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Research Paper
No. 17 2000–01

Genetically Modified Governance Issues

ISSN 1328-7478

Published by the Department of the Parliamentary Library, 2001

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Genetically Modified Governance Issues

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6 February 2001

Acknowledgments

Advice from Angus Martyn and Katrine Del Villar of the Law & Bills Digest Group.

Support and advice from Rod Panter, Bill McCormick and Matthew James of the Science, Resources, Environment and Resources Group.

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Contents

Glossary

Artificially Selected

Conventional plant breeding techniques such as cross fertilisation, progeny selection and backcrossing

Biotechnology

Using biological systems for industrial purposes

Chimera (adj. Chimeric)

An organism composed of two or more genetically distinct tissues

Clone

An organism developed from a single ancestor

Genetic Engineering

Manipulation of genetic material to achieve changed functions in living organisms; e.g. increased production of a metabolite

Genetically Modified/Genetically Modified Organism

An organism that has been changed by using genetic engineering techniques at the molecular level

Genetically Modified Food

A food which has been derived from an organism which has been modified by gene technology

Governance

The way authoritative control is exerted ie through power, regulation, management, direction, command, system of government etc.

Metabolite

An organic compound, e.g. a sugar, produced in metabolism

Policy Principles

Disallowable instruments for the purposes of section 46A of the *Acts Interpretation Act 1901* (Gene Technology Bill proposed section 21(4))

Precautionary Principle

Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environment degradation (Principle 15, 1992 Rio Declaration).

Recombinant Organism

An organism formed by genetic engineering techniques where the artificial combination of DNA molecules of different origins takes place, and hence there has been manipulation of genes or genetic material

Somatic Cells

Any plant or animal cell other than sex cells or their precursors

Substantially Equivalent

When a genetically modified food is deemed to have the same safety status as its conventional food counterpart

Transgenic Organism

An organism that has been altered through the insertion of foreign genetic material

Further Information

Useful biotechnology dictionaries may be found at:
http://biotech.icmb.utexas.edu/search/dict-search.html or http://biotechterms.org/

Acronyms

ABA	Australian Biotechnology Association
ACA	Australian Consumers' Association
AFGC	Australian Food and Grocery Council
AMA	Australian Medical Association
ANZFA	Australia New Zealand Food Standards Authority
ANZFSC	Australia New Zealand Food Standards Council
AQIS	Australian Quarantine Inspection Service
ARMCANZ	Agriculture and Resource Management Council of Australia and New Zealand
Bt	*Bacillus thuringiensis*
COAG	Council of Australian Governments
CSIRO	Commonwealth Scientific and Industrial Research Organisation
EU	European Union
EC	European Commission
EPBC Act	Environment Protection and Biodiversity Conservation Act 1999
FSANZ	Food Standards Australia New Zealand
GE	Genetic Engineering, Genetically Engineered
GM	Genetically Modified
GMAC	Genetic Manipulation Advisory Committee
GMO	Genetically Modified Organism
GMP	Genetically Modified Plants
GRDC	Grains Research and Development Corporation
GT Act	Gene Technology Act 2000
GT Bill	Gene Technology Bill 2000
GTR	Gene Technology Regulator
GTTAC	Gene Technology Technical Advisory Committee
IOGTR	Interim Office of the Gene Technology Regulator
LMO	Living Modified Organism
NACMA	National Association for Marketing Agricultural Commodities
NFF	National Farmers' Federation
NHMRC	National Health and Medical Research Council

NRA	National Registration Authority for Agricultural and Veterinary Chemicals
OECD	Organisation for Economic Cooperation and Development
OGTR	Office of the Gene Technology Regulator
PHAA	Public Health Association of Australia
SCARM	Standing Committee on Agriculture and Resource Management
SIA	Seed Industry Association of Australia
TGA	Therapeutic Goods Administration
UCS	Union of Concerned Scientists
USDA	US Department of Agriculture
USEPA	US Environment Protection Agency
USFDA	US Food and Drug Administration
WHO	World Health Organisation
WTO	World Trade Organisation

Major Issues

The creation of genetically modified organisms (GMOs), especially those used for the production of foods, has stirred up considerable controversy about who is minding the food store. Those involved in developing the technology or commercialising it for food or therapeutic uses are caught in a bind trying to assess, in the context of local and international trade perspectives, how their particular industry should proceed. There has been increasing attention paid to regulatory solutions both within Australia and overseas. Some guidance can be obtained by observing the pathways that other governments have taken to work towards management frameworks for GMOs. The Interim Office of the Gene Technology Regulator (IOGTR) has listed existing regulatory systems of other countries and their findings, along with a summary of national regulations in their submission to the Gene Technology Bill *Inquiry*.[1]

Because the establishment of a legislatively based Australian regulatory framework for GMOs is in train, at Commonwealth and State levels, this paper aims to provide a summary of the major issues involved in the context of authoritative control or governance of the technology, genetic engineering (GE). The uptake of science based information, and the way it may be used in the governance process is of particular interest.

Different viewpoints of protagonists and antagonists in the GE debate may attract the attention of the media. However, the debate should now have moved on to the central issue, the way forward, namely: how can GMOs be appropriately regulated for in a manner in keeping with the democratic tenets of our society? The sting in the tail of economic rationalism and globalisation, although initially slowly understood, has now been acknowledged widely, the market does decide; consumer choice and the right to know are critical factors in the uptake of biotechnology. Governments have responded with upgraded or, in the case of Australia, new legislation.

Negative environmental and economic consequences due to introduced weeds and feral animals, e.g. prickly pear and rabbits, are common knowledge in Australia. In hindsight, attendant losses could have been prevented if there had been appropriate governmental oversight. Weeds alone are estimated to cost Australia $3.3 billion per annum in control costs, lost production and contamination[2]. Genetic engineering can be viewed simultaneously as a risk as well as a solution to such problems. A major difference between the recognition of the impacts of feral incursions in the first half of the twentieth century, and risks arising from genetic engineering technology, is that the general population is now better educated

and informed thanks to extensive public education systems and the Internet. Additionally, there are better vehicles for the public expression of viewpoints.

At this stage, there appears to be more evidence about environmental than health based risks. However, in both cases, concerned national and international bodies agree that both vigilance and further research are required. Governments have different ways of managing for risk, the EU favouring the Precautionary Principle while the United States is wary of trade implications if such an approach was adopted internationally. Australia has included the Precautionary Principle, Principle 15 of the *Rio Declaration*, in the *Gene Technology 2000 Act*.

The genetic engineering era has coincided with a trend to smaller government and increased encouragement for the private sector to fill the void through mechanisms such as contracting out or self regulation. There is a trend towards reduced employment of experts, namely, scientists and technical specialists in government agencies. This is happening when the products of sophisticated technologies require extensive scrutiny so as to prevent health and environmental mistakes. There has been a corresponding adoption of the concept 'acceptable risk' rather than 'zero risk' in public policy design, e.g. in quarantine policy[3]. Containment of escalating scrutinising costs has been a major driver of this policy direction. Lack of concrete data to assess risk in a scientifically adequate manner is a significant problem.

GM food was marketed prior to the comprehensive development of appropriate testing technologies and protocols. Resolution of toxicology issues has lagged behind the marketing of GM foods. Some objections to GM foods have arisen, not because of a Luddite reaction to the technology or a refusal to consider the benefits that biotechnology may offer, but because the cart was placed before the horse in terms of safety assessment. As exemplified by the recent UK inquiry into Aventis' GM fodder maize, Chardon LL, that the UK Government had proposed for addition to the UK's National List (of permitted seeds) in March 2000, the adequacy of data as presented by applicants has fuelled consumer unease. Lack of credible management frameworks and communications has contributed to consumer wariness.

Smaller government may place increasing pressures and responsibilities on local governments. Local level concerns about GM crops were expressed by local councils in a number of Australian states during 2000. The *Gene Technology Act 2000* provides for the recognition of designated areas under State laws for preserving the identity of GM crops or non-GM crops for marketing purposes, but this may not necessarily resolve local government level GMO related administrative and financial matters.

At a grass roots level, consumer groups are demanding a coherent and transparent framework to control burgeoning biotechnology industries. Those in therapeutic and food related industries realise that there are benefits to be derived from regulatory certainty. Nations growing and trading GM crops have perceived that there is a need to balance both consumer and industry demands.

1—Introduction

This paper updates a 1999 precis of genetic engineering (GE) issues, *Genetically Modified Foods—Are We Worried Yet?,*[4] as well as examining various themes and obstacles pertinent to the governance of this technology. Since 1999, the need for governance of genetic engineering technologies has become more pressing for trade, consumer, environmental, ethical and health reasons. This is exemplified by Australia's first attempt to establish a national legislative framework for genetically modified organisms (GMOs), the *Gene Technology Act 2000 (*GT Act*)*. The Gene Technology Bill[5] was introduced to the Australian Parliament on 22 June 2000 and was passed in December 2000, after some amendments arising from the Senate Inquiry into the GT Bill[6] were taken on board. Further amendments on human cloning and experiments involving combinations of human and animal cells (section 192) that do not pertain to genetic modification as defined by the GT Act (section 10.1) were also included. Addition of the human cloning amendments to the Act serves as a recent example, that not only illustrates one of the threads in this paper, namely, difficulties involved in the governance of science based issues, but also highlights differing views about which organisms are covered by the GT Act.

Genetic engineering raises questions about the governance of science based issues generally, and lessons learnt from the GE debate can be applied to other technology governance issues. Firstly, it is difficult for a science based issue to be publicly debated if concepts are not understood, whether the concept "science" itself, or more narrowly, what meaning is agreed to for terms such as "genetic engineering" or "genetically modified organisms".

Unfortunately, the word 'science' carries an unjustified mystique that can discourage vital debate about science based issues. This may perturb the way science based decisions are reached by governments. 'Science' is merely a shorthand way of describing knowledge that has been acquired by observation and deduction, and is collected incrementally. Science can be viewed as a type of history. Sometimes 'scientific facts' may have been arrived at from incomplete observations or from faulty deductions. 'Science' is not necessarily an exact discipline. The European Commission's (EC) communication on the Precautionary Principle states:

> Scientific uncertainty results usually from five characteristics of the scientific method: the variable chosen, the measurements made, the samples drawn, the models used and the causal relationship employed. Scientific uncertainty may also arise from a controversy on existing data or lack of some relevant data. Uncertainty may relate to

> qualitative or quantitative elements of the analysis. … more abstract approach … to separate all uncertainties into three categories—Bias, Randomness and True Variability.[7]

Risks arising from simple or complex technologies require management through regulation. When governments regulate for a science based issue, such as genetic engineering, apart from definitional uncertainties for terms such as 'genetically modified', they are grappling with an incomplete body of knowledge. For this reason, the degree of risk that society is prepared to manage must be gauged, in terms of whether low, medium or high chances for hazardous, dangerous or injurious outcomes are likely to arise. If risks are not enumerated, communicated and evaluated adequately, a major consequence may be limited legislative management with potential consequences not only to public health and the environment but also for national prosperity. After some debate, the issue of scientific uncertainty was addressed in Australia's *Gene Technology Act 2000* (section 4aa), using the precautionary approach of Principle 15 of the *Rio Declaration*[8]*:*

> Provides that where there are threats of serious or irreversible environmental damage a lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation….

Central to the GE debate is the need for legislative approaches for the creation of national GE regulatory frameworks. In keeping with democratic tenets, in progressing government regulation, both the Interim Office of the Gene Technology Regulator (IOGTR) and the Australia and New Zealand Food Authority (ANZFA) have undertaken considerable public consultation processes before final or draft documentation has been submitted for consideration by elected government representatives. Of course there are other considerations that may mould final outcomes, for example, the tussle between industry and consumer concerns.

Necessity for public engagement is acknowledged in Australia's *National Biotechnology Strategy*, released in July 2000,[9] with an introduction by the Commonwealth Biotechnology Ministerial Council and the advisory body from research and business sectors, the Biotechnology Consultative Group. Biotechnology Australia reports to the Biotechnology Ministerial Council and co-ordinates non-regulatory aspects of the government's activities such as public awareness and the *National Biotechnology Strategy*. Some may view the interface between science and government as being as problematic as insufficient public education about genetic engineering issues in the past, weakness in the interface contributing to a less than adequate public communications process. The Dutch science writer and philosopher Ad van Dommelen points out in *Hazard Identification of Agricultural Biotechnology* that:

> When politicians must base their decisions on contested science expertise, a society should at least strive to spell out the involved scientific controversies as clearly as possible. Failing to do so may lead to undemocratic situations in which political decisions are presented in an unjustified scientific guise.

Furthermore

> If politics and science cannot be separated in practical decisions like developing biosafety regulation for genetic engineering, then democratic politics requires us to at least distinguish their respective base of legitimation. … Differences between the two should be not amalgamated in policy procedures and should remain separately visible in the process of decision-making on the introduction of new technologies.[10]

The passage from community consultation to the development of regulatory mechanisms for managing GMOs has been characterised by controversy globally. Biotechnology lobbyists may be seen as pioneers of a new era where gene technologies can solve previously unsolvable problems, especially health and food security issues. Genetic engineering has been directed to managing weed and feral incursions that limit agricultural productivity. This paper examines some obstacles to this vision. For example, insufficient legislative instruments may hinder further take-up of GE crops. In Australia's case, the Senate Inquiry into the Gene Technology Bill, *A Cautionary Tale: Fish Don't Lay Tomatoes,*[11] including minority reports, provided recommendations to refine the Gene Technology 2000 Bill. Although grounds for further alterations and additions to the GT Bill were identified, most recommendations were not included in the GT Act. The GT Act represents a beginning and holds the promise of further developments in GE regulation in the future in response to international and national requirements.

While Australia has elected to take a legislative and regulatory pathway with the passage of the GT Act, Dr Richard Jefferson of the Centre for the Application of Molecular Biology to International Agriculture (CAMBIA) takes the view that over-regulation may hinder research and innovation. Also, it could increase the power of multi-national companies because they have the financial resources to pay for regulatory costs[12].

As Australia develops a regulatory framework, a number of unknowns need to be considered. Issues relating to the following questions are discussed in the paper, but it is for the reader to decide on their preferred answers.

Questions about the contested aspects of the technology include:

- What constitutes adequate environmental and health safeguards for this technology?
- What constitutes 'acceptable scientific certainty' and 'acceptable risk'?

Questions about matters that are currently unfolding include:

- What level of regulation will voters and industry tolerate?
- Will consumers refuse to buy GM foods, whether for ethical, political or science based reasons?
- How will the GMO issue impact on local and international trade?

- How successful will the administration of the domestic regulatory framework be? (ie. re crop trials and commercialisation of crops, medical uses, control of feral animal populations, GM food labelling)
- What are the limitations of the framework?
- How will Commonwealth, State and Territory and Local governments respond?
- Will the regulations be flexible enough to cater for new GMO information and developments, especially environmental and health effects?
- What communication strategies are and will be employed, who will undertake them and what are the likely respective biases?
- How will the trading blocs respond?
- How will international level trade in GMOs proceed?
- How will the World Trade Organisation/*Cartagena Protocol on Biosafety* interaction proceed and how will this affect Australia?
- The extent of the acceptance, rejection and influence of the Precautionary Principle by governments?

The recent EU-US Biotechnology Consultative Forum *Report,* commissioned by the Presidents Clinton and Prodi, succinctly identified contextual elements that must be considered when considering regulation of new technologies, the far reaching effects of new technologies, globalisation, the role of the citizen and safeguarding the future[13].

Please note that this paper was completed in mid January 2001. For subsequent developments, check pertinent web sites provided in the bibliography. Please note that some documentation may have been withdrawn from specified web sites.

2—What GE Products are Being Used in Australia?

Food

Many foods on sale in Australia contain genetically modified (GM) ingredients. However, until GM labelling regulations come into force on 7 December 2001 it will not be clear to the consumer if foods contain GM ingredients or not. The Australia New Zealand Food Standards Authority (ANZFA) envisages that a leaflet explaining GM labelling requirements will be made available at supermarket outlets in 2001.

The Table to Clause 2 of *Standard A18 - Food produced using Gene Technology* now lists 7 approved GM foods, various lines of canola, cotton and soybean[14]. When the Australia New Zealand Food Standards Council (ANZFSC) approves further GM foods they will also be listed. Two GM staples that were previously given interim approval in 1999 were approved for use by the ANZFSC on July 28 2000: Monsanto's Roundup Ready soybean and Ingard cottonseed oil. The ANZFSC approved insect protected corn, glyphosate—tolerant cotton, glyphosate—tolerant corn, glyphosate—tolerant canola and high oleic acid soybeans at their 24 November 2000 meeting.[15] The advantage of high oleic acid soybeans is that they have lower saturated fat levels than conventional soybeans. By the beginning of October 2000, ANZFA had released a total of twelve GM food assessments for public comment. These include the imported GM corn lines, Bt-176 and Bt-11, and a number of Monsanto's New Leaf GM potato lines that ANZFA has declared safe for human consumption. Further assessment reports are expected to be released soon. At this time, it appears that various GM soybean, canola, corn, cotton, sugar beet and potato lines, included in many food stuffs,[16] are likely to be assessed favourably.

Trials and Commercial Releases

The extent of experimental GM crop trials currently under way in Australia is uncertain. The Genetic Manipulation Advisory Committee's (GMAC) web site[17] provides a list of crops being trialled, and has listed the location and size of some trials, but the exact lines (specific genetically modified crops - eg potato line RBMT15-101) are not stipulated. GMAC also lists current proposals separately. GMAC has guidelines for crop trials, but different conditions apply depending on risks involved for each successful application.[18] The lack of transparency about the location of GM trial crops caused a flurry of press commentary in March 2000 about extensive GM canola trials where locations were not revealed because of commercial-in-confidence reasons[19]. Under the GT Act (section 185.2A), the Regulator must disclose information about GMO field trials unless this might 'involve significant risks to health and safety'. If locations cannot be revealed, the Regulator is obliged to explain the decision in a publicly available statement (section 185.3A).

At present, although the GMAC web site contains a considerable amount of information, it would be relatively difficult for a farmer to establish a locational list of GM trials, e.g. in the Wagga district. (In their first *Information Bulletin* the Interim Office of the Gene Technology Regulator (IOGTR) announced new measures for disseminating GMO information at their web site, requesting ideas for improvements in the process).

The GMAC Secretariat provided the following statistics to the Department of the Parliamentary Library:

> The following statistics summarise the characteristics of the field trial proposals submitted to IOGTR up to January 2001: Of the 155 proposals submitted, 149 have been

> approved, six did not proceed, and there are six proposals under consideration. Of the 111 extensions to proposals submitted, 101 are approved, one was advised not to proceed, and nine extensions are under consideration. The 155 proposals submitted are run by commercial companies (37%), CSIRO (36%), Universities (16%), and State government agencies (11%). The following is a list, with frequencies, of the organisms which have been genetically modified in the 155 proposals received: Agrobacterium - 1, Apple - 1, Baker's yeast - 1, Barley - 4, Bovine herpesvirus - 1, Bovine rhinotracheitis vaccine virus - 1, Brassica juncea - 1, Canola - 17, Carnation - 6, Chrysanthemum - 1, Clover - 7, Cotton - 42, Field pea - 8, Fowlpox virus - 1, Grapevine - 3, Helicoverpa armigera - 1, Lactic acid bacterium - 1, Lentils - 1, Lettuce - 1, Lupin - 6, Papaya - 2, Peas - 3, Pig - 1, Pineapple - 2, Poppy - 4, Potato - 7, Pseudomonas - 4, Rhizobium - 2, Rose - 3, Rumen bacteria - 2, Salmonella - 3, Sugarcane - 5, Tobacco - 2, Tomato - 5, Wheat - 4.

There have been 30 new proposals since February 2000. Since 63 per cent of the trials are being undertaken by government rather than the multi-national companies, this has significant consequences for any future liability actions. Government bodies may be positioned between those that own the technologies and any adverse consequences. Patrick Holden from UK's Soil Association claimed that Australia was being used as an international laboratory for developing GM crops. On the other hand, the Grains Council of Australia counselled that it would be to Australia's detriment, not to take advantage of the food technology benefits to be derived from the use of agricultural biotechnology. [20]

The National Registration Authority (NRA) released a GM pesticide in 1989 and a salmonella vaccine in 1992.[21] The Genetic Manipulation Advisory Committee (GMAC) has approved a carnation and Ingard cotton. The latter is a Bt cotton, that is, it contains a gene for one of the toxins produced by Bacillus thuringiensis, a bacterium traditionally used by organic farmers to kill insect pests. Monsanto's Roundup Ready cotton, resistant to the weed killer, glyphosate, was approved for commercial use in September 2000, along with Roundup Ready/Ingard cotton.[22] The latter carries the herbicide resistance of Roundup Ready cotton along with the Bt gene derived toxin of Ingard cotton.[23]

Concerns have arisen because of claims that GM seed grown in Australian trials were intended for export to the US and Canada for commercial seed production. If seed is transferred between companies' Australian and American branches, and is non-commercial in Australia, there are no export controls.[24] In December 2000, GMAC announced Aventis' proposal to grow 1100 hectares of GM canola in WA, SA, Queensland and Victoria to obtain seed for a Canadian trial[25].

Therapeutics

A range of drugs is produced through genetic engineering: insulin, hepatitis B vaccine, human growth hormones and blood-clotting agents. Professor Shine, head of the Garvan Institute of Medical Research, pointed out recently that the advantage GM medicines had

over GM foods in terms of acceptability was that the medicines were derived from human genes. Labelling GE drugs as such does not seem to present a problem to drug companies[26] while there has been considerable reluctance on the part of food manufacturers to do so.

3—Surveys

Australian surveys have served to communicate a range of community perceptions about genetic engineering. The author's previous paper[27] summarised some public reporting of genetically modified (GM) food surveys up to May 1999, the conclusion being that there were considerable differences between the findings. This is still the case.

Public reports of some more recent Australian surveys are listed at Appendix A. They demonstrate a galvanising of opinions about GM foods. However, surveys are often privately commissioned, for commercial and/or public relations reasons, and reports of these surveys in the press may be only summaries derived from press releases of the commissioners. In the case of the Biotechnology Australia July 2000 survey cited in Appendix A, the results were derived from a press release. While it is understood that in this instance there was considerable data generated, the actual survey report is not in the public domain and so accurate contextual evaluation is restricted. Consequently, the number of surveys undertaken reveal that there is considerable interest in the issue, however, without examining the surveys themselves, it is difficult to reach a concrete conclusion about the reported results.

4—Regulation

Australia

It was recognised by the mid-1970s that some form of guidance for those using biotechnology was needed. For example, there were concerns for laboratory workers conducting experiments with GM *Escherichia coli* in the US. In 1975, both Australia and the US produced GE research guidelines. This was followed by the creation of the Recombinant DNA Advisory Committees[28] of the US National Institute of Health. By 1981, Australia had a voluntary regime established by a Recombinant DNA Monitoring Committee. Their 1986 five year review indicated the view that existing State and Commonwealth agencies had legal responsibility for releases of novel agents and that specific gene technology legislation was not needed.[29] The US first regulated for biotechnology[30] in 1986 with the Co-ordinated Framework for Regulation of Biotechnology involving the USDA (Department of Agriculture), the EPA (the Environment Protection Agency) and the DHHS (the Department of Health and Human Services).

In Australia, the Genetic Manipulation Advisory Committee (GMAC) was established in 1987, in addition to a Group of Officials on Biotechnology Regulations. It was not until 1992 that a legislative approach was proposed in response to the House of Representatives Standing Committee on Industry, Science and Technology Report, *Genetic Manipulation: The Threat or the Glory?*.[31] The prospective establishment of the Gene Technology Office (GTO), along with legislation to ensure uniform laws and compliance, was not announced until October 1997.[32] The establishment of the Interim Office of the Gene Technology Regulator (IOGTR), within the Therapeutic Goods Administration (TGA), to begin drafting GE legislation and undertake necessary consultation process, was announced in the 1999–2000 Commonwealth Budget. The instrument needed to achieve the creation of the Gene Technology Office and a Commonwealth legislative framework, the *Gene Technology Act 2000* (GT Act), was passed by the Australian Parliament in December 2000.

The difficulty in arriving at an agreed regulatory regime, in Australia, is exacerbated by Australia's federal structure and the number of departments and agencies necessarily involved. The Biotechnology Ministerial Council comprises the five pertinent ministers, the Ministers for the Environment and Heritage; Agriculture Fisheries and Forestry; Health and Aged Care; Education, Training and Youth Affairs; and the Minister for Industry Science and Resources, who is also Chairman. Areas of regulatory and administrative control are under the aegis of a number of agencies within these Ministries, along with the Department of Foreign Affairs and Trade. A recent summary of Government biotechnology activities is provided in *Australian Biotechnology. Progress & Achievements*[33]. The extensive number of agencies involved can be found at Appendix B. The GT Act will be administered by the Minister of Health and Aged Care when it comes into force on 20 June 2001.

Uncertainty about Australia's regulatory situation was exemplified by Tasmanian moves in 2000 to implement a year long moratorium on the growing of GM crops under their *Plant Quarantine Act 1997*. Unless legally tested by the Commonwealth, the validity of respective State actions was viewed as uncertain. Use of planning powers of local governments (derived from State legislation) to block GE trials were variously being explored. (See the *Gene Technology Bill 2000* Bills Digest for an amplification of legal issues[34] as well as the IOGTR submission to the Inquiry into the GT Bill[35]). The GT Act allows for the recognition of designated areas under State laws which then will enable the States and Territories to preserve the identity of GM crops or non-GM crops for marketing purposes (section 21aa).

The sheer communications complexity involved between intra-State, intra-Commonwealth and State/Commonwealth agencies promises misunderstandings and confusion at the very least. At each jurisdictional level, at a minimum, environment, health and agriculture agencies, along with premiers' departments are involved. While encompassing many jurisdictional agencies, negotiations to establish a consistent national regulatory scheme proceeded at a Premier's department (or equivalent) and Cabinet levels. When the GT Bill

was placed before Parliament, the *Draft Gene Technology Regulations* were not yet in the public arena, making it difficult to readily identify the devil in the detail. The *Draft Regulations* were available[36] when the GT Bill was debated in December 2000 and the revised *Draft Regulations* were released in January 2001. However, the *Draft Intergovernmental Agreement* between the States, Territories and the Commonwealth was not a public document when the *Gene Technology Act 2000* was passed by the Australian Parliament. The *Draft Intergovernmental Agreement* is still not in the public domain.

Management of GMO issues at a local government level do not appear to have been fully explored and may well prove to be problematic. For example, the audit of Aventis Crop Science Pty Ltd, which includes consideration of the recent dumping of GE waste of an Aventis canola with resistance to the 'Liberty' herbicide, glufosinate ammonium, at a Mount Gambier tip, found that there was a risk of uncontrolled seed dispersal. The possibility of weeds acquiring the traits from the GM canola was also viewed with concern.[37],[38] This breach of GMAC conditions also reminds us of the potential for a considerable gap to exist between in practice and theoretical management of GMOs at this time. While IOGTR found that the breaches did not increase human health risks and environmental risks were low, they identified that Aventis did not always comply with GMAC recommendations, namely:

- Always establishing a 15 metre buffer zone of non-transgenic canola around plantings at summer trial sites to minimise pollen escape
- Monitoring of a 50 metre zone for all sexually compatible species
- Monitoring for, and removal of, volunteer plants after the trials; and compliance with the procedures for the transport and disposal of field trash.[39]

While the GT Act represents the first steps along a GE legislative track, at this stage, it does not necessarily hold the promise of resolving such issues or supporting local government requirements.

Overseas Regulation

Australia has lagged behind some major players in the development of a GE regulatory framework; both the European Union (EU) and the US have not only had regulations in place for years but are in the process of re-assessing their management of GMOs. For instance:

The United States had the Co-ordinated Framework for Regulation of Biotechnology in place by June 1986, the participants being the three departments: US Department of Agriculture (USDA), the DHHS (the Department of Health and Human Services) and the USEPA (the Environment Protection Agency). The International Consumers for Civil

Society have issued a summary of current US regulation of agricultural biotechnology.[40] The USFDA's (Food and Drug Administration - an agency of the DHHS) May 1992 policy required that GM foods should be labelled as such if there were significant compositional differences from regular equivalent foods.[41] Draft voluntary guidelines for GM labelling were issued in January 2001.[42] By 1990, the USFDA had their first food related regulation for a substance derived from the use of recombinant DNA techniques, chymosin, a milk-clotting enzyme used to make cheese.[43] (Note that the USFDA's powers are derived from the Federal *Food, Drug, and Cosmetic Act 1906).*

The EU has had a range of GE Directives in place for up to a decade.[44] Amendments to one of its GE Directives, namely, *Directive 90/220/EE of 23 April 1990 on the deliberate release into the environment of genetically modified organisms*[45] are yet to be finalised. The amended Directive is expected to be in force in 2001. The EC's *Communication* to the European Parliament on 3 November 2000 briefly describes the history of *Directive 90/220/EC* along with amendments that have been accepted, either totally, partially or in principle.[46] Interim measures now allow EU member states to test sugar beet, maize, rapeseed, soybean, cotton and tomato seeds if GM presence is suspected. A 0.5 per cent contamination level is permitted for seeds covered by EU authorisation, those seeds without authorisation have a zero threshold for GM material. Legislation will follow.[47] European Commissioner Byrne recently described an interim approach, beyond *Directive 90/220/EEC*, looking at the whole regulatory framework for GMOs, including traceability and labelling, introducing legislation on novel feed, and updating seed and food legislation.[48]

GE decisions of other nations, trading blocks and international bodies are influencing Australia's course of action. The EU/US disagreements are of particular importance. The EU/US have not reached an agreed position at the Codex Alimentarius Commission (CAC) level (international food standards setting body) about what 'scientific certainty' means in the context of living modified organisms (LMOs) and it appears increasingly unlikely that they will do so. Other likely impacts on future international regulatory and trade directions may stem from meetings of the Intergovernmental Committee for the *Cartagena Protocol on Biosafety* (*Biosafety Protocol*). At their December meeting, signatories agreed to set up an international biosafety information centre, while the next meeting, in October 2001, will examine the decision making process and how *Protocol* commitments will be met.[49]

In December 2000, the EU-US Biotechnology Consultative Forum established by President Bill Clinton and the European Commission's President Romano Prodi, established a number of recommendations designed to restore public confidence in agricultural biotechnology. Both Presidents agreed to pursue a co-operative approach and to consider the recommendations.[50] Of particular interest is the EU-US Biotechnology Forum's Recommendation 19 that biosafety principles in the *Protocol* should be forwarded. The new US administration's response, if any, to Recommendation 12, which is on the role of precaution and managing 'substantive uncertainties' is awaited. The Forum's rational for Recommendation 13, on regulation, that 'a rush to judgement [of

GMOs] will be self-defeating to both the public and industry', is a salutary but belated warning.

5—Australian GE decisions

In late 2000 two major Australian GE decisions were taken. Firstly, the gene technology legislation: namely, the *Gene Technology Act 2000, Gene Technology (Licence Charges) Act 2000* and *Gene Technology (Consequential Amendments) Act 2000*, was passed. Secondly, the GM food labelling specifics, namely: *Standard A18 - Food Produced Using Gene Technology*, in the *Food Standards Code*, was gazetted.

Australia has not as yet indicated when, or whether, they will sign the *Cartagena Protocol on Biosafety*.

Gene Technology Act 2000

The object of the *Gene Technology Act 2000* (section 3) is:

> … to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.

The GT Act provides for the establishment of the Office of the Gene Technology Regulator (OGTR) and the Gene Technology Regulator (GTR). The GTR's functions include making decisions about GMO licences and drafting policy principles and policy guidelines as requested by the Ministerial Council. Other roles include informing and providing advice to other regulatory agencies and the public, undertaking or commissioning GMO risk assessment and biosafety research, as well as harmonising risk assessments for GMOs and GM products (section 28). The aim of the government is to have the OGTR operational by 20 June 2001. A Ministerial Council will set policy principles (section 21).

Science/Government Interface

The GT Act demonstrates difficulties encountered with the interface between science and government. The GTR and the Ministerial Council are to obtain their advice from the same source, GTTAC (Gene Technology Technical Advisory Committee). Beyond concerns about the selection process for GTTAC scientists, and despite the intention to co-opt additional scientists when needed, it can be argued that the proposed circular model could limit access to a range of scientific opinions. Given that advice provided may be in

the realm of 'contested science expertise' and that GMAC has attracted some criticism, the way scientific advice is provided to governments is fundamental to the governance issue.

If it was the intention of the Interim Office of the Gene Technology Regulator to separate process and decision making from policy matters, when drafting the GT Bill, there were at least two potential obstacles to this in the GT Bill. Amendments have partially corrected this in the GT Act.

The GTR (the decision maker) can be constrained by the Act's 'policy principles' that are issued by the Ministerial Council (the policy makers) (section 21). Policy principles are disallowable instruments, that is, they may be rescinded by Parliament and they may be related to ethical issues or regulations. The impact of the regulations is not known at this time. For instance, it is unclear at this stage what potential there is for the decision maker, the GTR, to be constrained by the policy makers, the Ministerial Council, and, further to this, what impact this could have on GMO administration in Australia.

The second potential problem was resolved by an amendment to the GT Bill (section 100.7a). The three committees proposed in the Bill (GTTAC, the Gene Technology Community Consultative Group (GTCCG) and the Gene Technology Ethics Committee (GTEC) cover ethical, societal and scientific concerns. Under section 101, only the science based committee, the GTTAC, could be directly involved in providing advice on GMO licences and other applications. In the GT Bill, GTTAC was not to include a member of either the consultative or ethics committees, but, an amendment (section100.7a) ensures that the community and ethical input of these committees are to be represented on GTTAC. (Note that a further amendment in the GT Act formally upgraded the GTCCG, a group, to a committee, the Gene Technology Consultative Committee (GTCCC)).

The Minister of the Department of Health and Aged Care will appoint GTTAC members, the major constraint on the Minister being that the majority of jurisdictions (ie States, Territories and Commonwealth) agree to each appointment. It could be argued that there is potential for the development of a perception that the science/politics divide could be muddied at State, Territory or Commonwealth levels. On the other hand, the selection of GTTAC members by the GTR (the decision maker) could hold the potential for accusations about bureaucratic dominance and lack of transparency. The Regulations do require conflict of interest and disclosure of interest requirements.[51]

Whether the principle of separating science and politics is a given, or if a continuum between science and policy is seen as preferable, other models for the selection of scientists for GTTAC could perhaps have been considered. For example, in order to build in a wider range of participation and expertise, scientists could have been nominated by the range of professional organisations with subject expertise areas as specified at section 100 in the GT Act. The Minister then could have selected from the changing pool of professional organisations. For example, the Australian Research Council (ARC) and the Rural Research and Development Corporations (RDCs) have recently recommended

the formation of a National Biotechnology Network of Scientists to serve as a reference group for emerging science and technologies including commercial and environmental perspectives. If formed, it would be a useful organisation to draw upon.[52]

Organisms Covered by the Act

Human cloning is covered by the GT Act even though the replacement of the whole nucleus is involved rather than 'genetic modification', ie the modification or insertion of a gene or genes. Also, the GT Act covers instances where human cells have been introduced into animal embryos, in the case of Amrad's recently acquired patent for mixed embryos.[53] On the other hand, transgenic goats, with a human gene to enable the production of human albumin in their milk, were and are within the intended scope of the Act[54], namely, genetically modified organisms.

Until additional regulations are written for the Senate's section 192 amendment to the Gene Technology Bill 2000, there will be some uncertainty about what organisms are covered by the GT Act. The *Act* has a broad definition of gene technology (section 10.1) that covers modification of genes or other genetic material but excludes:

> (a) sexual reproduction; or (b) homologous recombination; or (c) any other technique specified in the regulations for the purposes of this paragraph

That is, human cloning is not specifically covered in section 10.1.

Under the GT Act 'genetically modified organism' means:

> (a) an organism that has been modified by gene technology; or (b) an organism that has inherited particular traits from an organism (the initial organism) being traits that occurred in the initial organism because of gene technology; or (c) anything declared by the regulations to be a genetically modified organism, or that belongs to a class of things declared by the regulations to be genetically modified organisms; but does not include (d) a human being, if the human being is covered by paragraph (a) only because the human being has undergone somatic cell therapy; or (e) an organism declared by the regulations not to be a genetically modified organism, or that belongs to a class of organisms declared by the regulations not to be genetically modified organisms.

Issues covered by section 192 are human cloning (ie duplicating a whole human being as defined by the GT Act (section 192), the insertion of a combination of human and animal cells into a human uterus, or putting human cells or a combination of human and animal cells into animal eggs. These processes were not specified in the Gene Technology Bill 2000. These important matters were not given the in depth examination that was given by Interim Office of the Gene Technology Regulator's (IOGTR) to other issues covered in the development of the draft Bill. The amendments (section 192) are certain to require clarification though additional regulations and may well require additional legislation in

the future. Given the intention to roll back powers to the States, clarity may be obtained in the States' cloning legislation.

As Nicholas Tonti-Filippini has pointed out, section 192 was formulated hastily[55] and fails to address the complexities involved. Section 192 deals with biotechnological manipulation at the human cellular/subcellular levels rather than at the molecular level that pertains to the modification of genes or other genetic material. For example, there is room for doubt about whether or not the insertion of human genetic material from the 'initial organism' into an enucleated human cell is necessarily covered by these provisions, especially if the result is not an exact duplicate whole human being. When seeking clarification from the IOGTR on this point it appeared that the National Health and Medical Research Council (NHMRC) will be advising the IOGTR and the States about the implications of section 192. This lack of clarity serves as a cogent example of pitfalls in the governance of issues that deserve, not only an extensive examination of scientific and ethical parameters, but also, an informed public debate about them.

Environmental and/or Health and/or Agriculture Watchdog?

Power vested in one person, the GTR, could also be seen as potentially problematic. While the GTR's role is to make individual decisions about GMOs, the cumulative effects of the GTR's individual decisions will have an extraordinary influence on the way GMOs are managed in Australia. It should be noted that while the GTR will be advised by scientists, the GTR may not necessarily be science trained. For example, the Interim Regulator has legal qualifications. The GT Bill 2000 *Inquiry's* recommendation that the Regulator should be a statutory authority consisting of three people was not taken up.[56]

Each jurisdiction will contribute a minister to the Ministerial Council and it will be up to each State or Territory to decide whether to send an environment, health, industry or agriculture minister to the Council. Consequently, this Ministerial Council may operate differently from other government models. For example, the National Environment Protection Council (NEPC) comprises jurisdictional environment ministers and the Murray Darling Basin Ministerial Council includes ministers from environment and agricultural (or their equivalent) departments from each State or Territory. While ANZFSC currently comprises all jurisdictional health ministers (including New Zealand), the November 2000 *Food Regulation Agreement* provides for a replacement council, the Australia and New Zealand Food Regulation Ministerial Council, comprising health ministers as well as ministers from other portfolios.[57] It is arguable whether competing environment, health and agricultural agendas could hinder or enhance the objectives of the GT Act. The chair of the Ministerial Council will initially be the Commonwealth Minister for Health and Aged Care because this portfolio will administer the GT Act. It is anticipated that the chair will rotate. Some see a Trans Tasman approach, perhaps along the same lines as ANZFSC, as desirable, given close trading ties and the Trans Tasman Mutual Obligation Agreement. At this stage, New Zealand is not a participant. Since Australia has not as yet signed the *Cartagena Protocol on*

Biosafety, and New Zealand has, some administrative adjustments of arrangements between the two countries may be required, if the *Protocol* comes into force.

There is an international trend for the creation of single, centralised, food safety agencies, e.g. UK, the EU and Canada. Although this approach was advocated by the US National Academy of Sciences in order to avoid jurisdictional disputes,[58] the suggestion has not been taken up. In Australia, it is intended that ANZFA will be replaced by Food Standards Australia New Zealand (FSANZ). It is not clear how food science, public health, trade and food industry interests will be accommodated within the new agency. In Europe, the peak biotechnology industry body, EuropaBio,[59] has advocated that the forthcoming European Food Safety Authority should have the final say about GM food safety matters.

In Australia, the administration of gene technology will not be so clear cut under the proposed arrangements because the Gene Technology Regulator (GTR) is only responsible for those areas where there are existing regulatory gaps (e.g. where existing regulators ANZFA, the NRA, the TGA and AQIS currently have no control). An array of circumstances may arise where the GTR will not have sole responsibility for biosafety issues. In practice, there lies a potential for the type of relationship that exists in the US between the three major Federal government players, with competing interests, namely, health, environment and agriculture.

Biotechnology public awareness communication is enshrined in Australia's *National Biotechnology Strategy*, launched by the Biotechnology Ministerial Council and chaired by the Minister for Industry Science and Resources. Because much consumer concern about gene technology relates to food safety and consumer choice, an overarching health communication strategy could be seen as preferable. While it is important that Biotechnology Australia (BA) and the Bureau of Resource Sciences do provide biotechnology communications to the public, both have industry facilitation roles. It could be also argued that the dual GT Act objectives of health and environmental safety could prove to be onerous and conflicting burdens for the GTR.

Dissimilar GMO management approaches by various Australian agencies may lead to mishaps or oversights. The Bills Digest also suggests that the delegation powers of the GTR to other agencies could also lead to problems.[60]

Gene Technology Act 2000 Gaps

Because the draft *Intergovernmental Agreement* (the draft *Gene Technology Agreement* (GTA - the agreement between States, Territories and the Commonwealth Government)) is not publicly available, the workability of the GT Act holds some uncertainties. Those making submissions to the *Inquiry* into the GT Bill did not have access to the draft GTA or the *Draft Gene Technology Regulations* and so were unable to comment in the full

context of the proposed gene technology regulatory framework. The GTA is not expected to be publicly available until it is signed early in 2001.

It is likely that States and Territories will have different legislative responses, complementary rather than mirror legislation used by NEPC, for example. As States and Territories introduce their legislation the Commonwealth will wind back pertinent responsibilities. All jurisdictions appear to have reached agreement about the GTA.

Opting Out

Tasmania was unwilling to sign the GTA without the inclusion of opting out mechanisms[61] and in early November 2000 the Commonwealth agreed to grant Tasmania opt out rights.[62] While is understood that a 'policy principle' will be developed to cover this situation, the section 21aa amendment, previously mentioned on p.9, caters for Tasmania's GM-free marketing concerns. Tasmania is currently exploring their future position on the issue through a GMO inquiry. Previously, at the Commonwealth's GT Bill *Inquiry*, an IOGTR adviser had suggested that there were a number of ways that could be explored to accommodate Tasmania's needs. If there were health and environmental risks the GTR could disallow the release of a GMO. If Tasmania wanted to create a GM-free image a possible solution would be for 'policy principles' to be developed by the Ministerial Council that entailed 'protecting Australia's diverse farming practices' that might lead to the declaration of GM-free zones in various areas in Australia. States and Territories could also use their own legislation 'whether land planning legislation or, in Tasmania's current case, plant quarantine legislation'.[63]

Despite section 21aa, Mr Kim Chance, the Western Australian Opposition agriculture spokesman, indicated that although Labor would work in the system, wider opt-out provisions for the States would have been preferable, and that a WA Labor government would test these provisions.[64]

Problematic Matters

The *Gene Technology Bill 2000* Bills Digest discusses the Bill in detail. Some unclear areas in the Bill include:

- Fines may be imposed for offences against the GT Act but it appears that Common Law is the only vehicle for a third party to bring an action against an offender

- For an offender to be successfully prosecuted for an aggravated offence under the GT Act (section 38) it must be proved that they:

> intended his or her conduct to cause significant damage to the health and safety of people or to the environment; or,
>
> was reckless as to whether that conduct would cause significant damage to the health and safety of people or the environment.

- Uncertainty about liability if the industry applicant has complied with OGTR's conditions

- Commercial-in-confidence rights will limit transparency

- The operational relationship between the Environment Minister and the Gene Technology Regulator (GTR) and lack of the right of veto over GMOs, apart from with respect to matters of national environmental significance, are cause for concern. The GTR 'must take into account' the Environment Minister's advice re risk assessment and risk management plans for the intentional release of GMOs into the environment (section 50(3)), but as the decision maker, the GTR isn't obliged to take the advice. The GTR is answerable to Parliament however. The Environment Minister could commission scientific studies on the impact of GMO releases but they would have no force in law. There are those that argue that intervention by the Environment Minister may threaten the independence of the GTR. The success of some of the environmental aspects of the GT Act is dependent on successful communication lines between the Environment Minister and the GTR, a chancy scenario that holds the promise of misunderstandings at the very least.

- The Organic Federation of Australia wanted the GT Act to include provisions for tracking GM grain sales and a compensation fund for farmers if contamination occurs from an unknown source.[65] (Bristow was of the opinion that the OGTR may have the right to impose insurance or assurance bond provisions under the GT Bill).[66] Although the ANZFSC ministers' announcement about GM food labelling revealed that it would be pertinent for food manufacturers to have a paper trail to protect themselves if there are claims that their food labelling is misleading, the GT Act does not make provision for tracking GM grain sales. In Europe, while this has been proposed, in the recent grain contamination scare the agrobiotech industry was quick to point out that, in fact, their sector was able to track the contamination back to its source. The EC have issued an advance working document on traceability and labelling of GMOs and products derived from GMOs.[67] Will the Australian private sector be able to achieve a workable tracking system for both products and grains under protocols, guidelines or codes of practice? Some funding was allocated for the examination of tracking when Australia's Biotechnology Strategy was released.

- The GTR is obliged to consult 'appropriate' local councils but it is by no means certain what standing the word 'appropriate' has (section 50(3e)). Even if a local council is consulted, while the GTR 'must take into account' their advice, the GTR is, again, not obliged to take their advice. Neither is it clear who will pay local councils for costs incurred due to administrative business arising from GE applications within their

jurisdictions. (The Naracoorte-Lucindale Council, South Australia, is an example of a local government authority that has expressed reservations about GM trials in their area).[68]

- The GT Act requires (section 138) that the *Record* (of GMO and GM Product Dealings) - be kept for all notifiable low risk dealings, and, included in this a description of each dealing on the *GMO Register*. It is intended that the *GMO Register* will list GMOs that have no licencing requirements. It is not known how quickly the information will be made available on the OGTR's web site. While the GTR 'may consult' States and Territories about items proposed for the GMO list, he or she is not obliged to do so. Neither is the GTR obliged to notify States and Territories about GMOs that have been included in the *Register*. States and Territories can of course check the *Register* for new additions but it would appear that a notification system would be preferable.

- The financial impact of the GT Act on agencies other than the OGTR is an unknown at this stage. The KPMG OGTR costings study questioned the likelihood of OGTR achieving full cost recovery in the next three to five years.[69]

Biosafety Protocol

Senator Robert Hill, the Minister for Environment and Heritage, issued a press release in a supportive response to the international agreement to the text of the *Cartagena Protocol on Biosafety* in January 2000[70] but has since been reported to have reservations. Signatories to the *Protocol* will agree to provide advanced informed consent (AIA), in some cases, about the transport of LMOs (living modified organisms) across national boundaries. Importing countries will be able to use the Precautionary Principle to refuse to accept LMO imports but may have obligations to cooperate with further risk assessments. The relationship between the World Trade Organisation (WTO) and the *Protocol* rules are as yet untested. At ABARE's Outlook Conference on 2 March 2000, the Australian Ambassador for the Environment cautiously indicated Australia's position. He stated:

> We therefore sought to ensure that the Protocol did not impose unnecessary additional requirements on Australian exporters of LMOs, nor on Australia as either an importing or exporting country. Furthermore, we were conscious that if our key trading partners become Parties to the Protocol, Australian trade in LMOs would be affected by the Protocol regardless of whether we become a Party … The Government is carefully assessing Australia's interests in the Protocol, in close consultation with industry and other groups, in the context of a decision on whether to sign the Protocol. These interests include:
>
> - The future production and export of LMO commodities in Australia;
>
> - Our own domestic arrangements for the environment and human health regulation of genetically modified organisms, including for export;

- The regulation of LMO commodities in our key export markets, including under the Protocol; and

- The uncertainties as described above, that is, how the Protocol will operate in relation to the WTO, the references to the precautionary approach and the key issues that have been left for further negotiation.[71]

Whether Australia will or will not sign and/or ratify the *Protocol* in the near future is uncertain, albeit unlikely, there being a considerable tussle at Cabinet level on the issue. A backbench committee has commenced informal hearings.[72] Either way, implications derived from the implementation of the *Protocol* by some trading partners will need to be addressed by Australia. In May 2000, at Nairobi, the *Protocol* was opened for signature and at least 81 countries have signed at the time of writing, including the European Community and New Zealand. As yet, only two countries have ratified the *Protocol*, Bulgaria and Trinidad and Tobago.[73]

Food Labelling

On 28 July 2000, the Australian and New Zealand health ministers, ANZFSC, considered the Inter-Government Taskforce's recommendations on the labelling of genetically modified foods in *Standard 18* of the *Food Standards Code.*[74] ANZFSC opted for:

- labelling of food and food ingredients where novel components such as DNA and protein is present in the final food

- where food has altered characteristics

Exemptions include:

- highly refined foods where the effect of the refining process is to remove novel DNA and /or protein

- flavours which are present in a concentration less than or equal to 0.1 per cent in the final food, and

- food prepared at the point of sale.

The *Standard* allows:

- an ingredient to contain up to 1 per cent of unintended presence of genetically modified product.[75]

A report, commissioned in October 1999, from a consortia comprising KPMG, Harley Juffs & Associates, Millward Brown and AgriQuality New Zealand,[76] proposed more moderate

costing estimates for the labelling of GM foods (circa $300 million per year) than the previous report produced by KPMG ($3 billion per year).

The lack of GM food testing facilities in Australia will hamper compliance strategies. The *Protocol of Compliance* is expected to clarify the way that industry can demonstrate due diligence, using tools such as audit trails and testing. The GM food labelling as specified in the *Standard A18* (which will become *Standard 1.5.2* in the *Joint Australia New Zealand Food Standards Code*) will not be in force until 7 December 2001, that is, twelve months after gazettal of the *Standard*. Three years after gazettal, ANZFA is required to report on the implementation of the *Standard*.

On 26 May 2000, it was announced that the *Food Standards Code* will be examined in the light of National Competition Policy principles (i.e. whether it restricts competition, imposes costs or confers benefits on business). This may further impact on the gene technology food standard.

Deregulation in the food industry has attracted criticism from both sides of the fence. The Australian Consumers' Association (ACA) has claimed that ANZFA has failed 'to ensure the primacy of consumer interests in food regulation', asserting that ANZFA has lowered standards to match those of international agencies and that 'public interest has been progressively subordinated to the interests of the food industry'. It has also reported that 'Cadbury Schweppes and Golden Circle have warned that further deregulation of food standards could deceive consumers and create severe health risks'.[77]

When developing the draft GT Bill issues such as the Biosafety Protocol, industry and trade concerns and food labelling matters had to be taken into consideration. Some guidance can be obtained by observing the pathways that other governments have taken to work towards management frameworks for GMOs. IOGTR has listed existing regulatory systems of other countries and listed their findings, along with a summary of national regulations.[78] Various national attempts to regulate for GMO food related issues are also included in the OECD's June 2000 *Compendium of National Food Safety Systems*.[79] National biotechnology regulatory schemes may also be found at the OECD's web site.

6—What Obstacles Require Solutions?

For the promise of gene technology to be realised, it is likely that not only will adequate consumer information, including reliable identification of GM derived products be required but potential or identified environmental and health hazards will also need to be noted and managed by governments. Of particular importance are adequate testing, assessment and monitoring regimes.

Health Fears

GMO Assessments

Australian assessment of GE crops and foods is largely a paper exercise involving scrutiny of data supplied by each applicant because neither GMAC nor ANZFA have laboratories. The report of the *Strategic Review* of Australian Government Analytical Laboratories is due shortly. The industry body, the Australian Biotechnology Association, argues affirmatively, in their submission to the *Strategic Review's* question: should Government be in the business of running analytical laboratories?:

> The growth and development of biotechnology industries is dependent upon the credibility and rigour with which analysis of emerging products and technologies is undertaken. In many emerging technologies the Government adds an independent credibility that commercial laboratories by their nature cannot.[80]

Because OGTR will be self-funding, although it will be within the GTR's aegis to commission data, it remains to be seen to what extent they will be able to commission original research and from whom they commission research. ANZFA's recent announcement about the creation of ten ANZFA scientific fellows later this year, 'to complement ANZFA's own internal expertise'[81] could be seen as a response to the need to bolster its science base. However, it is not known whether the expertise of the fellows will be used to produce original work. There are dangers inherent in reliance on externally generated data and procedures.

For instance, it was reported in May 2000 that Monsanto had recently realised that when they reported to the US regulators in 1993 that the GE, Roundup Ready soybean, contained a single new strand of DNA, they were wrong. There were, in fact, two 'rogue' fragments of DNA in the soybean. Monsanto has been informing regulatory agencies about this, describing the fragments as 'inactive' and arguing that since the Roundup Ready soybeans were found to be safe in 1993 their conclusion still stands.[82] While this could well be so, the case highlights the dangers of accepting an applicant's data at face value and the lack of peer review of what could be commercial-in-confidence information.

- While the GTA includes provisions (section 65) that oblige licence holders to inform the GTR if there is additional information about a GMO relating to health or environmental risks or unintended effects, if these conditions do not apply, then the Regulator does not have to be informed. That is, using the Monsanto case, there is no obligation for the licence holder to inform the Regulator that the GMO that has been released, as described to him or her, is actually different in some way. The danger is that there may be a possibility, albeit however slight, that health and environmental effects may be detected in the future and the Regulator will not have a record of the exact nature of the GMO in question.

- The other potential problem pertains to the licence holder. The licence holder may be the farmer, the seed supplier or the overseas importer. They may not be informed by the seed developer about new information about a particular GMO with which they are 'dealing'. The overseas GMO seed developer has no obligations to do so under the GT Act unless they are the overseas importer.

Benchmarks and assessment tools appear to be primarily derived from overseas agencies. In 1999, it was noted at an OECD meeting that safety assessment practices were insufficient, and a new approach was required.[83] This being the case, assurance by ANZFA that they have used 'principles developed by the World Health Organisation, the Food and Agriculture Organisation and the OECD'[84] in their safety assessments does not necessarily promote public confidence in GMOs. There is a difference between efficiencies that can be gained where nations share knowledge and safety approaches, and dependency on international approaches because of national infrastructure problems, such as the lack of a national Australian agency that caters for all food safety and health issues. This year, the report of the OECD's Working Group on Harmonisation of Regulatory Oversight further warned that 'while different authorities may use similar information and similar assessment procedures, they sometimes arrive at different conclusions'.[85]

GM food was marketed in Australia, and elsewhere, prior to the comprehensive development of appropriate testing technologies and protocols. In particular, resolution of toxicology issues has lagged behind the marketing of GM foods. Some objections to GM foods have arisen, not because of a Luddite reaction to the technology or a refusal to consider the benefits that biotechnology may offer, but because the cart was placed before the horse in terms of safety assessment. Factors such as wariness about data presented by applicants along with the lack of credible management frameworks and communications have fuelled consumer unease.

A consortium of European scientists recently argued that it is difficult to assess risks arising from GM foods. They note that it is far easier to detect adverse effects from pharmaceuticals than GM foods, and even then, about 3 per cent of pharmaceuticals are withdrawn from sale because harmful effects have been detected.[86] While there are notable exceptions, eg thalilomide, diethylstilbestrol (DES) etc, harm arising from the use of inappropriate pharmaceuticals is largely confined to the individual taking the medication. Unwarranted GM crops approvals may carry risks of unremediable ecological harm.

There is limited knowledge about health benefits or risks arising from specific chemicals in non GM foods and synergistic effects of compounds in non GM foods. Genetic engineering adds another level of complexity and highlights the need for further research into foods generally, whether foods that contain beneficial compounds e.g. anti-cancer compounds in the brassicas, or, those that carry risks if eaten excessively e.g. comfrey, or, those that contain novel proteins or novel synergies induced by genetic engineering.

The recent UK inquiry into Aventis' GM fodder maize, Chardon LL, that the UK Government had proposed for addition to the UK's National List (of permitted seeds) in

March 2000, provides an example of scientists raising questions about the adequacy of the applicant's data. One expert witness, the director of the International Feed Resource Unit in Aberdeen, Professor Bob Orskov, indicated that the data submitted by Aventis was inadequate, the animal feed had not been tested on cattle, only rats and chickens. Another expert witness had concluded after analysing Aventis' safety data that there were significant statistical differences between the GM and non-GM varieties with respect to fat, protein and fibre composition.[87]

The Public Health Association of Australia (PHAA) raised concerns about the adequacy of testing for Monsanto's Roundup Ready soybeans as a result of a paper by Dr J Carman.[88] A subsequent scientific study on three further ANZFA GM crops assessments (two corn and one canola line) conducted for the PHAA, raised further concerns about and the adequacy of the data submitted to ANZFA as well as the assessment process. Concerns included the up to 16 per cent liver enlargement of rats fed the GM canola, non disclosure of information because of 'commercial in confidence' reasons, small test sample sizes and the lack of independent scientific scrutiny of Monsanto and Optimum Quality Grains data.[89]

A report by EcoStrat GmbH, commissioned by Greenpeace International, examined a range of company studies on GM crops with a particular focus on methodologies used. The report is based on both laboratory and field based studies. Previously, the UK's ACRE (The Advisory Committee on Releases to the Environment) had examined the work of one of the authors, Angelika Hilbeck, from the Swiss Federal Research Station for Agroecology and Agriculture. Her experiments had established increased mortality of lacewings fed with Novartis Bt maize. While her report was found to be balanced and reasonable, the Committee found insufficient evidence to justify a ban on Novartis Bt maize. Hilbeck et al indicated since their work was laboratory based, conclusions about field effects could not be drawn. ACRE recognised the need for further research on the effects of GM crops on non-target organisms.[90]

In brief, the EcoStrat GmbH report concluded that the requirement for company application packages submitted to regulatory agencies to provide test results for acute ecotoxicological effects of the insecticidal protein for a range of Bt crops, on non-target species, was insufficient. The report maintained that, in addition to the acute toxicity data, chronic lethal and sublethal toxicity parameters in the testing procedures should have been provided. Of interest was the request by two of the eight scientists involved for anonymity,[91] perhaps anecdotal evidence about pressures that GE scientists may be experiencing.

A recent Scientific Steering Committee of the European Commission report on risk assessment of genetically modified plants (GMP) can be used to summarise limitations of the process.

> The SSC highlights the rapidly increasing complexity of the changes in plants arising from the insertion of a variety of genes and a variety of combinations of genes. Current evaluation methods regarding human and animal health and the environment, suffer from

> different limitations when dealing with the variety of issues, which might emerge from the development and introduction of GMPs.
>
> The SSC also wants to underline that a similar situation already exists today for other methods of plant breeding. For example, chemical mutagenisis, radiation or cell fusion produce random genetic changes in plants and an evaluation of the long-term impact of these unpredictable changes on health and environment is poorly documented. That means that no benchmarks or standards presently are established for contents of inherent nutrients and toxicants in ordinary food and feed plant products by which to make an initial acceptance through substantial equivalence for GM plant products. It is therefore questionable whether such traits could be used as comparators for substantial equivalence assessments of GMPs.
>
> The development of regular assessment schemes, based on sound protocols and a clarification of 'substantial equivalency' is essential. For specific gene constructs this needs to begin in parallel with the development of any new gene technology or construct.[92]

GM foods

ANZFSC's 28 July decision to label foods with GM ingredients on sale in supermarkets, and the gazettal of the standard, *Standard A18* on 7 December 2000 will provide some certainty for consumers and guidelines for businesses.

The major regulatory gap pertains to food preparation outlets which were not included in the ANZFSC decision. Since there is evidence that Australians are increasingly either eating out or buying takeaways, this omission is inconsistent with a consumer choice rationale for GM food labelling. However, it could be argued that food preparation outlets could voluntarily advertise that they either do or do not use GM ingredients and/or insist that their wholesale suppliers indicate the GM or non-GM status of foods they sell.

Standard A18 explicitly does not regulate for food derived from animals fed with GM fodder. This issue is gaining attention in the EU, especially in the UK where the public is mindful of the BSE/CJD (Bovine Spongiform Encephopathy/Creutzfeldt Jakob Disease) debacle originating from meat and bone meal animal fodder.

Also exempted from prohibited sale are GM foods covered by applications made on or before 30 April 1999 to ANZFA, under section 13 of the *Australia New Zealand Food Authority Act 1991*. The provisos include the stipulation that there is evidence that the food is lawfully permitted by a national food regulatory agency of one country other than Australia or New Zealand and that the ANZFSC is not aware of any significant risk to public health and safety.

The health ministers' GM food labelling decision will not take effect until 7 December 2001. The *Standard*, which was agreed to at the ANZFSC 24 November 2000 meeting also refers

to a draft compliance guide to assist businesses that has been issued for public comment. The *Standard* provides the following labelling examples:[93]

For single ingredient GM foods:

- soy—'genetically modified' or 'from genetically modified soya beans'

For GM food ingredients in a food:[94]

- Soy Protein Isolate (genetically modified)

Labelling for non GM foods:

- No statement required

Negative Claims for non-GM foods:

Claims must not be misleading or deceptive, and the *Draft Guidelines* suggest that since absolute negative claims such as 'GM free' have been tested in court such a claim must be supported by evidence. The negative claim example 'Best endeavours to use non-genetically modified food ingredients' is provided.

Compliance and Enforcement

The establishment of a GM standard in the *Food Standards Code* is one thing, enforcement and compliance is another. To what extent will the GM standard be just words? While the onus is on food manufacturers and suppliers to provide documentation for audit trails, if queried, who will be checking for compliance? States and Territories have the responsibility for this.

With widespread governmental down-sizing and out-sourcing trends there is no reason to believe that the ability of States and Territories to adequately enforce food standards has improved since the 1995 Office of Regulation Review survey. The *Review* found that while most government food agencies in the survey agreed that it was their policy to enforce all food provisions, over half the agencies indicated that they were unable to do so in practice.[95]

Similarly, recognition of the regulations, and compliance with the GT Act, could be an issue. In New Zealand, it was reported in July 2000 that 18 per cent of GMO research projects had not been correctly authorised.[96] As Peter Pockley, Australian science writer and broadcaster, states 'the Environmental Risk Management Authority did not begin to flex its muscles until last April'. In fact, 152 out of 1065 GM experiments had not been approved. The application fee of $3000 per project may have been a contributory factor.[97] In Australia, breaches are reported to GMAC and are listed in their annual reports. When

the GT Act is in force there are provisions that require quarterly reporting of GMO licences issues, breaches of GMO licences and auditing of monitoring activities (section 136A.2) to the Minister. But mindful of possible recognition and compliance shortfalls, Recommendation 1 of the *Primary Producer Access to Gene Technology Report* was for constant and cautious monitoring, and public reporting.[98] And the GT Bill 2000 *Inquiry* recommended that:

> suitably qualified inspectors be employed by the Regulator to enforce the compliance provisions in the Bill.[99]

In the EU, despite Directives for genetically modified foods and crops, successful implementation is some time away because of the lack of testing methodologies, facilities and inspectors.[100] For example:

- The British Working Party on Food Authenticity, while agreeing that Real Time PCR (Polymerase Chain Reaction) techniques made it possible to differentiate between GM and non-GM soya there are problems below 1 per cent GM content of an ingredient.[101] (PCR tests for novel DNA sequences and ELISA (Enzyme Linked ImmunoSorbent Assay) tests for novel proteins. The EC has compiled costings which include: PCR tests take from 1-3 days, cost 104 - 310 euros per test and have been estimated to be 99.9% accurate. ELISA tests take between 2-8 hours, at 10 euros per test, and are 95% accurate. Another simpler ELISA test takes 5-10 minutes at 3.6 euros per test.[102]) GeneScan Australia Pty Ltd, with links to an overseas testing laboratory, is an example of an Australian company that has the capacity to provide a GM food testing service.[103] However, a recent UK government performance check for GM soy on 80 laboratories in 19 European countries found that 20 per cent of laboratories failed to detect GMO presence in foods, and 60 per cent of the sample reported a GMO presence when there was none.[104]

- A recent German survey found that over a third of tested food products contained GM corn or soya, 31 out of the 81 having less than 1 per cent GM content. That is, food manufacturers were not necessarily always complying. The surveyors were lobbying for the 1 per cent GM contamination threshold to be reduced to 0.5 per cent.[105]

In the US, the recent detection of Starlink GM maize (corn) in supermarket foods, including some Kraft and Taco Bell products, has also highlighted the ease with which non-approved GM products can be included in human foods. Starlink has been only approved for animal use because the pesticide Cry9 it contains may cause nausea and allergic reactions in humans.[106] Aventis has subsequently submitted new data to the USEPA, applying to allow Starlink to be permitted for human consumption for a limited period[107] of up to four years. The Starlink scare extends beyond US borders:

- Japan has detected traces of Starlink corn in imported US products

- New Zealand has stopped imports of products that could contain the GM corn[108]

- ANZFA, AQIS and the USFDA are investigating the Australian situation and at this stage, because Kelloggs (the distributor for Taco Bell) use local corn for their products, ANZFA considers that it is unlikely that Starlink has entered the human food chain in Australia. However, it is not known whether Starlink corn has been used in imported processed foods from the US. It is also not known whether Starlink has been imported as animal feed. Although Starlink is illegal in Australia, at the time of writing, it does not appear that any government agency is testing for its presence in foods intended for human consumption.

Antibiotic resistance

Antibiotic resistance marker genes are used to detect whether desired genes have been successfully inserted in cells. For example, genes may be inserted to confer desired properties e.g. production of a particular protein toxic to predators of the particular crop involved. The antibiotic resistant marker genes remain in some GM foods. The major question is: can antibiotic resistance genes transfer from GM foods to gut microorganisms and consequently be expressed in transformed cells?

The 1999 UK House of Lords Inquiry called for an end to the use of antibiotic marker genes[109] and Sir Robert May, the then UK Chief Scientist, and Professor Liam Donaldson, the UK Government Chief Medical Officer, supported the use of alternatives.[110] In 2000, the EU stopped short of banning them. While risks from antibiotic marker genes are deemed low, caution has been called for. Beyond the gene technology issue, there is concern about increased resistance to antibiotics generally. Unnecessary use of antibiotics is seen as unwise, whether as veterinary antibiotics administered to farm animals, or, in genetically modified organisms where antibiotic resistance marker genes are employed. A recent WHO/FAO report on the safety aspects of GM foods concluded that:

> … there is no evidence that markers currently in use pose a health risk to humans or domestic animals.

This is qualified by:

> In the case of genes that confer resistance to drugs important for medical use, the possibility of transfer and expression of genes is a risk that warrants their avoidance in the genome of widely disseminated genetically modified plants.[111]

In this light, IOGTR's statement about antibiotic-resistance genes in their risk analysis of Roundup Ready and Roundup Ready/Ingard cotton is somewhat surprising:

> Transfer of these genes to organisms other than bacteria would not present a hazard, since the antibiotics in question are only used to treat or prevent bacterial infections.[112]

While some dispute that antibiotic resistance genes, used as markers, could be transferred to gut microorganisms, it has been reported that foreign DNA can survive transiently in the gastrointestinal tract of mice and enter the blood stream. The 1992 USFDA *Draft Guidance* stated that it would be unlikely that antibiotic resistance genes, used as markers, could be transferred from plant genomes to gut microorganisms because there are no known mechanisms for the direct transfer of plant genomic DNA to microorganisms.[113] The 1998 *Draft Guidance* has tempered this approach indicating that the likelihood of such a transfer would be remote but the use of antibiotic resistance marker genes in crops should be examined with a number of questions in mind, including whether the antibiotic is an important medication e.g. vancomycin.[114]

- In their review, Beever and Kemp have described the detection of a plant DNA fragment in white blood cells of a cow fed a diet containing GM soybean meal stating, however, that DNA from the GM transgene could not be detected.[115]

- A recent, unpublished, German study by Kaatz found that herbicide resistant genes in rapeseed (canola) were found in bacteria and yeast in juvenile bees' intestines.[116] Brian Johnson, *English Nature's* top GM expert has said that the main question is whether the bacteria had incorporated the modified genes temporarily or permanently.[117] If indeed the bacteria and yeast have taken up a novel gene, with respect to human gut bacteria, this could potentially be problematic. Publication of this research is awaited with interest.

For regulators, the Kaatz study highlights uncertainty about biological and toxicological outcomes of the technology. It appears that the Precautionary Principle should be observed while the jury is still out.

Although viewed as a low risk phenomena, one suspects it could well be that the EU did not ban anti-biotic resistant markers because there are less risky options for the next generation of GM crops. For example, Novartis' new genetic marker, 'Positech', will enable them to phase out the use of antibiotic resistant markers where this is technically feasible. It is currently being tried with maize, wheat, barley, sugar beet and vegetables.[118]

Another concern is the use of viruses in genetic engineering. Some see this as perhaps even more dangerous because viral based human disease may be more difficult to manage than bacterially based disease. It has also been argued that recombinant viruses have the potential to cause increased losses in cultivated plants as well as affecting wild plant populations.[119] While it has been demonstrated that new viral strains can evolve through recombination between closely related strains under laboratory conditions empirical evidence is lacking for natural conditions.[120] Mae-Wan Ho from the Open University's Institute of Science and Society and Biology Department, also warns about the possibility that new viruses could be generated from the recombination between viral transgenes and viruses. That is, there is a potential risk for generating new infectious viruses.[121] There is considerable controversy as to whether it is risky or safe to use the cauliflower mosaic virus (CaMV), as a promoter. That is, CaMV is used to drive the expression of transgenes in a range of GM plants.

While this paper has predominantly used plant GE examples, there are significant concerns about the creation of GE viruses to control the fertility of feral pests, as exemplified by recent reports about a mouse virus genetically engineered by Australian researchers. The GE mousepox virus, with the capacity to produce large amounts of interleukin 4, dramatically increased the lethality of the smallpox virus by suppressing the immune systems of the experimental mice. The research could potentially be applied by bioterrorists to modify viruses that could be lethal to humans. The security implications are profound.[122]

GM animal feed, which is covered by the GT Act, has also attracted comment. Draft minutes of a recent meeting of the UK's Advisory Committee on Animal Feeding Stuffs were reported as stating that:

> The results indicate that DNA fragments large enough to contain potentially functional genes survived processing in many of the samples [animal feed] studied

While the UK Food Standards Agency spokesperson did not believe there were any health risks, the agency would continue to advocate compulsory labelling of foods derived from GM fodder fed animals.[123]

Allergens

A major GM food allergen management issue lies in questions about the adequacy of current safety assessments. Fortunately, problems may be identified before there is a commercial product. For example, according to the cited reference, CSIRO was advised to stop developing particular transgenic lupin and alfalfa lines. A sunflower gene had been introduced to each and the expressed sunflower protein was found to be an allergen in the pertinent lupin and alfalfa.[124] However, the Australian scientist concerned has received no such communication.[125] It is understood that a particular CSIRO transgenic line that contains a sunflower gene, is being developed specifically as a fodder to enhance wool production, rather than as a crop destined for use as a human food.[126]

Various decision trees that determine if foods have an unsafe allergic potential are in use. One such decision tree devised by the IFBC (International Food Biotechnology Council)/ILSI Allergy and Immunology Institute panel may be used to assess whether a product requires GM labelling or not in some countries. A 1999 report indicated that all elements in the decision tree could be criticised, particularly the tests proposed for assessing proteins from a source with no or unknown allergenicity.[127] Lehrer confirms that this is a challenge to the food industry. He tempers this by indicating that there is no cause for concern about allergenic potential for proteins introduced into foods from sources with no history of allergenicity, that have no amino acid sequence similarities to known food allergens, that are rapidly digested, and that are expressed at low levels relative to the

expression of major allergens. He suggests that allergy risk may be a higher priority in industrial countries than in emerging nations where nutrition per se is a higher priority.[128]

The previously mentioned Starlink maize situation (p. 27) is being watched with interest. Currently, the USEPA intends to examine new data submitted by Aventis that discounts claims about allergenic properties of the protein Cry9C.

Future Concerns

A Dutch report and technical literature study on implications of biotechnology for food safety provides a comprehensive overview of GM food safety issues, warning that beyond the first generation of GM crops, food safety evaluation would become far more challenging as an increasing variety of genes are introduced to crops. The authors argue that the concept of substantial equivalence will be of limited value where major GM modification has occurred. They state that:

> All genes that are used for the genetic modification will have to be assessed on an individual basis, but in addition the possibility of unintended side effects with relation to the safety or the nutritional characteristics of the plant products may increase. In order to maintain current safety standards for novel products, it will be necessary to augment efforts to develop more informative screening methods for unintended side effects of genetic alterations, such as mRNA-, metabolite-, and protein profiling methods. In addition to toxicological testing systems, both in vitro and in vivo, will be necessary in those cases where analytical studies are not sufficient to answer all food safety issues. With respect to the nutritional characteristics of genetically modified food products, it will become increasingly important to estimate intake levels of specific nutrients in different consumer groups.
>
> The safety assessment of genetically modified foods must be carried out according to the type of the genetic modification and the resulting alterations in the food product. No standardised safety testing protocols are available for (genetically modified) foods, in contrast to safety testing of pesticides, drugs and food additives.[129]

Environmental Fears

Biodiversity

To quote Environment Australia's submission to the Inquiry into *Primary Producer Access to Gene Technology* by the House of Representatives Standing Committee on Primary Industries and Regional Services:[130]

> Genetic engineering enables 'species barriers' to be crossed, with the potential to result in significant incursions on genome and gene pool integrity of natural species, populations and ecosystems … there is the potential for novel weed problems to be created, inserted genes to transfer to non-target species …

Cross-Pollination: The National Institute of Agricultural Botany (UK) has found, in a low frequency, cross-pollination between herbicide tolerant oilseed rape and adjacent plots of rape, producing sterile hybrids.[131] A major concern is the potential for cross breeding between GM and non-GM crops, and GM crops and related native species, especially given the cavalier way in which GM crops have been planted with insufficient buffer zones and refuges. In Australia, buffer zones are arrived at on a case by case basis. Arising regulatory issues include communication responsibilities and liability provisions.

Although the Canadian sister company of Advanta had used 4 km wide buffer zones (800 metre buffer zones are required), the GM-free oil seed rape seed that was exported to Europe from Canada was found to be GM contaminated. Advanta in Europe had assumed that there was no need to test the GM free seed in question because the 4 km buffer zone had been deemed to be sufficient. The UK's 50 to 200 metre buffer zones have now been called into question.[132] The UK Environment minister, Michael Meacher, speaking about the MAFF (Ministry of Agriculture, Fisheries and Food) review of buffer zone arrangements was reported as admitting that there was:

> … any distance which is going to prevent some contamination. The question is how we can minimise that to a level which is acceptable to those buying the product …

Furthermore, the MAFF had concluded that:

> Oilseed rape, maize and soya seeds from the US, Argentina, Canada, Australia, South Africa, Spain, France, Portugal and Romania should be viewed as suspect[133]

If a similar incident arose in Australia, where the Gene Technology Regulator had issued a licence with an insufficient buffer zone, the GT Act has very little liability redress without resorting to Common Law because it would appear that neither the GTR nor the grower can incur blame in such circumstances under the GT Act. Neither can the Commonwealth, States or Territories be prosecuted (section 6). Since many current trials of GM crops are carried out by government entities for industry, government agencies and officers, rather than industry, may be in the front line if liability questions are raised.

Apparently, there is no obligation to communicate to local property owners that trials or commercial plantings are occurring in their neighbourhood. GMAC provides details about current and proposed trials at its web site.[134] Despite this, there are claims about 'secret trials' and the lack of transparency of the approval process. The commercial-in-confidence conditions apply now, and will continue to apply under certain circumstances (section 185.3A) when the GT Act comes into force on 20 June 2001, meaning that it is possible that farmers of adjacent plots may not know what, in fact, has been introduced to their environment. Although local governments are notified about a proposed trial, it is not

clear whether all local stakeholders are identified or will be notified. One cannot assume that all farmers have access to the Internet to monitor developments for themselves. Neither is it clear who pays for the cost of local government notification and regulatory activity. The rights of a third party are not addressed in the GT Act.

A number of Australian incidents have drawn attention to uncertainty arising from lack of transparency. For example, have genetically engineered trial tree plantations been grown in Tasmania? Forestry Tasmania has denied that there are any GE tree trials underway while North Forest Products has indicated that GE had been 'dabbled' with at their North-West Tasmania laboratories.[135] 'Super trees' have been researched in Tasmania since the late 1980s.[136] Recently, Senator Herron's reply (for the Hon Dr Michael Wooldridge) to Senator Brown's questions on notice about 'small scale contained research' on species of eucalypt, acacia and pine was that there were four small scale *Eucalyptus* projects listed on the GMAC database. However, GMAC's records did not indicate 'if, when and where field trials are contemplated'.[137] While there are no commercial GE trees grown in the US and Canada, there are believed to be approximately 300 experimental trials in the US according to a recent US report on risks to the environment from GE trees.[138]

GM weeds: A number of cases of GM weeds have been noted. *New Scientist* reported that in South Carolina, where fields previously planted with GM cotton were planted with GM soybeans, GM cotton has become a weed which could provide refuge for the cotton boll weevil[139] and encourage the return of a pest that is currently under control. A Saskatchewan (Canadian) farmer, Percy Schmeiser, has been successfully prosecuted for breach of contract by Monsanto.[140] The farmer claimed that his farm was contaminated by GM canola, having never purchased seed from Monsanto. Schmeiser engaged in the age old practice of collecting and saving seed to plant the next season. On this occasion some of the resultant crop was found to be GM. While the farmer claims this happened because of cross pollination, Monsanto claimed that this could not be so. The farmer has launched a counter suit. There is no provision for this type of episode in the GT Act. This raises question about the weakness of the proposed regulatory provisions for liability on both sides of the fence.[141]

Bacterial Resistance: Recently, GMAC rejected a Western Australian application to inoculate guts of cattle sheep and goats with genetically modified bacteria to make them resistant to the active ingredients of 1080 arguing that there was a risk that the GE bacteria could escape into the feral animal populations. There was a risk that animals, such as rabbits, cats and foxes, could become resistant to 1080 poisoning.[142] While the vigilance of GMAC is reassuring, the incident alerts us to what could happen.

Pesticide Use: There are claims that range from the need to increase or decrease pesticide use when planting GMO crops. The fundamental reason for using GE crops is to lessen pesticide usage, not only because of costs involved but because the range of available pesticides is limited and their efficacy is reduced as target organisms become more resistant to them. For example, wheat farmers in Western Australia view prospective GM

wheat as the solution to their current problems because herbicides are becoming less effective.

Ecotoxicological effects are central to worries about increased pesticide use, along with human health concerns. Accordingly, in Australia, the NRA and ANZFA have examined glyphosate when making decisions about its use. The NRA reviewed glyphosate because of concerns about its toxicity to aquatic life and ANZFA has assessed glyphosate-tolerant soybeans.[143]

In terms of ecotoxicity, while glyphosate is seen as preferable to other herbicides, reservations may arise because of its increased use with the growing prevalence of GE Roundup Ready crops. Although inconclusive, Swedish oncologists Hardell and Eriksonn recently reported that exposure to the herbicide glyphosate increased risks to Non-Hodgkin Lymphoma (using a small sample). The authors stated that 'glyphosate deserves further epidemiological studies'.[144]

There is mixed evidence on claims as to whether GM crops use more herbicides than for conventional crops or not:

- Marlin Rice's study showed that between 1996-1998 US Mid West growers of Bt corn were able to reduce insecticide use each year, 26 per cent in 1998, 19 per cent in 1997 and 13 per cent in 1996.[145]

- Citing a range of pertinent papers, WWF Canada assert that emerging evidence demonstrates that GE crops do not necessarily reduce the need to use pesticides and that economic costs and benefits have been miscalculated.[146] In particular, they quote the report *Do Genetically Engineered Crops Reduce Pesticide Use* as indicating pesticide reduction benefits are overstated.

- The Australian disagreement between ANZFA and Dr Stanley Robert was, in part, about the amount of herbicide used on GM soybeans,[147] Robert maintaining that in the US two to five times more Roundup was used on GM soy than regular soy. As well as querying claims about reduced use of herbicides, Dr Robert questioned the results of some tests on GM soybeans supplied to health authorities because they were based on GM soybeans[148] that had not been exposed to preharvest spray.

- An EC review of economic impacts of GM crops, while indicating yields for GM soybeans may have lower yields than traditional crops, reported that, in the short term, there appeared to be cost savings and reduced herbicide use with GM soybeans. However, a study on Bt corn, although showing decreased insecticide applications, showed increased insecticide costs.[149]

Pesticide/herbicide reduction will vary according to local pests. But from a regulatory point of view, risks need to be ascertained, as demonstrated by some Australian examples.

Before the commercial release of Monsanto's Roundup Ready cotton was approved, GMAC would not allow commercial releases until Avcare and the Cooperative Research Centre for Weed Management, had developed guidelines, because of fears about herbicide resistant crops.[150] IOGTR, in their draft advice, recommended that Roundup Ready cotton should be approved, stating that it 'would pose no additional risk to human health and safety or to the environment', after GMAC had conducted a risk assessment. The recommendation was conditional on an appropriate management plan 'to minimise the potential for adverse effects' because GMAC had found that there were some risks if the crop was not correctly managed. (Note that the management plan issue was for SCARM (Standing Committee on Agriculture and Resource Management) to consider, not GMAC. SCARM comprises jurisdictional heads of agriculture related agencies including New Zealand and, in turn, reports to the ARMCANZ (Agriculture and Resource Management Council of Australia and New Zealand), jurisdictional agriculture ministers, including New Zealand.) The commercial release of Roundup Ready/Ingard cotton has been announced, subject to a management plan that takes into consideration the combination of the Roundup Ready herbicide resistance and Ingard pesticide resistance. IOGTR has agreed, subject to review if adverse effects are reported.[151]

The advent of herbicide-resistant plants has been accompanied by applications to vary maximum residue limits (MRLs) of pesticides for particular crops. Applicants request the lowering or raising of levels, or temporary MRLs to be set for a particular crop e.g. cotton, as do non-GM applicants.

Substantial equivalence and non-target organisms: An unexpected doubling of sugar levels in GM maize leaves, where the plant's seeds would have passed substantial equivalence tests, has suggested that changes may also have occurred in inedible parts of plants. This might have local ecological consequences.[152]

Bt toxin: Stanley Robert raised the question of Bt toxin produced in the roots of Bt corn, exuded into the soil, bound to soil particles and shown to be toxic to [insect] larvae.[153]

Compliance

The Mount Gambier incident, (see p. 10), was identified as constituting an environmental risk. Monsanto reported that 69 tonnes of GM cotton seed was accidentally mixed with regular seed, in Queensland, did not constitute a risk of contaminated seed being planted. Monsanto identified the mishap when undertaking an internal audit and reported the incident to the IOGTR. GMAC considered there was no environmental or health risk. It is understood that the seed was mixed in with regular cotton seed in cattle feed.[154] Those with concerns about GM animal feed might not agree. In both incidents controls were not sufficient.

To summarise, enough GM concerns have been identified to necessitate informed and directed Australian vigilance. In this light, the CSIRO has announced a three year study on GM cotton, clover and canola crops to identify environmental impacts and, if any, to explore mitigation strategies.[155]

Trade Implications

The International Service for the Acquisition of Agri-biotech Applications (ISAAA) has reported that 44.2 million hectares (109.2 million acres) of GM crops were planted in 2000, globally, an increase of 11% between 1999 and 2000. About 24% of the hectarage can be attributed to developing countries. The US, Canada, along with the developing countries, Argentina and China, grew 99% of the GM crop area. Australia grew 150000 hectares in 2000. While the global hectarage of herbicide tolerant soybean and cotton has increased, transgenic corn has markedly decreased in the US and Canada, and there has been a decrease in transgenic canola hectarage in Canada.[156] As well as consumer concerns, there is evidence that indicates international trade resistance to GM crops. Below are some surveys that point to this. For example:

- US Wheat Associates indicated that Japan, the Philippines, Vietnam, Malaysia, Singapore, Thailand, Bangladesh and Egypt expressed concerns about GM wheat.[157]

- A recent Australian Wheat Board marketing survey identified the Middle East and South-East Asia as customers who do not want GM wheat. They reported that non-GM grain was being stipulated in some contracts, and, given current estimates for separating GM from non-GM grain at between $5 and $30 per tonne,[158] the industry has cause for concern. (While co-mingling is fraught with trade risks, separation of grain would require duplication of storage, loading and transport facilities).

- Canada and Saudi Arabia asked the Australian Meat Council to confirm that Australian livestock is not GM fed. However, GM cotton seed meal is already being fed to Australian cattle. Because of the risk of a consumer backlash regarding meat and milk derived from GM fed stock, whether national or international, companies such as Bonlac Foods, Murray Goulburn and National Foods have indicated that they cannot risk using GM fed livestock.[159]

A range of manufacturers is declining to use GM ingredients: from the Scandinavian paper manufacturer Stora Enso[160] to Macdonald's. Some are refusing to use GM ingredients in some or all of their products e.g. Unilever, Nestle, Kraft.[161] Novartis decided more than a year ago that while continuing with their GM seed development research they would be phasing out the inclusion of GE ingredients in its food products, baby food and nutritional products being given priority.[162] (Note there have been concerns about phyto-oestrogen levels in baby foods - whether GM or not).

Litigation and Insurance

With incidents of insurance and legal consequences of alleged GE regulatory infringements being reported globally, an Australian examination of risks of litigation should be considered. Liability clauses in the GT Act may not be sufficient. Section 62(3) states:

> Licence conditions may also include conditions requiring the licence holder to be adequately insured against any loss, damage or injury that may be caused to human health, property or the environment by the licensed dealing.

Keir Bristow from the Melbourne legal firm, Corrs, Chambers and Westgarths discusses GM liability issues in the Australian context and cites a 1999 Australian High Court decision about the contamination of a South Australian potato crop by blight. He suggests that this could provide a framework for potential litigants in GM contamination suits. However, there are likely significant differences in cases of GM contamination. Bristow indicates that liability could arise out of packaging or advertising statements, regulatory regimes, industry production standards and contractual warranties.[163]

While the EU ducked extensive liability clauses in the revision of *Directive 90/220/EC* on deliberate release of GMOs, in April 2000, Friends of the Earth reported that new liability clauses were being written, with a view to their insertion in the final Directive.[164]

In one of the most litigious of the gene technology countries, the United States, despite the comparative leniency of national regulations, civil law litigation may well prove to be a major controller of the technology.

- An anti-trust, class action claim against Monsanto (No. 1:99CV0337) was filed in the US District Court for the District of Columbia, December 1999.[165] Allegations include inadequate testing of GM seeds and crops for human health and environmental safety prior to marketing them and the fixing of prices for GM seeds.[166]

- In July 2000, the US federal court dismissed a Greenpeace challenge about the use of Bt crops. The USEPA successfully presented documentation related to the safety of Bt crop.[167] A coalition including Greenpeace and the Sierra Club have threatened to sue the USEPA for failing to protect the Monarch butterfly, the USEPA view being that there is no risk to the butterfly.

- The Alliance for Bio-Integrity suit, filed in 1998, against various FDA GM regulatory policies was dismissed in October 2000.[168] The Alliance intends to appeal the decision.[169]

In the UK, in July 2000, Aventa threatened to sue the UK government after the Minister of Agriculture announced that GM contaminated crops were to be destroyed. Adventa had wished to sell the crops to countries that would accept them.[170] In May 2000, the UK

Minister had indicated that this incident demonstrated that there was a need for environmental liability provisions.

In California, proposed legislation allows for severe civil penalties entailing liability for twice the value of the plants vandalised, including testing, research and development costs.[171] In the UK, Lord Melchett and fellow environmental protestors who had removed a GM crop were found not guilty of criminal damage. They claimed that they had a lawful excuse to attack the crop because in so doing they were preventing contamination of other crops close by.[172] The Australian GT Act has provisions for conduct that either hinders GMO dealings or involves damage to premises or facilities where GMO dealings are undertaken (section 192A) with penalties that include imprisonment or fines.

Arising from the threat of litigation are insurance implications for those involved in delivering GM products to consumers. In Britain, the major farming insurance agent NFU Mutual has stated that GM contamination is 'gradual like pollution' and hence is not covered by those taking out their insurance unless the pollution is sudden and unexpected.[173] In order to protect the interests of third parties, some witnesses in the recent GT Bill 2000 *Inquiry* proposed that producers of GMOs should be insured for contamination events before the Regulator could issue a licence.[174] A Minter Ellison product liability specialist, David Poulton, recently warned that Australians were becoming more litigious and that until the Australian GM regulatory situation was clear, an option for insurers could be to use exclusion clauses as was done with Y2K risks.[175] The Insurance Council of Australia saw the difficulty being about assessing risks rather than the actual risks involved.[176]

Trade

While it may be argued that domestic regulation does not necessarily have to reflect the regulations of our trading partners, after all domestic and export quality products may be produced simultaneously, there may well be efficiency gains if there is some degree of production and regulatory harmonisation. Furthermore, no matter what Australia's stance will be with respect to international developments such as the *Cartagena Protocol on Biosafety*, the proposed international Codex Alimentarius GM standard and other international approaches to the management of GE, for trade reasons, Australia will need to accommodate them.

Further Information

Further information about the pros and cons of gene technology may be found at websites of the following organisations: the Australian Consumers' Association (ACA),[177] Agrifood Awareness Australia,[178] CSIRO's Gene Technology in Australia,[179] *The Submission to the*

Inquiry into the Gene Technology Bill 2000 of the IOGTR[180] and AGEN.(Australian Gene Ethics Network).[181] These issues were also discussed in the author's previous paper.[182]

7—The Management of Science in Government

It is understood that one of the considerations in drafting the GT Bill was to separate policy and process functions of the Ministerial Council and the GTR respectively. Teasing out science-based decision making and governmental policy is somewhat more difficult to achieve. For example, the inclusion of human cloning (section 192) in an Act about genetic modification, at face value, appears to have been driven by government policy rather than the science-based decision making that underpinned the development of the GT Bill.

The extent of the GE debate, has arisen (nationally and internationally), in part, because of a lack of administrative transparency, limited communication about the science involved, and existing regulatory regimes. Testimony to the extent of the GM debate is the explosion of Internet sites, including electronic fora,[183] reacting to the issue.

Slow governmental responses at international and national levels to what is a newish, but rapidly developing technology, genetic engineering, are manifest. (It should be noted that recombinant DNA technology laboratory experiments were first reported only in the early 1970s and the first field trials were underway by the mid-1980s). For example, the Codex Alimentarius Commission (CAC) is yet to agree to an international genetically modified food standard.

It is not unusual for regulation to follow some considerable time after extensive uptake of new technologies, e.g. copyright legislation, has lagged behind the widespread use of new media software. The GE scenario is different because health and environmental safety are involved as well as the intellectual property issues.

Despite the GT Act, Australia still has regulatory gaps. For example, as previously discussed (p. 1) the status of a procedure involving the insertion of a human nucleus into an enucleated human egg cell is unclear at this stage. The product will not be an exact duplicate of the organism that donated the nucleus due to mitochondrial DNA in the enucleated cell and possible nuclear DNA mutations. The GT Act does not cover somatic gene therapies or organisms declared by regulations not to be GMOs (section 10(d)). Down the track, the latter provision could be construed as unclear or it could provide flexibility for future technological developments. GT Act regulations may either stipulate or exclude organisms from being classified as GMOs. However, the regulations can be disallowed by either the Senate or the House of Representatives. Accordingly, in the future, the Parliament has the option to vote on the GM status of an organism.

As previously discussed (Appendix B), other Commonwealth agencies have administrative responsibilities also. The GT Act is limited to Commonwealth powers supported by a Gene Technology Agreement (GTA), a whole of government approach, which depends on States and Territories setting up either mirror or non-uniform GE legislation. If there is not clarity about what a GMO organism is at Commonwealth level, there is a risk that there may be differing State legislative interpretations.

Science - based Regulatory Communications

Limited and belated science communication appears to be central to the controversy. For example, at an international level, at a relatively late stage, in March 2000, the Ad Hoc Intergovernmental Task Force on Foods Derived From Biotechnology pledged to map out scientifically safe guidelines on genetically modified foods by 2003.[184] The panel was set up by the international WHO/FAO food standards setting agency, Codex Alimentarius (of which Australia is a member). While the G8 powers recently agreed in principle to set up a new independent panel to examine the safety of genetically modified foods, at their July 2000 Japan meeting, division about the panel's membership is as yet unresolved.[185]

For some, the science is important, e.g. British Prime Minister Tony Blair identified that it was important to proceed 'according to the facts and science' and in order for consumers to decide about GM foods 'they need the best science available'.[186] Robert May, the Australian-born penultimate UK Chief Scientist, pointed out, albeit with some acerbity, that complex questions about GM foods 'cannot be answered in a sound bite'.[187]

Legislators, as non-experts, also need the best science available communicated to them, especially when one considers that the government/science interface is handicapped by the comparatively small number of parliamentarians with science backgrounds compared to those with economics and law degrees. In the Australian Commonwealth Parliament only a few legislators have science degrees (this does not necessarily mean that they are scientists): four Senators (Bourne, Hogg, Gibson and Tchen) and Members (M Evans, Forrest, Hollis, Jenkins, Lee and Wooldridge). Additionally, there are seven engineers and 13 legislators with medicine or health qualifications. 33 Parliamentarians have economics degrees and 58 have legal qualifications.

Recently, in the US, some 65 members of the US House of Representatives launched the House Biotech Caucus, a bi-partisan group serving as a clearing house for credible, science-based information to all Members of Congress.[188] It is hoped that this may enable legislators to grapple with increasing amounts of proposed legislation that require some understanding of inherent scientific issues. In the United Kingdom, the Parliamentary Office of Science and Technology (POST) provides Parliamentarians with science information and analysis. POST is supervised by a Select Committee, which includes three external scientists. A similar approach in the Australian Parliament might be worth consideration.

Submissions to government inquiries are an important vehicle for gathering scientific as well as socially based view points. Legislators look to inquiry reports when making decisions. A further obstacle to adequate science communication in government could lie in the question—how representative a spread of scientific opinion is actually achieved through the submission process? Using the GT Bill *Inquiry* as a case in point, has a range of science based opinions been achieved, in addition to those viewpoints that are socially, industry or trade based? At face value, it appears that few individual scientists, who are not dependent on industry research grants, have contributed in a major way. Approximately half of the 124 submissions appear to have been provided by concerned citizens, with the rest coming mainly from industry and government, as well as consumer, environment and anti-GE groups.[189] Scientists in paid employment are not necessarily in a position to be able to contribute to such a debate. Perhaps the science in the submission process could be strengthened by paying for a range of scientific opinions from national and international sources.

Careful examination of the scientific bases for possible health or environmental risks sometimes either may not take place, or the range of scientific opinions garnered fails to be publicly communicated because of non-scientific drivers. For example, there is a possibility that an adequate informed and balanced examination of scientific risks involved may have been submerged in the case of the current GT Bill *Inquiry* by the Australian Parliament's Senate Standing Committee on Community Affairs due to the brief time allocated for the Inquiry. In New Zealand, for example, a Royal Commission is underway. In the United States, the National Academy of Sciences was commissioned to report[190] on the issue. The White House Office of Science and Technology Policy and the Council of Environmental Quality are to undertake a six month study on the regulation of agricultural biotechnology.[191] In the United Kingdom, there have been a number a science-based government reports.[192] The most recent Commonwealth government inquiry was devoted to primary producer access to gene technology,[193] i.e. there was an agricultural industry based emphasis. There has been no recent Australian inquiry looking at GM health and environmental risks. A further example arose from a lawsuit between the Alliance for Bio-Integrity and the USFDA, in 2000. Previously undisclosed divergent scientists' opinions about the safety of GM foods were identified in USFDA 1992 files. While the USFDA said that they were merely examining points of view when examining the safety of GM foods, the lack of public communication in 1992 about the range of opinions was viewed by some with alarm. The Alliance used the reservations by some USFDA scientists about GM foods to call for mandatory testing and labelling of GM foods.[194]

Government and Industry and Science

The relationship between government and industry with respect to science funding, standards setting and communications strategies contributes to the nature of the debate. The $30.5 million announced in July 2000 to support Australia's Biotechnology Strategy was welcome (included $20m to set up a Biotechnology Innovation Fund, $3.3 million to identify the supply chain management of GM foods and $250 000 on an environmental risk study), but

critics can be found on both sides of the fence. On one hand it was suggested that our researchers lack the funding to take ideas beyond the 'proof of principle stage'.[195] On the other, what is the proportion of government funding for basic GE research to applied GE research? To what extent are industry stakeholders involved in government funded communications strategies? How much government funding is given to non-industry related GE communication strategies? How many scientists on government standard setting bodies are not receiving industry funding? While a strong relationship between university research and industry is strategically important for future Australian research output and technological development, as identified by the recent Australian Research Council report,[196] therein lies the potential for the independence of scientists to be compromised, along with science communications.

Scientists For and Against

There are those that may dispute that anything new has happened with the advent of applied genetic engineering, perhaps arguing that there is nothing new about humans artificially breeding more productive crops and animals. This stance is questionable in itself, because GE adds a new dimension, which frequently involves cross breeding with unrelated organisms, as opposed to traditional artificial selection, which involves cultivars within a species or closely related species.

There may be the expectation that there is little need to consider and minimise environmental and health risks by those who see few risks inherent in the commercialisation of GE technologies. These supposed certainties have had to be revised as contrary information has come to light. In part, the public backlash against GM foods has been engendered by a distrust of unequivocal, unbalanced claims about the safety of GE technologies. Sir Gustav Nossal, in favour of GM food labelling, has counselled that while GM food will be accepted eventually, the acceptance process should not be rushed until the public debate had been played out.[197]

Sweeping statements about being for or against GM food are about as meaningful as backing a horse at the races without studying the field's form. There are many notable scientists, who like Nobel laureate Peter Doherty, see great benefits to be derived from biotechnology and their views and vision about the promise of biotechnology should be heeded and valued. Scientists on both sides of the argument have contributed to petitions. Recently, Dr C. S. Prakash, in order to support his positive biotechnology stance collected signatures of over 2,600 scientists.[198] The World Scientists' Statement launched at Cartagena in February 1999 during negotiations on the *Cartagena Protocol on Biosafety* called for:

> … the immediate suspension of all environmental releases of GM crops and products, both commercially and in open field trials, for at least 5 years; for patents on living processes, organisms, seeds, cell lines and genes to be revoked and banned; and for a comprehensive public enquiry into the future of agriculture and food security for all.[199]

The Union of Concerned Scientists (UCS) in the United States has stressed the need for 'societal evaluation of the impacts of and alternatives to new technologies' and the need for a new US GE regulatory framework.[200] The UCS makes a useful distinction between different GE applications and their risks. On one hand, there are circumstances where GE risks are taken where benefits outweigh risks in situations such as basic research, or where individuals **choose** to take advantage of drugs obtained by the use of genetically engineered organisms, for example, those that rely on regular injections of insulin. The UCS indeed applauds these approaches. On the other hand, they question whether even small risks are worth taking where benefits are few, the risks are to be taken by society at large (and not by choice), and where alternatives exist.[201]

8—Communicating about Risk

The Senate Standing Committee on Natural Resources reported in 1979 that there was no such thing as 'no risk' or 'zero risk' and that 'scientific evaluation of 'acceptable risk' was a more accurate description of quarantine policy. Consequently, the Nairn report, in the context of quarantine, examined stakeholder needs, in the light of 'import risk analysis', that is, consultation, scope and resource requirements. Communication with stakeholders and the general public was viewed as essential.[202]

A fundamental problem in the risk assessment approach is the creation of quantitatively based, scientifically evaluated, risk assessments. Hard data is frequently not available. It is for this reason that the CSIRO has embarked on a three year study on the ecological implications on GM crops for Australia. Various mathematical models applicable to GM plants have been developed at the University of Melbourne, that demonstrate that risks can be assessed quantitatively in a transparent and repeatable way. One paper concludes that risks to wild populations may be appreciable.[203] One model simulation pertains to the competitive interaction of GM crops with related wild species in adjacent stands. This is discussed in the authors' submission to the IOGTR on the commercial release of INGARD (Bt insect - Resistant) cotton. The model yields an estimation that there is a 91 per cent chance that 1 per cent of a wild crop would be hybridised in 10 years, rising to a 99.7 per cent probability in 20 years.[204] However, in the long term, quantitative assessment of CSIRO's field data is required.

When weighing up risks and benefits from GMOs, in Australia, it should be noted that significant GE research is directed towards potential therapeutic applications. Individuals will choose to be exposed to low risk specific treatments where there are obvious benefits. Recent examples of communications by peak bodies that convey varying degrees of concern about genetic engineering risks include:

- Industry benefit, rather than individual choice and benefit, could well have been the motivation behind the New South Wales Farmers' Association decision when, in July 2000, it endorsed genetic research and the release of genetically modified (GM) products.

It should be noted that this was agreed to by a narrow margin and there was a codicil to the decision, that stringent government controls were met and that the technology benefited existing agricultural industries.[205]

- In July 2000, the Australian Consumers' Association (ACA), the Public Health Association of Australia (PHAA) and the Australian Medical Association (AMA) wrote to the Prime Minister and jurisdictional leaders arguing that many people require comprehensive GE food labelling to protect their health.[206] That is, in their opinion, unlabelled food presented an untenable risk. It should be noted that one of their science based arguments related to the antibiotic resistant marker gene issue. This argument could well be negated in a matter of years because of the development of an alternative marker or by a prospective chimeraplast (DNA/RNA molecule) technique that works, for some applications, without transferring genes between species.[207]

- The biotechnology industry has increasingly demonstrated that not only does it recognise government and consumer concerns but has reacted with public relations efforts about the benefits and risks of gene technology. For example, Agrifood Awareness Australia[208] which comprises the Australian Biotechnology Association (ABA), Avcare, the Grains Research and Development Corporation (GRDC), the National Farmers Federation (NFF), the National Association for Marketing Agricultural Commodities (NACMA) the Seed Industry Association of Australia (SIAA) has embarked on a public awareness campaign.

- EuropaBio's (the European Association for Bioindustries) paper about risks in the use of biotechnology is of interest not only because of its support for the forthcoming EU central food safety authority which hopefully could help reduce GE mishaps, but also, because its requirements are in stark contrast to Australia's proposed patchwork style GE framework. That is, as previously discussed, and as illustrated in Appendix B, there are a large number of administrative players. It could be argued that Australia's framework may have been designed, in part, to avoid the OGTR from stepping on turf of other Commonwealth agencies with existing GE responsibilities. The limits of Commonwealth versus State powers, as discussed in the *GT Bill 2000* Bills Digest[209] may be seen to be part of the problem also. EuropaBio recommendations were:

    - That any new agency created to evaluate food safety, also includes within its remit all safety evaluations of seed and plant products, especially those developed using biotechnology, including environmental risk assessments

    - That any agency created to carry out this task be given the authority to make final, binding decisions following safety assessments by units of the agency

    - That all Regulations and Directives relating to the regulation of seed and plant biotechnology products be amended to ensure comprehensive assessment of future products by the new agency

- That the new agency also be charged with co-ordination and assurance of regulatory compliance in the field once products have been approved. This is the area of greatest concern to consumers.[210]

The sticking point, at the end of the day, is that genetically engineered foods, in the short term, hold a promise rather than an immediate benefit to the average consumer in a developed country, particularly in a country such as Australia that rejoices in high quality unprocessed foods. For developing countries, GE crops such as 'golden rice' are seen by some to hold the promise of a second Green Revolution. The University of Melbourne agriculturalist, Professor Lindsay Falvery, argues that a major difference between the Green Revolution and the GE technology promise is that technology transfer to developing countries, including adaptive research, occurred in the Green Revolution, but 'this is not the current phase of GMO technologies.'[211]

The GT Act, GE and the Press

There has been a dearth of informed reporting about the merits or otherwise of the GT Bill, its tabling in June raising little comment in the press. Subsequently, there have been few attempts to give due credit to this complex document and the implications of the GT Act itself. Informed debate could have helped to strengthen and refine the proposed legislation. Although the IOGTR had made a concerted effort to engage in widespread stakeholder dialogue throughout Australia, the GT Bill was conceived prior to many countries signing (but not ratifying) the international agreement, the *Cartagena Protocol for Biosafety* (the *Biosafety Protocol*). It was written prior to quite significant shifts in national and international biotechnology industry viewpoints, along with changes in biotechnology regulations in the EU and the United States.

In a broader context, Professor David Tribe recently wrote:

> Where is the debate in the newspapers? Why are the advantages of GM food and the compelling reasons for its development not being clearly put in a balanced debate? Ultimately, we all depend on science for almost everything in our lives; the most urgent task of the media is to help us understand the issues in a more balanced way.[212]

It is unfortunate that the GM press generally discusses 'should we' or 'shouldn't we', when we 'are' clearly living in a GM world, rather than devoting more space to the implications of the proposed regulations and alternative regulatory options. In an attempt to address this problem, with a view to encouraging more in depth journalism, Agrifood Awareness Australia conducted a two day 'Gene Technology For Journalists' course with a special emphasis on providing participants with informed contacts.[213]

The Scientific Literature

A recent letter in the journal *Science* by a Spanish toxicologist noted the absence of citations of studies performed by biotechnology companies and asked:

> … why have the results not been subjected to the judgement of the international scientific community, as would be the course if such research were published in reputed journals?

He suggested that the companies should do so stating that:

> The general population and the scientific community cannot be expected to take it on faith that the results of such studies are favourable. Informed decisions are made on the basis of experimental data, not faith.[214]

It could be that his search of the medical literature (via the Medline database) might not have been definitive. Also, a significant amount of the literature may be included in plant or agriculture based databases rather than medical ones. For example, *Biosafety* web pages provide an up to date database on biosafety studies.[215] It is quite possible that the absence of citations may be due to commercial-in-confidence restrictions that are constraining, not just biotechnology companies, but scientists in universities and other research institutions from publishing their research in the public domain. This only strengthens concerns about the lack of adequate peer reviewed comment about the safety of GMOs, based on experimental data, in the public domain, but alerts us to yet another problem currently being examined in the United States, in another context, the high cost of therapeutic drugs.

The argument, opposed by the pharmaceutical and biotechnology industry and research institutions, is that industry should set reasonable prices for drugs that have been developed with the aid of publicly funded research. The GMO literature situation could be viewed as analogous, in part, because, in addition to the lack of a substantial peer reviewed scientific literature about the safety of GMOs in the public domain, there is the question, if gene technology research was in some way subsidised by public funds, to what extent should governments pursue the recipients' obligations to record results in the public domain? At face value, this is a simple question, but governments must grapple with compromise. National research excellence and attendant economic advantages (and survival) derived from strong partnerships with industry must be balanced, and seen to be balanced, with biosafety and adequate public communications. The way forward is not through public relations exercises which are inherently distrusted by the public, but by balanced and informed public science communication programs.

Concluding Remarks

Australia is approaching its first comprehensive gene technology regulatory platform while the EU and the US are involved in subsequent regulatory rounds. The establishment

of the Office of the Gene Technolgy Regulator (OGTR) is not expected until 20 June 2001. Growing consumer concern and increased concrete information about environmental impacts make it likely that the EU and US will need to make further regulatory adjustments. Australia will be compelled for trade reasons to develop a domestic regime that is consistent with international obligations. Australia must adopt a definite position about how processed foods and crops are labelled and tracked in a fail-safe manner. Australia must be able to guarantee what it promises to deliver, whether crops and products are labelled as 'GM', 'GM free' or 'may contain GM'.

The marketing of GM foods prior to the comprehensive development of appropriate testing technologies and protocols, wariness about data presented by applicants along with the lack of credible management frameworks and communications have fuelled consumer unease. Insufficient stakeholder consultation in the development and commercialisation of GMOs in the past has resulted in considerable questioning and public distrust, arising from ethical, political and scientific worries. Although Australia does not have a Bill of Rights, in practice, there is a general expectation that food choice, whether for personal, health, environmental, religious or ethical reasons, is a democratic right. The last year has seen a realisation by governments, industry bodies, scientists and farmers that viewpoints beyond their own, require accommodation, and, not to do so is to be out of step with community expectations about how decisions about our society should be reached.

In Australia, negative environmental and economic consequences of introduced weeds and feral animals could have been prevented if timely, science-based governmental oversight had been the norm. In hindsight, some of the GE controversy may have been preventable if governments' regulations had kept abreast of scientific and business activity. Starlink GM corn (see page 27) and Chardon LL cases (see page 24) have highlighted the lack of vigilance by government agencies, the whistle was blown in both cases by non-government bodies. The GM furore can be viewed as a salutary lesson for the management of future technologies and the need for regulators to decrease the knowledge gap with respect to legislation and policy for all stakeholders. After all, biotechnologists were surprised when confronted by consumer reaction to GM foods and consumers were perplexed by a little understood science.

The GT Bill was placed before Parliament at a time when questions were raised about the effectiveness of compliance with existing GMAC guidelines. The GE era has occurred at a time when government is shrinking and the private sector has been encouraged to fill the void. Unfortunately this is happening at a time when sophisticated technologies require extensive scrutiny so that there are no biosafety breaches. It is difficult to promise certainty, or low risk scenarios for GMOs when testing of GE products is in its infancy. While it is likely that future GE developments may remove risks associated with the first generation of GMOs, the second generation of far more complex genetically engineered interventions will require even keener scrutiny, better science and safety protocols.

For some the need for the Precautionary Principle approach, as advocated by the EU, may seem excessive. The United States' view is that:

> We agree that precaution can be an integral component of regulatory decisions, and that decisions usually need to be made in the face of uncertainty … without clarity of definitions and practical applications, the Commission's [Codex Alimentarius Commission] proposed precautionary principle could continue to raise concerns, particularly for use against foreign goods and services[216]

However, if health and environmental safety are regarded to be paramount, then society will have to pay for any remediation of mishaps in the future, and Australia's legislative, regulatory and enforcement position should reflect this. Certainly, recent contamination scares in US, EU and Australia, and claims about the extent and adequacy of Australian GM food assessments[217] have highlighted inadequacies in current systems. Although this paper has mainly focussed on the science/government interface, informed outcomes from this interface must be in accord with community requirements for consultative communications, legislative strategies, and, most importantly, actual biosafety.

Appendix A

Surveys

- An April 2000 AC Nielson survey of 950 people found that 68 per cent were not happy about eating GM food and 90 per cent of those surveyed believed GM foods should be labelled. Only 20 per cent believed that GM food provided benefits and would be happy to eat it and 12 per cent did not believe there were benefits but were happy to consume it. Less than 20 per cent felt that they had been well informed, despite the government GM brochure designed for distribution in supermarkets. Essentially a strong scepticism was revealed.[218]

- An ANZFA survey found that 91 per cent favoured mandatory labelling of all foods produced using gene technology, 73 per cent would pay more for food declared GM-free and 74 per cent would not buy GM food regardless of the price.[219]

- A Good Business Sense survey conducted in the first quarter of 2000 found that 71 per cent of consumers did not wish to purchase GM foods.[220]

- Food industry members of Australian Business Limited in March 2000 were shown to be predominantly in favour of GM food labelling.[221]

- An Australian National University survey (by the International Survey Project) showed that support for GM labelling had grown from 90 per cent in 1994-5 to 96 per cent this year.[222]

- Biotechnology Australia, in a survey conducted by Quantum Market Research in May 2000, ranked issues of concern and the findings were: food poisoning (72 per cent), pesticide use (68 per cent), human tampering of food (65 per cent) - and GM foods (58 per cent). The survey also identified consumers' need for more balanced and factual information.[223] Biotechnology Australia further reported in July 2000 that 65 per cent of all respondents would eat GM foods if there was a benefit and that 37 per cent of people said that labels on GM foods would not alter their food purchasing.[224] It is understood that a further 9 per cent would actively buy GM foods, however, the results of the full survey are not available in print.

- In July 2000, a further AC Nielsen survey found that 93 per cent wanted GM food labelled and 65 per cent did not want to eat it. 21 per cent women and 33 per cent men said they would eat it. 23 per cent women and 37 per cent men supported GM drugs.[225]

- The Yann Campbell Hoare and Wheeler study commissioned by Biotechnology Australia focussing on the wider issue of biotechnology (rather than genetic engineering) indicated that of the 74 per cent of participants who had heard of biotechnology, 56 per cent thought that biotechnology would improve our way of life and 6 per cent thought that it would make things worse. When questioned about genetically modified animals used for medical purposes, 82 per cent saw this as a useful application for society, 50 per cent that there was some risk, and 60 per cent that such an application was acceptable. There was less enthusiasm by respondents when asked about inserting human genes into animals, 45 per cent not viewing it as being morally acceptable. Modifying genetic material of plants had the highest acceptability at 68 per cent but 63 per cent believed that inserting pest resistant genes into plant species carried risks[226].

- Market Attitude Research Services reported that 52 per cent saw large companies as the only biotechnology beneficiaries while 37 per cent disagreed and 10 per cent didn't know. 67 per cent thought that biotechnology should be introduced gradually while 20 per cent disagreed.[227]

Appendix B

Commonwealth Arrangements

Department of Health and Aged Care

The Minister has overall responsibilities for the following agencies:

Therapeutic Goods Administration (TGA): IOGTR has been placed within the TGA, with the acting Interim Gene Technology Regulator reporting to the Head of the TGA. On June 20 2001, the *Gene Technology 2000 Act* will come into force and the Office of the Gene Technology Regulator will commence. The TGA, under the *Therapeutic Goods Act 1989*, is responsible for human GE therapeutics. The Genetic Manipulation Advisory Committee (GMAC) currently examines GE applications. Formerly within the Department of Industry Science and Resources, it is now within the TGA. The Minister of Health and Aged Care appoints GMAC members.

- Under the GT Act (GTA) GMAC (the Genetic Manipulation Advisory Committee) will be replaced by the GTTAC (Gene Technology Technical Advisory Committee).

- Under the GT Act the Gene Technology Regulator (GTR) will be responsible for administering all gene technology regulatory matters that do not impinge on the GE administrative and/or regulatory obligations of other Commonwealth departments or the policy guidelines of the Ministerial Council specified in the *Act.* A role of the GTR is to assess specific applications. It is not clear in the *Act* where the statutory independence of the GTR ceases and the Ministerial Council's policy guidelines takes over in cases that could arise where specific crops are named in policy guidelines.

- During the two year transitional period after the enactment of the GT Act, GMAC approved GMOs will be treated as if a GMO licence has been issued for them (section 190).

ANZFA, under the *Australia New Zealand Food Authority Act 1991*, administers the Australian *Food Standards Code*, including *Standard A18 Genetically Modified Foods.* Significant changes to standards must be approved by the Ministerial Council, the Australia New Zealand Food Standards Council (ANZFSC) which comprises Health ministers from all jurisdictions.

The National Health and Medical Research Council (NHMRC) funds and supports research and also provides research guidelines.

Department of Industry, Science and Resources

Responsibilities include the activities of non-educational science organisations such as CSIRO and the development of biotechnology industry in Australia.

Biotechnology Australia has responsibility for the development of consumer public awareness strategies in consultation with Australian biotechnology industries, as well as implementing the *National Biotechnology Strategy*.

Agriculture Fisheries Forestry–Australia

In addition to their Biotechnology Policy group:

The Australian Quarantine Inspection Service (AQIS) has operational border control responsibilities for import and export matters. Duties include protecting Australasia from the introduction to Australia of products or living materials considered as potentially dangerous. (AQIS makes decisions that are consistent with ANZFA and TGA guidelines and policies).

The newly created policy arm, Biosecurity Australia, has responsibility for import risk analysis for both plants and animals and their products and operates in accordance with international standards consistent with World Trade Organisation (WTO) requirements. Biosecurity Australia will be responsible for any technical assessments, eg. risk assessments, called for by the WTO.

The National Registration Authority (NRA) is responsible for approving agricultural and veterinary products for use in Australia. (With the creation of the IOGTR, the NRA's role is limited to registering chemicals for use on crops e.g. glyphosate on Round-up ready cotton. However, prior to the existence of the IOGTR, in the case of Bt cotton, the crop had to be considered as a pesticide. In future, Bt crops will be considered by the GTR).

The Bureau of Rural Sciences' Food and Gene Technology Program examines agricultural implications of gene technology, provides the Department with scientific and technical advice and examines the management of commercial transgenic crops in Australia.[228]

Department of Education and Youth Training

The Australian Research Council provides research funding to Australian universities, research institutes, CRCs (Centres for Research) etc.

Department of Employment, Workplace Relations and Small Business

The National Industrial Chemicals Notification Scheme includes industrial chemicals that may contain biologically active constituents.

Department of the Environment and Heritage

Under the Environment Impact Assessment (EIA) provisions of the *Environment Protection and Biodiversity Conservation Act 1999* (EPBC Act), the Environment Minister can veto activities involving GMOs on the grounds of their impact on 'national environment significance' provisions (under Part 3 of the Act).[229] However, the Minister cannot order an EIA to be undertaken for a GMOs per se. GMOs are not listed as of 'national environmental significance' in the EPBC Act (Division 1 Part 3).

The interface between the EPBC Act and the GT Act is uncertain. An amendment to the EPBC Act, which would have ensured that all GMO releases were vetted by the Environment Minister, has not been taken up. It is understood that the Democrats agreed with the Environment Minister to pass for the EPBC Act last year on the condition that such an amendment was subsequently made.[230]

Further details about Australia's existing administrative situation may be found at the IOGTR web site.[231] Biotechnology Australia also provides a comprehensive link page to government agencies with responsibilities for GMOs.[232]

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