commercially available first generation GM crops. Second-generation GM crops are not yet commercially available and their economic effects could therefore not be predicted. However, these products are expected to have greater consumer benefits (e.g. 'nutriceuticals').

England's major supermarket chains use GM-free food for their own products, and are even moving to codes of practice to exclude purchasing any animals or animal products that have been fed with GM feed (Soil Association 2002).

Price premiums for GM-free produce are appearing in markets such as Japan, Korea and Europe (Saunders and Cagatay 2001). Saunders and Cagatay concluded:

> ***"Current evidence of the impact of available technology on producer costs is mixed with reduction in some cases and the potential for more flexibility in production. However, there seems to be [a] definite shift away from GM-food by consumers. There is trade diversion away from countries which are producing GM-food to those which do not; such as a rise in GM-free imports into Japan from the EU and Australia and a fall of imports from the US. In addition, many of the main markets for NZ products are stating that GM-food or even animal products produced using GM-feed are not acceptable.***
>
> ***"NZ has a unique position in being an island nation which does not have the potential for cross pollination from GM crops and therefore can maintain a GM-free status; unlike many other continental countries. Even countries like the UK have problems with the cross pollination of canola and other crops. NZ thus is uniquely placed to take advantage of any consumer preference shifting toward GM-free food."***

Chapter 7: Cultural and Ethical Issues

7.1 Concerns for Tangata Whenua

Many Maori have expressed concerns about the potential adverse impacts of genetic modification on Maori culture and life. Key areas of concern include effects on traditions such as whakapapa, mauri and rangatiratanga.

Spiritual and physical dimensions are interlinked in the Maori world view. This can be a key aspect underlying some concerns of Maori regarding genetic modification (ERMA New Zealand 2002).

It must be noted that this is an area in which understanding both of tikanga Maori and genetic modification is needed to fully comprehend the implications for Maori. For this reason, Maori policy staff within Environment Bay of Plenty strongly recommend that Council seek advice on this issue from an appropriately qualified Maori representative. It is recommended that arrangements be made for such a presentation to Council in early 2003.

The following is a brief summary of matters which are likely to be of potential significance to Maori with regard to GMO applications, as outlined in a recent ERMA discussion paper (ERMA New Zealand 2002).

Potential issues of significance for tangata whenua

A Treaty outcomes

- the relevance to unresolved Treaty claims to the Waitangi Tribunal
- the continued ability of Maori to exert their developmental right as implied by the Treaty, where these are recognised by the Waitangi Tribunal.

B Environmental outcomes

- the continued and improved availability, quantity and quality of traditional food resources (mahinga kai)
- the continued availability, quantity and quality of traditional Maori natural resources
- the retention of New Zealand's diverse range of indigenous flora and fauna
- the protection of indigenous flora and fauna valued by Maori
- the purity of water (inland, coastal and offshore) and the need to retain and extend its productive and life-sustaining capacity
- the purity of land and the need to retain and extend its productive and life-sustaining capacity
- the purity of air and the need to retain and extend its productive and life-sustaining capacity
- the purity of human health and wellbeing
- the restoration and retention of natural habitats.

C Cultural outcomes

- the recognition and protection of Maori cultural, spiritual, ethical, or socio-economic values
- the protection of the mauri of peoples
- the preservation and maintenance of traditional Maori knowledge by Maori
- the maintenance, expression and control by Maori of their traditional practices e.g. kaitiakitanga, tapu, and rahui
- the protection of the mauri (spiritual integrity or life force) of valued flora and fauna
- the protection of the mauri of land
- the protection of the mauri of waterways (inland, coastal and offshore)
- the protection of the mauri of air and other taonga.

D Health and wellbeing

- the protection of taha wairua: spirituality, balance with nature, protection of mauri
- the protection of taha whanaunga: responsibility to the collective, the capacity to belong, to care and to share
- the protection of taha hinengaro: mental health and well-being, the capacity to communicate, to think and to feel
- the protection of taha tinana: physical growth and development.

ERMA has grappled with the question of how to treat spiritual issues when assessing the effects of a GMO application. A High Court decision found that spiritual effects can be considered when making a decision on a GMO application (ERMA New Zealand 2002). However, the question of how much weight to attach to spiritual issues in the decision-making process remains.

Currently, ERMA is undertaking a project to develop a robust and effective process for taking Maori concerns into account in decision-making under HSNO.

In addition, the University of Auckland (with funding by FRST) is undertaking research work on incorporating tangata whenua perspectives into scientific decision-making, particularly regarding GMOs.

Other cultural groups

Section 5(b) of HSNO requires ERMA to recognise and provide for, *inter alia*, the ‘maintenance and enhancement of the capacity of people and communities to provide for their own economic, **social, and cultural wellbeing**’. In addition, the definition of ‘environment’ in the Act, like that in the RMA, includes people and communities, and social, economic, aesthetic and cultural conditions.

It should be noted that the requirement in section 5(b) of HSNO regarding social, economic and cultural dimensions applies to all cultural groups in New Zealand, not only Maori. This must be considered by ERMA with regard to all applications.

7.2 Tangata Whenua Involvement and ERMA

Under HSNO, ERMA is required to explicitly take into account ‘*the relationship of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga*’ (section 6(d)). ERMA is also required to take into account the principles of the Treaty of Waitangi (section 8).

7.2.1 Nga Kaihautu

ERMA has established a Maori advisory committee, Nga Kaihautu Tikanga Taiao (Nga Kaihautu), to advise on Maori issues relevant to ERMA's decision-making.

ERMA keeps Nga Kaihautu informed about applications, and has a strong relationship with Nga Kaihautu, including involvement in making policy decisions. Nga Kaihautu is able to give independent public advice to ERMA. Importantly, both ERMA and Nga Kaihautu have been involved in building relationships with science institutions at hapu and iwi level to enable discussions at the pre-application stage (ERMA New Zealand 2002).

Nga Kaihautu is establishing a more formal network of contacts between Maori across New Zealand, and making arrangements to involve those people in the work of ERMA. The focus will be on resource managers within hapu and iwi, and Maori representatives on IBSCs. The intention of developing this contact network is to provide a means for routine consultation with Maori, provide avenues for Maori to put forward issues for consideration by ERMA, and to provide a larger range of experts for input on HSNO issues.

7.3 Ethical Considerations

Although ethical matters are not explicitly identified in HSNO as matters to be considered, ERMA considers there is a presumption in the Act that they should be considered.

The Royal Commission noted that sections 5,6 and 8 of HSNO imply 'certain values that enable ethical decision-making'. ERMA is required under HSNO to reach an independent view of the cultural and ethical dimensions of any proposal it considers (ERMA New Zealand 2000).

Toi te Taiao

Toi te Taiao, the Bioethics Council whose establishment was recommended by the Royal Commission, was established in December 2002. Chaired by Sir Paul Reeves, the council's role is to enhance understanding of the cultural, ethical and spiritual dimensions of biotechnology. The Bioethics Council is a Ministerial Advisory Committee. It will provide independent advice to Government on biotechnology issues with significant cultural, ethical and spiritual implications, promote public debate and provide information on these issues.

Chapter 8: Liability

One of the issues raised in the Royal Commission report was that of liability for damage caused by genetic modification. The Royal Commission considered that it was not necessary to establish special legislation to address liability issues related to GMOs and that existing legal provisions were sufficient.

Government subsequently referred the issue to the Law Commission. The Law Commission produced a paper assessing the adequacy of existing liability laws to deal with the issue of loss associated with GMOs (Law Commission 2002).

The three main types of damage that might be caused by a GMO can be classified as:

(i) personal injury (e.g. an allergic reaction);

(ii) property and environmental damage (e.g. establishment of an invasive plant species);

(iii) financial or economic loss (e.g. loss of organic certification) (Ministry for the Environment 2002).

Particular features of GMOs make development of a liability regime difficult. The Law Commission identified these as including the following:

- it is difficult to determine the level of risk posed by GMOs;
- it is difficult to determine the amount of damage that could be caused;
- GMOs have the potential to create catastrophic levels of harm and to cause irreversible damage;
- The potential adverse effects may not be evident in the short term;
- It may be difficult and expensive for plaintiffs to establish that GMOs have caused the damage, and to prove the extent of damage;
- GMOs are a source of spiritual and ethical concern for some members of the community (Law Commission 2002).

The Law Commission concluded: *"our inquiry suggests that current statute and common law will not ensure that all damage that could potentially be caused by GMOs will be compensated".* However, the Commission also noted that *"it is unlikely that any liability regime could guarantee this".*

> "'***Genetically modified organisms pose the two possibilities of a low probability but catastrophically damaging event, and of damage that is very slow in appearing. None of the existing mechanisms are able to guarantee compensation for either circumstance because nothing is likely to be able to compensate catastrophic or irreversible damage, and few remedies will be available for liability claims which may take decades to surface. In either of those situations, the options are that the losses lie where they fall, or that government steps in."*** **(Law Commission 2002).**

The Commission suggested that three core policy decisions are needed to determine whether a separate liability regime needs to be developed for GMOs. These are:

(i) How different are GMOs from other human activities and technologies?

(ii) To what extent should those directly involved in GM be held accountable for anything that goes wrong? The Commission was concerned about the potential damage that a stringent liability regime could do in terms of discouraging researchers and industry.

(iii) What should be the role of Government? Is Government a potential guarantor for any damage caused by GM? Should the Government, on behalf of the public at large, provide compensation for those who suffer damage but cannot receive compensation through any liability regime?

The Commission stated that *"the Government will have to decide how responsibility for any risks of new technology is to be apportioned among the industry, individuals and the state".* This, they concluded, was a policy decision, which it is not the Law Commission's role to make. The Law Commission did not resolve the question of who should be responsible for any adverse consequences of GM, but recommended that this be "*widely debated and clearly agreed upon".*

In summary, the question of liability for damages resulting from GMOs is not yet fully resolved. The recent MfE discussion paper on amendments to HSNO for new organisms including questions on liability. It is possible that the outcomes of consultation on that paper will provide some further guidance.

Chapter 9: Role of Local Government

9.1 Involvement of other Regional Councils

As part of the research for this report, letters were sent to all regional councils in New Zealand, advising of the preparation of this report and enquiring whether they were undertaking any work in this area.

The majority of councils replied that they were not doing any work on the issue of GMOs, as they considered it to be a central government responsibility. The exceptions were Nelson City Council and Marlborough District Council, both unitary authorities. It is possible that they have undertaken more work in this area because of their shared territorial authority and regional council functions, and also because of active community interest in the issue in their areas. More detail on the work done by these councils is given below.

Hawkes Bay Regional Council has briefly debated the issue on several occasions, in response to submissions made by members of the public. The Council has decided that the matter is essentially one to be determined from a central government perspective. However, they intend to host a public information forum to raise community awareness of both risks and benefits associated with GMOs in the environment.

Northland Regional Council co-hosted a public forum on the issue of GMOs, together with the three district councils in the region. However, at a political level, Northland Regional Council has decided that the issue is one for determination by central government.

Environment Waikato has not undertaken any policy work on the issue, nor developed a council position. A deputation and petition on GMOs was received by Council but no recommendations were made to take the issue further. Environment Waikato noted that *"we do have policy covering contaminants and biosecurity matters and this may be relevant in the future, however these policies are not specific to genetically modified organisms".* They also expressed interest in being kept informed of Environment Bay of Plenty's progress with this report.

Wellington Regional Council, Taranaki Regional Council, Environment Southland, Environment Canterbury, Auckland Regional Council and Gisborne District Council all advised that they are not doing any work in this area. Most advised that this was because they considered GMOs to be a matter for central government policy determination. Some expressed interest in being kept up to date with Environment Bay of Plenty's progress on the matter.

All territorial authorities in the Bay of Plenty region were also contacted. None are currently undertaking any work on the issue of GMOs.

9.2 GMOs and the RMA

It is highly unlikely that regional councils can make rules in plans preventing the planting of GM crops or raising of GM stock. To make such a rule would require a council to be able to make a rule controlling the use of land. Under s30(1)(c) of the RMA, regional councils can only make rules controlling land use for the purpose of soil conservation, water quality and quantity, natural hazards and hazardous substances. It is unlikely that GMOs would be considered hazardous substances under the RMA. Although hazardous substances are not currently defined in the RMA, the fact that they are differentiated from new organisms under HSNO strongly suggests that GMOs would not be considered a hazardous substance under the RMA. (There is a possibility that a toxin produced by a GMO might be considered a hazardous substance, but this is purely conjecture at this point.)

It may be possible for a regional council to make a rule regulating the discharge of a GMO, or element of a GMO (e.g. pollen), as a contaminant. To do so would require determining that the GMO or its product was (i) a contaminant and (ii) that its release qualified as a discharge under the RMA definition. This would theoretically not prevent the planting of a crop (unless it could be shown that it was not possible to prevent pollen discharge), but could require (i) controls on release of heritable material; or (ii) prohibiting growth of crops from which discharge could not be prevented.

A letter from MfE to the Chairman of Northland District Council in November 2000 stated:

> ***"There is no exclusion [from the RMA] for genetically modified plants or animals. Regional councils' functions include the control of discharges. The scope of a council's functions could therefore include addressing the environmental risk arising from the development of genetically modified organisms in its region."***

However, the letter went on, the regional council would need to undertake a section 32 analysis showing why such a rule is necessary. Under section 32, the regional council must have regard to:

- Why such a rule is necessary; and
- Consideration of other methods for achieving the same purpose; and
- Reasons for and against having such a rule.

This could be problematic given the framework for assessing risks of GMOs that already exists under HSNO. A recent letter from Marion Hobbs to Councillor Summerhays of Environment Bay of Plenty states that if councils want to deal with GM organisms through their plans,

> ***"They would need to show why the rule was necessary. A council would have to show how an application had any environmental risks outstanding which needed to be addressed under the RMA, which had not already been dealt with through the ERMA assessment process." (Marion Hobbs, 22 July 2002)***

MfE in its letter to Northland Regional council states:

> ***"The interface between the HSNO Act and the RMA, in terms of new organisms, is not dealt with explicitly in the legislation. However, in formulating rules to deal with the adverse effects generated by genetically modified organisms, a council is required by section 32 to consider whether the rule is necessary. A council would have to demonstrate how an application had any environmental risks outstanding which needed to be addressed under the RMA. Given the rigour of the HSNO process, there is a broad consensus that the management of genetically modified organisms is currently appropriately addressed under the HSNO Act."***

A report prepared for Marlborough District Council by Environmental Management Services Ltd suggests that it would not be possible for a regional council to make a rule regarding environmental effects of a GMO as this falls within the ambit of issues assessed by ERMA when approving the GMO under HSNO. It is a legal principle that a specific piece of legislation (in this case, HSNO) overrides the general (the RMA).

The Environmental Management Services report argues that a council could use the RMA to control GMOs in order to achieve the purpose of the Act, provided that controls exercised would be for a different purpose than those under HSNO.

The Environmental Management Services report states that under the RMA, a council is able to "consider the way in which the use of GMOs will affect the social, economic and cultural wellbeing" of people and communities.

> ***"However in so doing it should not reevaluate the effects of GMOs on the health and safety of those people and communities. Nor should it reevaluate the effects of GMOs on the 'life supporting capacity of air, water, soil and ecosystems' unless it can demonstrate that it has before it some material considerations beyond those contemplated when approvals for GMO release were presumably provided by ERMA under HSNO."***

There is some doubt about whether this is a legitimate interpretation. Both HSNO and the RMA use the same definitions of 'environment', which include people and communities. HSNO also incorporates provision for economic, social and cultural wellbeing as a principle to be recognised and provided for in achieving the purpose of the Act. It is therefore difficult to see how additional matters could be considered under the RMA when they had already been considered by ERMA under HSNO.

Role of HSNO vs RMA

The purpose of HSNO is to protect the environment from hazardous substances and new organisms. A risk to the environment associated with a new organism other than from heritable material (e.g. contamination of water by effluent from GM livestock) is dealt with under the RMA.

In their report on liability associated with GMOs, the Law Commission stated 'it is possible that environmental damage caused by GMOs could be dealt with under the RMA', noting in particular the duties under section 17 to avoid remedy or mitigate any adverse effects on the environment (Law Commission 2002). They noted that 'these powers are broad and their potential applicability for GMO damage has not been tested'. Perhaps the Law Commission, or a similar authoritative source, could be asked to advise on whether local government can control the use of GMOs under the RMA?

MfE suggested that Environment Bay of Plenty consider how the RMA deals with non-GM animals in determining how the RMA might treat GMOs. However, this is not considered to be a particularly helpful suggestion given some of the unique properties of GMOs and the potential risks they pose.

9.3 District Councils

District councils are able to write rules to control the use of land for a wider range of purposes than are regional councils. If a council wished to ban the growing of GM crops or animals in its district, it could possibly write rules prohibiting the growing of GM crops. (However, it must be noted that this is a theoretical possibility that has not been tested in law.)

Any such option would need to go through the plan change or variation process, and thereby be publicly debated.

Nelson City Council

Nelson City Council, another unitary authority, has declared its city GE-free. At this stage it has decided not to change its Regional Policy Statement or Plan to enact the GE-free status, but to continue to lobby central government on the issue. The Council has been reluctant to use the RMA due to (i) legal uncertainties and (ii) the financial and staff resources that would be required for any policy or plan changes.

A report to the Council raises some excellent points regarding policy options. In addition to questions of legality and cost, the report raised the issue of the extensive consultation that would be required as part of the change to the RPS or district plan. Important points include:

- The council would need to be prepared to defend its position before the Environment Court if necessary;

- *"Because, as far as it is known, Nelson City would be the first council in New Zealand to attempt to address genetic modification issues through planning controls it is almost certain that any proposal would be highly controversial. Vigorous opposition from major corporate interests could be expected. Large numbers of public submissions are also likely. The costs of administration, receiving, reporting on, considering and determining controversial hearings is always expensive and time consuming."* The report also pointed out that this would divert resources from other statutory planning processes of the council (i.e. advancing/finalising other plans/parts of plans).

It is also worth considering the following point raised in the Council's report:

> ***"To prepare a legally defensible, justifiable plan variation will take at least 3 months, and a further 6 months to go through the statutory two stage notification and hearing process. It could well be a further 12 to 18 months before any Environment Court action was finalised. It is highly likely that points of law could arise requiring a High Court decision. The entire process could well take in excess of three years. At the end the best that could be achieved are some controls which would apply only within Nelson City. How they would be administered or enforced is problematic. In a national context a local control in Nelson City would be inconsequential."***

Concerns raised by Nelson City Council in submission to Government

Nelson City Council has also been proactive in presenting their GE-free position to Government. The Council made a submission to the Minister for the Environment on the recommendations of the Royal Commission on Genetic Modification. In the submission, the Council expressed a number of concerns. These included concerns about potential future costs to local government, and the need for a precautionary approach. Nelson City Council expressed the view that the Royal Commission's recommendation to 'preserve opportunities' will place pressure on local government from communities to use RMA processes to provide and enforce separation buffers via RMA processes.

> ***"Indeed because it is unclear how the Royal Commission's recommended MAF separation strategy and Industry Code of Practice will work in practice, nor what level of public input there will be into their development and implementation, it is almost inevitable that interested members of the public will look to the established and proven RMA processes to provide a means of addressing the issue."***

Marlborough District Council

Marlborough District Council commissioned a report on options for control of GMOs under the RMA. This has been presented to their Council and will now be distributed to industry and community groups for consultation, to determine whether it would be desirable and practical to develop RMA policy.

Marlborough District Councillors have also met with politicians from other councils in the South Island to discuss the next steps.

9.4 GE-free zones

9.4.1 GE-Free NZ

A number of organisations have formed the Coalition for a GE-Free Environment Aotearoa New Zealand. They are promoting adoption of GE-free zones around New Zealand, from household to district council level. Member organisations include the Green Party, GE-Free NZ, Greenpeace New Zealand, Soil and Health Association, the Safe Food Campaign, Jews for GE-Free Food, Bio-Gro, the Biodynamic Farming and Gardening Association in New Zealand, and Environment and Conservation Organisations (ECO). The coalition, and other groups, encourage local communities to form groups with an interest in the issue and approach their local council to encourage the declaration of GE-Free zones.

Some district councils in New Zealand have declared themselves GE-free. This is a symbolic step only with no legal backing and thus is not enforceable.

Councils that have declared themselves to be GE-free in New Zealand include Nelson, Napier and Waitakere City.

9.4.2 Waitakere City Council

Waitakere City Council declared their city GE-free in field and food in late 2001. Some investigations into how to achieve this status in practical terms were subsequently undertaken, and options presented to Council. However, the Council has resolved not to take this work any further at present. It seemed there were questions about the legal basis for regulations in the district plan regarding GM, and the Council has decided to stay out of the process for the time being.

After the GE-free resolution was passed, Council held a conference with relevant city businesses, including food manufacturers. Food manufacturers were extremely positive about the GE-free resolution and anecdotally, Council thinks that it has encouraged more food manufacturers to move into the city. Council is encouraging food suppliers not to sell food containing GM ingredients. An organics forum was held, and an ‘organics cluster’ has been set up in the city. The Council’s role has primarily been one of facilitating communication and strengthening networks.

9.5 Unresolved Questions

There are a number of unresolved questions about the role of local government (if any) with regard to GMOs. These questions were posed to MfE during the preparation of this report, but MfE declined to answer them. The MfE staff member contacted stated that it is not MfE’s role to provide legal advice, and suggested that Environment Bay of Plenty obtain its own legal opinion. It appears curious that the central government agency with a primary responsibility for the policy and legislative framework for GMOs cannot provide certainty on these questions. This is of particular concern given the current drafting of the HSNO Amendment Bill which may include a conditional release category for GMOs, and could also include regional councils as an enforcement agency for GMOs.

Questions to be resolved include:

- Can a regional council make a rule requiring consents to be granted for discharge of GM contaminants to air/land/water?
- Could a GMO, or heritable material from a GMO, be considered a ‘hazardous substance’ under the RMA? (and therefore be regulated under section 30).
- Could a GMO (or associated heritable material, including pollen) meet the definition of a ‘contaminant’ in the RMA?
- If so, could a regional council regulate the discharge of a GMO (or heritable material from a GMO) as a contaminant under section 15?
- Would a site that has been used for growing GM crops, and which retains heritable material from GMOs, be considered contaminated? If so, who is liable to remediate it? Should the regional council take regulatory action, and/or record it on databases?
- Can a district council include methods in its plan (e.g. zoning) or write land use rules regarding the raising of GMOs?

Options for progressing with these questions are presented in chapter 10.

Chapter 10: Policy Options for Environment Bay of Plenty

In making any decision, Council may wish to consider both the potential adverse effects of GMOs and the potential for adverse effects on some sectors of the New Zealand economy if use of GMOs was further restricted. In particular, the effects on research and development, forestry and medicine should be considered.

Council should also recognise that the effects (both actual and potential) of GMOs are not the same across the board but will vary depending on the type of GMO and where it is used.

It should also note that extensive public consultation and assessment of the risks and benefits of GMOs has occurred at national level through the Royal Commission on Genetic Modification.

Finally, Council should have regard to the rigorous assessment processes by which ERMA assesses potential risks of GMOs under the HSNO Act.

10.1 Options for consideration

If Council wishes to take action, it should be done as soon as possible. This is necessary if it is desired to have input into the Government policy process, which is already well advanced. A draft HSNO amendment bill will be circulating for comment early in 2003 (probably March or April). At present the Government has not signalled any intention of extending the moratorium beyond October 2003. It is debatable whether the Government will extend the moratorium, despite pressure from some quarters.

Some of the options below may be hypothetical, as the role of the RMA in regulation of GMOs has not been tested. Despite extensive inquiries to obtain reliable information on the place of the RMA, answers are not conclusive. Uncertainties regarding the interface between HSNO and the RMA make it difficult to provide guidance on the achievability of potential options. As noted in chapter 9, a request to MfE for clarification of legal points regarding the RMA, HSNO and GMOs was declined.

The following possible actions have been identified.

1. Leave the issue to Central Government

Decide that the issue of GMO regulation is one for central government determination and that Environment Bay of Plenty should not be involved. Rely on existing ERMA processes and HSNO. Step back from the issue.

2. Observer status

As above, but continue to have input on relevant government discussion papers, bills and consultation processes where relevant.

3. Adopt a Council policy position for current and future advocacy

For example, Council could determine that GMOs are acceptable for animal pest control, medicine, or other defined applications, but not for crops, until results of impacts research are available.

Council could then advocate to central government for changes to current government policy where inconsistent with Council's position.

4. Lobby Government for a determination on the role of the RMA with respect to GMOs

Invite other interested local authorities and Local Government New Zealand to join in requesting a legal opinion, or a decision from the Ministry for the Environment, on the regulation of GMOs under the RMA, in line with questions identified in this report. The interface between the RMA and HSNO for GMOs, and the role of local government with regard to GMOs, also need to be discussed. Emphasise to Government that this is an issue of national importance and needs to be resolved at central government level, not by individual councils.

This request could be generated by this Council independently, but is likely to have more weight if combined with other councils and/or Local Government New Zealand.

5. Urge Local Government New Zealand to seek resolution of questions regarding local government and GMOs

Urge Local Government New Zealand to coordinate a generic regional council/local government dialogue with Government. This is recommended so that questions regarding the role of the RMA, local government and GMOs can be resolved at a national level, rather than individual councils having to confront the issue across the country.

6. Consider submitting on the HSNO Amendment Bill for New Organisms

Carefully consider the outcomes of consultation on the HSNO Amendment discussion paper, and the draft HSNO Amendment (New Organisms) Bill due for circulation in the first quarter of 2003. In particular, consider the implications for regional councils. Request that Local Government New Zealand also scrutinise the draft bill in order to determine any potential implications for local government, particularly regional councils.

7. Address issue through regulation (e.g. regional plan change)

This must be considered a theoretical option only as its legal basis is uncertain at this time. It is also questionable whether this would be more effective than seeking solutions at a national level through routes identified above. As noted in chapter 9, any proposed RPS or plan change would be highly controversial and attract a range of submissions from different interest groups and industries. It would be a lengthy and expensive process, with an uncertain outcome. It would be likely to reach the Environment Court, given the range of interests involved and the uncertainty of the legal position. If a rule controlling the discharge of GMOs was determined to be vires and did enter a regional plan, it would still require costly compliance monitoring and a range of biotechnology skills not currently available within this Council. Even then, the environmental benefits of such a rule are uncertain.

Staff are reluctant to advocate this option as they are unsure of whether it is legally achievable, necessary or desirable. The option is presented merely for the sake of completeness.

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