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Senator John Quirke	ALP, South Australia
Senator John Tierney	LP, New South Wales
Senator John Watson	LP, Tasmania

Senator Sue West	ALP, New South Wales

LIST OF ACRONYMS

AAT	Administrative Appeals Tribunal
AD(JR)	Administrative Decisions (Judicial Review)
ABA	Australian Biotechnology Association
ACEL	Australian Centre for Environmental Law
ACF	Australian Conservation Foundation
AFGC	Australian Food and Grocery Council
AGS	Australian Government Solicitor
ALRC	Australian Law Reform Commission
ANZFA	Australia New Zealand Food Authority
AQIS	Australian Quarantine and Inspection Service
BA	Biotechnology Australia
CSCG	Commonwealth State Consultative Group on Gene Technology
CSIRO	Commonwealth Scientific and Industrial Research Organisation
CFN	Consumer Food Network of the Consumers' Federation of Australia
DHAC	Department of Health and Aged Care
EIA	Environmental Impact Assessment
EPBC Act	Environment Protection and Biodiversity Conservation Act 1999
GEFZ	Genetic Engineering Free Zones
GMAC	Genetic Manipulation Advisory Committee
GMO	genetically modified organism
GM	genetically modified
GTCCG	Gene Technology Community Consultative Group
GTEC	Gene Technology Ethics Committee
GTR	Gene Technology Regulator (also referred to as 'the Regulator')
GTTAC	Gene Technology Technical Advisory Committee
HSI	Humane Society International
ICA	Insurance Council of Australia
IGA	Intergovernmental Agreement on Gene Technology
IOGTR	Interim Office of the Gene Technology Regulator
MLA	Meat and Livestock Australia Limited
NGAA	National Genetic Awareness Alliance

NFF	National Farmers' Federation
NHMRC	National Health and Medical Research Council
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NRA	National Registration Authority
OFA	Organic Federation of Australia Inc
OGTR	Office of the Gene Technology Regulator
TGA	Therapeutic Goods Administration
WTO	World Trade Organisation
WWF	World Wide Fund for Nature

PREFACE

This Senate report is very timely. There is widespread and growing community debate about gene technology and increasing concern about health and environmental issues. The community has learned to be cautious about claims by governments, corporations and scientists that things are safe for them. The benefit of DDT and, more recently, the safety of British beef during the mad cow disease episode are just two claims that have engendered considerable scepticism.

The Senate inquiry into the Gene Technology Bill 2000 has provided a great opportunity for serious discussion about this legislation and whether it will provide the protection the community wants.

The Bill is an important piece of legislation designed to protect the public health and safety of people and to protect the environment from risks associated with gene technology.

A broad range of interested individuals and organisations and the community generally expressed their concerns and fears about aspects of the Bill, and in particular, the adequacy of the proposed regulatory framework to address these concerns.

There were a number of features to emerge from our inquiry. One of the most important was the significant number of and qualifications of scientists opposed to, or very concerned about, gene technology, its applications and possible consequences. Protagonists of gene technology who described opponents as ‘a noisy minority’ or ‘extremists’ did not reflect the breadth of concern in the community or the weight of serious and scientific opposition. And they did little to persuade people to their point of view with such derogatory language.

The importance of community consultation and community involvement in decision making was emphasised during the inquiry. The Committee was told that there is a need for Government to listen to the community, to explain developments in the rapidly evolving gene technology area and to have regard to community concerns in this area. The Committee heard that the community has more concerns about gene technology used in food than other areas, for example pharmaceuticals, where there is significant research and testing before products are released for use.

A common emphasis during the inquiry was that industry and researchers cannot be relied upon to be sufficiently rigorous and objective in evaluating risk and implementing appropriate strategies to manage those risks – at least to the level where the community can feel reassured.

There remains a great need for community education. While the level of concern about possible risks is growing in the community, there is still inadequate information – particularly information that is impartial, unbiased and comprehensive – available to the community and consumers to evaluate the risks associated with gene technology.

Individuals also have difficulty in assessing and processing available information to help them make informed choices. The Committee attaches great importance to ensuring that a national education campaign, by an independent source, be implemented to provide information on gene technology and its potential risks.

Many other concerns were raised during the inquiry. These include the language used - whether gene technology is the same as genetic modification, genetic manipulation, genetic engineering or transgenic processes. Modifying the language to try and assuage peoples' concerns seemed, on the evidence to the Committee, to only add to a suspicion about what exactly the protagonists were doing.

One major area of concern was the gene crossover, sometimes described as transgenic, from one species to another. There was much less concern about wheat genes being used in wheat than bacterial genes being used in wheat for example. The use of viral promoter genes was a cause of even graver concern, in particular what might be the consequences of viral changes in subsequent generations. The Committee was told that little to no research had been done on later generation viral consequences. Assurances that there is 'no evidence' of harm may in fact mean no research has been done, and that worries the community. While there may be genetic exchange between species occurring in nature, genes from fish do not get into tomatoes under normal circumstances.

The Committee is concerned that the great weight of responsibility of decision making in this area should fall on more than one person – hence the Committee's recommendation that the Regulator be a statutory authority not a single individual. Further, there should be opportunities to appeal decisions of the Regulator by third parties as well as licence applicants.

Other areas of concern include the importance of providing for GM-free zones, issues related to animal welfare, human genes used in animals, deficiencies in the risk assessment processes and investigative capacities of the Regulator and concerns over the cost recovery, funding measures and insurance.

Due to the wide ranging nature of the issues and concerns raised, the Committee believes that the Bill when enacted will require close supervision and ongoing assessment with a need for an independent review in three years – much sooner than the current proposed review after five years.

Australia needs an effective regulatory system that is open, transparent and accountable. The consequences of 'getting it wrong' are too grave to contemplate, especially in the longer term. The proposed regulatory regime needs to ensure that there is widespread community confidence in the system. Australia's regulatory system should represent international best practice.

Overall, the Committee found that the Bill to introduce regulation into the gene technology area is overdue and very welcome. However, the weight of evidence supported a great deal of caution. That is why the report is called - *A Cautionary Tale: Fish Don't Lay Tomatoes.*

RECOMMENDATIONS

Chapter 3

The Committee RECOMMENDS that the risk assessment provisions of the Bill should be amended to give greater weight to the consideration of the impact of the release of GMOs into the environment, especially given Australia's unique flora and fauna and the importance of maintaining Australia's biodiversity.

In view of the confusion caused by the lack of clarity on the status of medical research, and particularly human medical research, under the legislation the Committee RECOMMENDS that the Bill be amended, where appropriate, to explicitly state how such research will be dealt with by the OGTR.

The Committee RECOMMENDS that relevant State and Territory animal welfare legislation and the NHMRC code of practice for the care and use of animals for scientific purposes, be examined to determine whether more stringent provisions need to be applied with respect to animals and genetic modification.

The Committee would consider it undesirable if commercial in confidence information compromised the objectives of the Bill or the transparency of the regulatory regime, and RECOMMENDS that where an application for an intentional release of a GMO into the environment includes the size and location of this proposed release, the information should be made available publicly providing that the penalties for any intentional damage to that release are an effective deterrent against eco-terrorism.

The Committee RECOMMENDS that an independent organisation conduct a national public education campaign to provide information on the benefits and risks of gene technology, drawing on, but not limited to, the expertise of scientists, primary producers, academics and consumer organisations.

The Committee RECOMMENDS that the operation of the Act should be independently reviewed after three years to ensure that its objects are being met.

Chapter 4

The Committee RECOMMENDS that an individual with a financial or other interest in a regulated entity be precluded from holding the office of Regulator.

The Committee RECOMMENDS that an individual who has worked for a regulated entity be precluded from holding the office of Gene Technology Regulator until the expiration of a two-year period.

The Committee RECOMMENDS that the Bill be amended to include a requirement for quarterly reporting by the Regulator and that these reports include relevant

information on the functions and operations of the Regulator including facilities licensed and breaches of licence conditions.

The Committee RECOMMENDS that the Regulator be established as a statutory authority consisting of a board of three people who will take ultimate responsibility for decision-making.

The Committee RECOMMENDS that as part of the review of the scheme as recommended by the Committee, the review consider the feasibility of introducing a 'one-stop shop' model having regard to the operational effectiveness of the proposed 'gap filler' arrangements.

The Committee RECOMMENDS that the Objects of the Bill contain the same words that appear in the *Environment Protection and Biodiversity Conservation Act 1999* in relation to the Precautionary Principle.

The Committee RECOMMENDS that in preparing risk assessment and risk management plans for the intentional release of GMOs into the environment, the Regulator be required to follow a process that should be no weaker than the Environmental Impact Assessment process set out in the *Environment Protection and Biodiversity Conservation Act 1999.*

The Committee RECOMMENDS that a complete listing of broad categories of risk that the Regulator must consider as part of the risk assessment and risk management plans, be prescribed in the regulations to the Bill.

The Committee RECOMMENDS that the Bill be amended to require that in prescribing or imposing conditions of licences, the Regulator may satisfy him or herself that applicants have made provision for suitable insurance coverage to cover the risks associated with the dealings.

The Committee RECOMMENDS that the Bill be amended to include provisions for the mandatory review or renewal of all licences granted by the Regulator; and that this review or renewal take place at intervals of not more than three years.

The Committee RECOMMENDS that the Bill be amended to require that the Regulator not issue a licence for the release of a GMO without conditions that ensure, as much as possible, that contamination of non-genetically modified produce or land cannot occur.

The Committee RECOMMENDS that as a condition of a licence, a licence holder be required to monitor, on a continuing basis, any risks associated with the activities or dealing involving GMOs that are subject to the licence and the results of such monitoring be reported annually to the Regulator.

The Committee RECOMMENDS that as a condition of a licence, a licence holder be required to submit to an independent audit of his/her activities by the Regulator to ensure compliance with licence conditions.

The Committee RECOMMENDS that suitably qualified inspectors be employed by the Regulator to enforce the compliance provisions in the Bill.

The Committee RECOMMENDS that the Regulator fund the employment of adequate numbers of inspectors to provide for sufficient frequency of inspection to act as a deterrent to non-compliance.

The Committee RECOMMENDS that the Bill be amended to require that monetary penalties for breaches of a condition of a licence, especially in the case of a breach of condition of licence that causes significant damage or is likely to cause significant damage, be substantially increased.

The Committee RECOMMENDS that the Bill be amended to provide, in addition to a monetary penalty, a further penalty for each day a breach of a licence continues.

The Committee RECOMMENDS that the Bill be amended to provide for terms of imprisonment to be imposed for major offences relating to breaches of condition of a licence.

The Committee RECOMMENDS that further discussion about, and proposals (including the KPMG Report) relating to, cost recovery and the operation of the OGTR be deferred until after the Productivity Commission report and its recommendations are available. The Committee further RECOMMENDS that until such time, the Government fully fund the operation of the OGTR.

Chapter 5

The Committee RECOMMENDS that the Bill be amended to require that the Gene Technology Technical Advisory Committee include a member of the Gene Technology Community Consultative Group and a member of the Gene Technology Ethics Committee, and preferably that that person should be the Chair of their respective committee.

The Committee RECOMMENDS that the Bill be amended to require the Minister, in appointing members of the Gene Technology Technical Advisory Committee, appoint members representative of a range of scientific disciplines and a diverse and broad range of scientific views.

The Committee RECOMMENDS that the Bill be amended to require that the Gene Technology Community Consultative Group provide advice on individual licence applications made under the Bill.

The Committee RECOMMENDS that the Bill be amended to provide that the Regulator may, if he or she deems it necessary, refer individual licence applications to the Gene Technology Ethics Committee for advice.

The Committee RECOMMENDS that the Gene Technology Technical Advisory Committee, the Gene Technology Community Consultative Group and the Gene

Technology Ethics Committee be consulted by the Ministerial Council when issuing policy guidelines.

The Committee RECOMMENDS that the Bill be amended to provide for the right of third parties to apply for review of a decision of the Regulator.

Chapter 6

The Committee RECOMMENDS that provisions in the Bill requiring the Regulator to accept State or Territory viewpoints to prevent the release of GMOs within their jurisdictions be strengthened.

The Committee RECOMMENDS that all field trials currently being conducted in Australia be audited by the IOGTR as soon as possible and the results of the audit be made publicly available.

CHAPTER 1

INTRODUCTION

Terms of Reference

1.1 The Gene Technology Bill 2000 and two related Bills, the Gene Technology (Consequential Amendments) Bill 2000 and the Gene Technology (Licence Charges) Bill 2000, were introduced into the House of Representatives on 22 June 2000. The Bills were debated in the House on 28, 29 and 30 August. The Bills passed the House on 30 August and were introduced into the Senate on the same day.

1.2 On 28 June, the Senate referred the provisions of the Gene Technology Bill 2000 to the Committee for inquiry and report, with particular reference to:

Objectives

(a) whether measures in the Bill to achieve its object 'to protect health and safety of people and to protect the environment' are adequate;

(b) whether the proposed regulatory arrangements and public reporting provisions will provide sufficient consumer confidence in the regulation of the development and adoption of new gene technologies;

The Office of Gene Technology Regulator

(c) the structure of the Office of the Gene Technology Regulator (OGTR) and its assessment processes compared with other proposed stakeholder models and similar overseas bodies;

(d) whether the powers and investigative capability of the OGTR are adequate to ensure compliance with conditions imposed in licences;

(e) whether the proposed cost recovery and funding measures for the OGTR are appropriate and will allow for adequate resourcing of the Office;

Other proposed bodies

(f) the role and membership of the proposed Ministerial Council;

(g) the functions and powers of the Gene Technology Community Consultative Committee and the Gene Technology Advisory Committee;

(h) procedures for review of decisions and, in particular, the rights of third-parties to seek review of decisions;

Other issues

(i) liability and insurance issues relating to deliberate and accidental contamination of non-genetically modified crops by genetically-modified crops and how those issues are being addressed in international regulatory systems;

(j) the validity and practicability of any proposed clause allowing individual States the right to opt out of the scheme and the implications of such an option in the context of Australia's international trade and related obligations; and

(k) the alleged genetically-modified canola contamination in Mount Gambier and the processes followed by the Interim Office of Gene Technology in investigating and reporting on the allegations.

Conduct of the inquiry

1.3 The inquiry was advertised in the *Sydney Morning Herald*, *The Age*, *Australian Financial Review*, *Advertiser* and *Mercury* on 7 July, and *The Weekend Australian* on 8 July 2000 and through the Internet. Submissions were also invited from Federal, State and Territory Governments, professional and community organisations, and other groups and individuals involved with the gene technology debate in Australia. Due to the tight timeframe for the inquiry, the closing date for submissions was originally 4 August 2000, although the Committee continued to receive submissions throughout the course of the inquiry.

1.4 The inquiry attracted interest throughout Australia with the Committee receiving 125 public submissions. The Committee also received a substantial amount of additional material from witnesses. The list of submissions and other written material received by the Committee and for which publication was authorised is at Appendix 1. Submissions that were received electronically may be accessed through the Committee's website at www.aph.gov.au/senate_ca. The Committee held public hearings in Canberra on 14 and 25 August, Adelaide - 22 August, Hobart - 23 August, and Melbourne - 24 August. A list of witnesses who appeared at the public hearings is included in Appendix 2.

Development of the Gene Technology Bill 2000[1]

1.5 The development and use of gene technology in Australia has been overseen variously since 1975 by the Academy of Science on Recombinant DNA, the Recombinant DNA Monitoring Committee (created in 1981) and from 1987 by the Genetic Manipulation Advisory Committee (GMAC).

1.6 GMAC is an independent committee of scientific experts which assesses the risks to human health and the environment that may be presented by the application of gene technology and provides advice on how the risks can be managed. GMAC recommendations are sought, and complied with, voluntarily. However, in the absence of regulatory powers, GMAC has limited capacity for independent, legally enforceable auditing and monitoring of compliance. There is no legal basis for the imposition of penalties or other action in the event of non-compliance.

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1 Much of the background information in this section has been drawn from Submission No.77 (IOGTR), the Explanatory Memorandum and Explanatory Guide to the Gene Technology Bill, and the Parliamentary Library Bills Digest No.11 2000-01.

1.7 In 1992, a report by the House of Representatives Committee on Industry, Science and Technology, *Genetic Manipulation: The Threat or the Glory?*, recommended that the Commonwealth should pass legislation to regulate genetically modified organisms (GMOs) and, in particular, their release outside contained facilities. During 1992-95 there were on-going Commonwealth-State discussions regarding legislative options to implement regulation. However, negotiations ceased in 1995 when agreement could not be reached on a legislative model.

1.8 The proposal for a national legislatively-based regulatory system for gene technology was revived in October 1997 and a Commonwealth-State Consultative Group on Gene Technology (CSCG) was formed. Community and industry perceptions and expectations were a major driving force behind the need to move from a voluntary to a regulatory system of controls.

1.9 The development of a new national regulatory system has been approached from a whole-of-government perspective and involved a number of stages. The process has drawn upon the collective knowledge of agencies responsible for health, environment, agriculture, industry and primary production across Commonwealth, State and Territory jurisdictions. Active consultation has been on-going during this period with a broad range of individuals and organisations, including universities conducting research involving GMOs; consumer, environmental, health professional, industry, retailer and food industry; and primary producer groups.[2]

1.10 The CSCG considered a range of options to improve the current administrative controls, finally opting for full government regulation. By November 1998 the CSCG had prepared a paper 'Regulation of Gene Technology' that was circulated for public consultation. Consultations were held throughout Australia seeking views about the broad policy principles that might underpin the new regulatory scheme. As a result of these consultations, the CSCG agreed to a set of policy principles that it used to develop proposals for the operational details of the new regulatory system.

1.11 The CSCG, in collaboration with the Interim Office of the Gene Technology Regulator (IOGTR)[3], prepared a further discussion paper entitled 'Proposed national regulatory system for genetically modified organisms – How should it work?'. This paper was widely circulated in October 1999, with a broad range of individuals and organisations invited to attend targeted consultations which were held in all States and Territories during November and December 1999.

1.12 A draft Gene Technology Bill was then prepared based on the input from relevant Commonwealth agencies, States and Territories, non-government

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2 Submission No.77, p.24 (IOGTR) and Explanatory Memorandum, p.36.

3 The IOGTR was established in May 1999 within the Commonwealth Department of Health and Aged Care to oversee the development of the legislation to implement a national regulatory system and work with GMAC.

stakeholders and the general community. The draft was released, with a plain language explanatory guide, for public consultation in late December 1999. Again a wide-ranging consultative process took place with public forums in all capital cities and a number of regional areas.

1.13 On the basis of these consultations changes were made to the draft Bill before being introduced into the House of Representatives on 22 June 2000. A summary of views elicited from the main affected parties as a result of consultation is described in the Explanatory Memorandum. Although not intended as a comprehensive summary of the views of all parties, it does emphasise areas of support and dissension in relation to proposed options and areas where costs and benefits of various approaches were raised.[4]

1.14 The fundamental importance of the cooperation and agreement that has been reached between the Commonwealth and the States and Territories in developing the regulatory system proposed in the legislation was emphasised in submissions from a number of State Premiers.[5] The significance of this agreement was underlined by State officials, some of whom had been involved in the previous unsuccessful attempts to develop a nationally consistent approach to regulation. Dr Susan Meek from Western Australia encapsulated this point by stating that this Bill 'represents the highest level of agreement ever achieved between the Commonwealth, States and Territories on this issue to develop a gene technology regulatory system'.[6]

1.15 To implement the comprehensive regulation of gene technology as is proposed requires both Commonwealth and State legislation which, to be as effective and efficient as possible, must be complementary. The importance of the national regulatory scheme, as agreed by the Commonwealth, States and Territories after such a lengthy consultative process, passing the Commonwealth Parliament in a form not materially different from that which was introduced, was also stressed by the States. The Committee notes the comments that any significant amendment of the Commonwealth Bill would require additional renegotiation that could subsequently jeopardise the legislation's implementation. However, this will not prevent the Senate from giving the Bill its usual thorough review during its consideration of the legislation.

1.16 The Tasmanian Government, however, while participating at officer level in the CSCG negotiations since late 1997, does not endorse all aspects of the proposed regulatory system. Of particular concern is the exclusion of an opt-out clause in the legislation, which is addressed in term of reference (j). A parliamentary inquiry has

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4 Explanatory Memorandum, pp.37-41. More detailed information about the consultation process and changes made to the draft legislation arising from the process may be found in Submission No.77 (IOGTR), additional information dated 18 September, pp.8-11 and Attachments C and D.

5 Submission Nos.84 (Mr Peter Beattie, Qld); 91 (Mr Richard Court, WA); 110 (Mr John Olsen, SA); 115 (Mr Steve Bracks, Vic).

6 *Committee Hansard*, 14.8.00, p.23 (Dr Meek).

been established in Tasmania as part of the process of assisting Tasmania develop its own policy in relation to GMOs. In the interim, the Tasmanian Government has recognised that appropriate regulatory controls must exist if GMOs are to be accepted into agricultural systems.[7]

1.17 The IOGTR acknowledged in its submission that during consultations on the draft Bill, people indicated that 'it is often difficult to understand how the legislation will work by simply looking at the draft Bill because a lot of the administrative detail is included in the regulations'.[8] The same point was made repeatedly to the Committee during the inquiry, complicated by the fact that no draft regulations were available for consideration at that stage. A draft of the Regulations was released in late August and will be subject to national consultations during the latter months of 2000. Model State legislation, which is substantially similar to and will complement the Commonwealth legislation, has also been released for public comment.

1.18 The final component of the proposed regulatory system is the Gene Technology Intergovernmental Agreement, which underpins the entire national scheme. The Agreement will set out many of the understandings between the governments that have allowed the national scheme to be developed, thereby helping to minimise the number of disputes which may arise during the scheme's operation. It is expected that the Agreement will:

- describe the main components of the cooperative national scheme and commit all governments to introduce substantially similar legislation;
- set out the functions and membership of the Gene Technology Ministerial Council;
- provide for the maintenance of a nationally consistent scheme over time;
- describe the roles and responsibilities of each jurisdiction in the administration and enforcement of the scheme; and
- provide for the review of the implementation and effectiveness of the national scheme in five years time.[9]

The Agreement is yet to be considered by the Heads of all Australian Governments, prior to it being released publicly.

1.19 In discussing why Australia needs a national regulatory framework for GMOs, the IOGTR offered the following comments which recognise and highlight many broadly held concerns:

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7 Submission No.89 (Tasmanian Government, Mr Jim Bacon, Premier).

8 Submission No.77, p.25 (IOGTR).

9 Explanatory Guide to the Gene Technology Bill, July 2000, pp.81-2.

> While the level of concern about possible risks is growing in the community, there remains inadequate information available to the community and consumers to evaluate the reality of these risks and their likelihood of occurrence. Individuals may also have difficulty in assessing and processing available information to help them make informed choices about comparative levels of risk from other technologies and what levels of risk they consider to be acceptable to their health and safety.
>
> There is a perception that industry cannot be relied upon to be sufficiently rigorous and objective in evaluating risk and implementing appropriate management strategies and that government should fulfil this role.
>
> However, given the rapid growth in the use of gene technology, the government's current capacity for intervention is inadequate…
>
> The current system also attracts criticism for not being sufficiently open and transparent in its risk assessment and management processes, and for not having adequate enforcement capabilities. The resulting lack of credibility (particularly in relation to decisions regarding the release of GMOs into the environment) may undermine public confidence and jeopardise the ability of industry to market GMOs and GM products assessed as safe. In addition, unnecessary costs may be generated through less than optimal coordination between regulators.
>
> A national, uniform regulatory system is fundamental to the development of industry based upon gene technology in Australia.[10]

1.20 As can be seen from the terms of reference, it has been the Committee's duty to examine the proposed national regulatory system to ensure that the concerns expressed in the above comments have been satisfactorily addressed in the legislation.

1.21 Although the Committee acknowledges the extended consultative process undertaken prior to the Bill's introduction into Parliament, it is concerned at the timeframe with which the Parliament and the Committee have been expected to consider such fundamentally important legislation. Draft Regulations have only been recently released and the Intergovernmental Agreement has not been sighted. The Committee agrees that the implementation of a nationally effective and enforceable regulatory scheme is critical to the development of gene technology in Australia and to boost public confidence in the development and use of gene technology generally. However, the Committee considers that it is imperative that before passing this legislation, Parliament and the Committee be allowed sufficient time for a thorough examination of the proposed scheme and, in particular, of the risks associated with the different applications of gene technology and their possible long term effects.

10 Submission No.77, pp.20-21 (IOGTR).

Acknowledgments

1.22 The Committee expresses its appreciation to the individuals and organisations who made submissions to the Committee or gave evidence to the inquiry. As always, the Committee places great value on the submissions it receives as primary sources of information. Many witnesses provided additional written information and copies of published articles. This material was most helpful to the Committee during its deliberations on the inquiry.

1.23 The Committee would also like to thank the staff of the Antarctic Cooperative Research Centre at the University of Tasmania and of the CSIRO Division of Health Sciences and Nutrition at Parkville in Melbourne for their assistance in enabling the Committee to hold public hearings at their facilities. In particular, the Committee would like to thank Dr Colin Ward and Mr Doug Gale from the CSIRO at Parkville for enabling the Committee to inspect their facilities and gain a first hand appreciation of the successful research being undertaken within their Division.

1.24 The Committee commends the IOGTR for the comprehensive consultative process it has undertaken in the development of this legislation. The Committee was impressed with the volume of detailed information, including the Explanatory Guides, that has been made publicly available, and especially with the Explanatory Memorandum accompanying the Bill, the detail of which is rarely seen in such documents. Finally, the Committee thanks Ms Elizabeth Cain and the officers of the IOGTR for their assistance through the timely provision of detailed information in response to requests from the Committee.

CHAPTER 2

BACKGROUND ON GENE TECHNOLOGY

Introduction

2.1 The focus of the Committee's inquiry was to examine the proposed regulatory system for genetically modified organisms (GMOs) as set out in the Gene Technology Bill 2000. Understanding what is involved in gene technology is important when considering the consequences of the products of this technology, and the adequacy of the regulatory arrangements that have been formulated to ensure the protection of the community and our environment.

2.2 This chapter aims to provide sufficient information for people to understand gene technology, without purporting to provide a detailed scientific explanation of the concepts and processes associated with gene technology. The chapter also highlights some of the concerns raised in evidence about the way the Bill defines genetically modified organisms, and the risks and benefits associated with gene technology.

What is gene technology?

2.3 The principle of altering various organisms is not new–for centuries, a range of techniques have been used to alter the properties of plants and animals through selective breeding or plant grafting. Today, gene technology has greatly increased the number of plant and animal traits that can be manipulated and, significantly, transferred across the species barrier.

2.4 Gene technology, sometimes also referred to as biotechnology[1], has been used to describe techniques involving the genetic modification of organisms. Gene technology refers to 'the transfer of DNA between living cells to produce a certain outcome'.[2] Gene technology has also been described as the field of research that uses 'gene transfer techniques to produce recombinant proteins and genetically modified organisms'.

2.5 The Gene Technology Bill 2000 defines gene technology as 'any technique for the modification of genes or other genetic material'. The Bill defines a genetically modified organism (GMO) as:

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1 Note: some people consider gene technology to be a form of biotechnology, with biotechnology to refer to techniques including cross-breeding, as well as those usually associated with modern gene technology, such as recombinant DNA. See for example, Submission No.8 (Serve-Ag Pty Ltd) which states: 'Biotechnology includes harnessing the natural biological processes of microbes, plant and animal cells for the benefit of humans. GM is a branch of biotechnology.'

2 See Therapeutic Goods Administration, *Genes, genetics and transgenics*, p.2 [website: http://www.health.gov.au/tga/gene/genetech/genetics.htm].

- an organism (any biological entity that is viable, capable of reproduction or capable of transferring genetic material) that has been modified by gene technology; or
- 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
- 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.

2.6 The use of the term GMO to describe a genetically modified organism is often used interchangeably with the expression GEO or genetically 'engineered' organism, although some may claim that genetically modified is not an adequate description where recombinant DNA techniques have been used. Organisms that have been genetically manipulated have also been described as having been 'genetically improved (GI)'. This report uses the term GMO to refer to organisms that have undergone genetic modification, except where the report has quoted directly from evidence or submissions which use an alternative expression.

2.7 The term transgenic is often broadly used to mean genetically modified. A more generally recognised understanding of the term is that a transgenic organism is one in which genes have been incorporated from a source other than its parents, ie there is a transfer of genetic material from one species to another.[3]

2.8 Apart from viruses, all living things are made up of cells or small structures bound by a membrane and filled with a solution of interacting chemicals.[4] Biological instructions are necessary for an organism to reproduce itself and to produce the substances–proteins–required for it to function. These instructions are encoded in a substance called deoxyribonucleic acid[5], or DNA for short.

2.9 DNA is a complex chemical molecule called a polymer ('having many parts') a beaded string-like chemical structure that is made up of many smaller chemical units. These smaller parts are called nucleotides and are themselves comprised of three elements: a sugar, a phosphate group and a ring structure of nitrogen and carbon, called a base. There are four bases called adenine (A), guanine (G), thymine (T) and cytosine (C). A DNA molecule comprises two strands of a number of nucleotides joined together. The two strands are wrapped around each other to form a double helix. The sugar and phosphate parts form the backbone of the DNA molecule, with the bases facing inwards like the rungs of a ladder (see below). The chemical

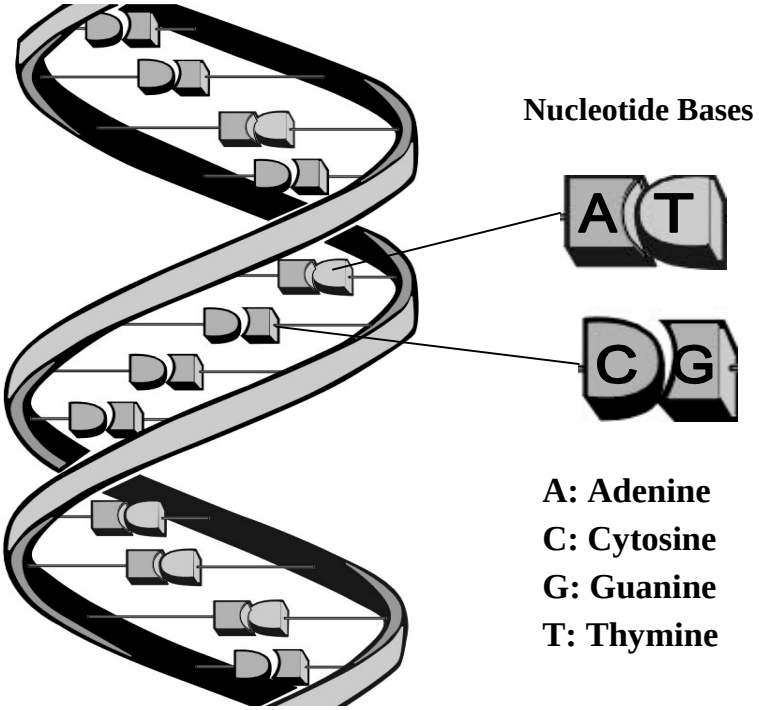
3 *Genes, genetics and transgenics*, p.5.

4 Viruses are comprised of a 'nucleic acid genome surrounded in a protein coat'. Viruses are parasites which use the host (infected) cell's replication apparatus and ability to synthesize protein. Bacteria can also be infected by specific viruses called bacteriophages.

5 The term 'deoxyribonucleic acid' describes certain characteristics of the molecule.

characteristics of the bases are such that the adenine binds to thymine and cytosine binds to guanine across the ladder.

Figure 1: Diagram showing double helix structure of a DNA molecule



2.10 The pairing of bases, known as complementary base pairing, is an important feature of the double helix because it means that if you know the order of bases on one strand, you can determine the order on the other—something that is crucial to ensuring that the integrity of genetic information is retained during the replication of DNA during cell division and during the production of proteins. This raises concerns with the Committee in terms of the addition of new genetic material during the genetic modification process.

Genes and gene expression

2.11 A gene is a discrete segment of DNA that provides the information necessary for synthesising a particular protein at the right time and place, enabling an organism to function. The genetic information is determined by the sequence of bases in the DNA.

2.12 An important component of a gene is a sequence of DNA that occurs at the beginning of a gene, called the promoter. The gene promoter determines whether the gene will be expressed in a particular cell.

Gene expression

2.13 Gene expression is the process by which the biological information contained in genes is made available to cells. During gene expression, one of the DNA strands is

used as a template to produce another molecule, RNA, or ribonucleic acid. This step is known as transcription. During a second step known as translation, the RNA directs the synthesis of proteins in accordance with the sequence of bases making up the strand of RNA. The RNA contains sequence codes for 20 amino acids, which are the building blocks of proteins.

Recombination

2.14 Recombination is the process whereby new combinations of genetic material are formed by the techniques of genetic engineering. There are three main applications of recombination used in genetic engineering or modification:

- the production of biologically useful proteins to be used in the treatment of human medical conditions and in industrial processes;
- the modification of plants, primarily to provide resistance to herbicides and insects attacks and resistance to infection by viruses; and
- the modification of animals to introduce new traits.

2.15 The use of recombinant DNA techniques allows variants of naturally occurring proteins to be produced.[6]

Selectable markers

2.16 In order to verify that a chosen gene has been incorporated into the DNA of the organism to be modified, selectable marker genes are also often attached to the gene. These are predominantly antibiotic resistance gene markers, but herbicide-resistance genes also may be used as markers. The theory behind the use of these markers is that, in the case of the antibiotic resistance markers, the gene confers resistance to a specific antibiotic. If the organism into which the chosen gene has been inserted is cultured in a medium containing that antibiotic, the organism will survive if it has incorporated the new DNA which includes the gene for antibiotic resistance. If

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6 Generally a small piece of circular DNA called a plasmid, found in bacteria, is used to introduce the desired gene into the host cell, usually the bacterium *E. coli*. Certain properties of the plasmid enable numerous copies of the desired gene to be copied and subsequently isolated for further analysis. Many plasmids contain antibiotic resistance genes which make it possible to identify those plasmids that have taken up the desired gene (see section on selectable markers). Plasmids are also used to direct the expression of desired proteins in *E.coli*, used to produce most of the recombinant proteins.

Viruses that infect insects, called baculoviruses, have also been used as vectors to introduce the desired gene into the insect host cell. This technique is used to produce the hormone erythropoietin and the anti-virus agent β interferon.

Some recombinant proteins used for the treatment of human diseases must be expressed in mammalian cells. Specific DNA sequences, derived from bacteria, are manipulated and propogated in bacteria before being transferred to an animal cell for protein expression. Human recombinant drugs produced with this technique include growth hormone, blood clotting protein and erythropoeitin. Some recombinant proteins used for the treatment of human diseases must be expressed in mammalian cells. Specific DNA sequences, derived from bacteria, are manipulated and propogated in bacteria before being transferred to an animal cell for protein expression. Human recombinant drugs produced with this technique include growth hormone, blood clotting protein and erythropoeitin. (*Instant Notes in Genetics*, pp.325-330).

the organism did not integrate the new DNA into its own genome, it would not survive in the medium.

Plants

2.17 Cross breeding and grafting have been used for centuries to produce hybrid plants by selectively crossing plants with desired traits. Genetic engineering can now provide a direct method for incorporating new traits into a plant.

2.18 One of the features of plants that make them particularly suitable for genetic modification is that a whole plant may be grown from a single genetically engineered cell. Two techniques are used to transfer genes into plants. The first involves inserting a gene from bacteria into a plant and the second, known as biolistics, is a procedure whereby gold or tungsten balls are coated with DNA and fired into the plant cell from a special gun. The DNA is released from the ball and integrates into the plant DNA.

2.19 Goals of genetic modification in plants include:

- herbicide tolerance;
- resistance to the attack of insects;
- resistance to infection from viruses;
- increased yield in food crops;
- drought resistance; and
- the ability to tolerate harsh environmental conditions, for example, salinity.

2.20 To make a plant herbicide tolerant, a bacterial form of an enzyme unaffected by a particular type of herbicide, for example, gylphosate, is transferred into the plant. Two approaches have been used to give plants insecticidal qualities. The first involves transferring a gene from a bacteria that produces protein which is toxic to some insects. The second technique genetically engineers the expression of a protein to interfere with the insect's ability to digest plant tissue. Providing resistance to viruses has been achieved by introducing a gene which encodes for a viral coat protein.

2.21 In addition to these qualities, plants have also been engineered to delay ripening of fruits to increase shelf life, alter colours in flowers, and improve the nutritional quality of crops.

Animals

2.22 While artificial selection, or selective breeding, of animals has been used to produce domestic animals with desirable traits such as increased milk yield, some desired traits cannot be introduced without affecting existing ones. Transgenic animals can be produced by the transfer of genes encoding the desired traits.

2.23 There are three techniques for producing transgenic animals, all of which involve the genetic modification of a fertilized egg sometimes called an early stage

embryo. The modified embryos are then transplanted into a host animal's uterus. The first method involves the use of a particular type of virus, called a retrovirus, which is used to infect embryo cells. Microinjection is another method which involves injecting DNA directly into the nucleus of the egg cell. Another method is through the use of cells that are taken from the early stage of an embryo. These so-called embryonic stem cells may be genetically modified before being reimplanted in the animal.

2.24 Animals may be used in GMO research, for example, the production of so-called 'knockout mice', that is, mice which have been engineered to remove a gene to provide information on the function of that gene. Another application is to use transgenic animals to simulate human diseases which are the result of defective genes and to test new drugs for their treatment, for example, in the case of arthritis and Alzheimer's disease. Finally, transgenic sheep and goats may be used to secret recombinant human proteins in milk, including blood clotting factors and plasma proteins.[7]

2.25 As well as the addition of genes, genetic modification may involve the cancelling or augmenting of an existing gene. Genes may also be activated artificially, for example by spraying a crop with a specific chemical.[8]

2.26 Evidence presented to the Committee raised a number of issues associated with gene technology and how it should be regulated. While proponents of gene technology have claimed potential benefits, opponents have also highlighted potential risks and the need to ensure that adequate safeguards are in place to manage or eliminate these risks.[9] These competing views are discussed below, with references to other chapters where the regulatory implications of these concerns are discussed.

Benefits associated with gene technology

2.27 Proponents of gene technology cite its potential benefits for agriculture, the environment and human health.

Agriculture

2.28 The Interim Office of the Gene Technology Regulator (IOGTR) argued that gene technology promises to be more precise, produce results more quickly and cost effectively, and introduce traits not possible through conventional techniques.

2.29 In relation to crop improvement, one of the major benefits was seen to be the speed with which desired traits may be inserted into the crop. AWB Ltd stated:

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7 *Instant Notes in Genetics*, pp.325-330.

8 Dr Rod Panter, *Biotechnology in Australia*, Parliamentary Library, Current Issues Brief 16, 1998-99, p.4.

9 Websites that include arguments for and against gene technology include: http://genetech.csiro.au/debate1.htm; http://www.afaa.com.au/paper_01.asp; http://203.89.217.15/pages/fact_sheets/fs10_public_consultation.htm

> …the process of wheat breeding has basically been going on ever since wheat was introduced into Australia to develop certain quality characteristics such as larger grains, better yielding grains in terms of flour extraction rates, better frost tolerance, rust resistance and these sorts of things. That breeding process has been continual. The time taken to do that through traditional plant breeding methods is quite significant–eight to 10 years…What gene technology will be doing will be taking those desirous genes from some of those lines which are showing, for instance, rust resistance and putting those genes into another type of wheat which shows a good quality flour product, for instance, so that it has got both good quality flour and rust resistance, which will be a much quicker process in terms of breeding than the traditional approach of growing each of those plants out and selecting on a year-to-year basis.[10]

2.30 Dr T J Higgins from CSIRO cited an example of conventional breeding attempts to introduce rust resistance from rye into wheat. While rust resistance was conferred on the plant offspring, other undesirable genes were also transferred which led to the production of sticky dough. Proponents of gene technology claim that gene technology is more efficient than conventional techniques because only the desired gene is transferred.[11]

2.31 While there may be risks associated with transferring undesirable traits through conventional breeding, a major concern about gene technology is not with the crossing of two of the same plant species, but the transfer of genes from one species, for example a fish, into another species such as a tomato, or a bacterium into a plant. This ability to 'cross the species boundary' through genetic engineering introduces an additional uncertainty and potential for serious harm. The ability of the Gene Technology Bill to manage the risks posed by gene technology and ensure that people and the environment are protected are discussed in Chapters 3 and 4 of this report.

2.32 The National Farmers' Federation (NFF) identified a number of production benefits from crops derived from gene technology including:

- varieties with increased resistance to pests and diseases which lead to benefits including reduced pesticide and herbicide use, reduced input costs and reduced adverse environmental impacts from chemical use;
- new varieties which make better use of soil nutrients, leading to reduced fertiliser use;
- reduced labour costs and energy costs;
- improved yields, quality and produce that is better adapted to requirements of the food industry and consumers;

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10 *Committee Hansard*, 24.08.00, pp.285-6 (AWB Ltd).

11 *Committee Hansard*, 14.08.00, p.3 (Dr T J Higgins).

- quicker adaptation of crops to environmental and climatic factors, such as reduced water use, salt resistance and drought tolerance;
- crops which incorporate the nitrogen fixing ability of lucerne, peas and soya into other crops, assisting improvement of soil nutrition and enhancing productivity; and
- accelerated breeding of plants with improved characteristics leading to productivity gains, such as faster growing trees for wood production and higher quality grains.[12]

2.33 Herbicide-resistance in crops is a major objective of plant gene technology for reasons including:

- increased production efficiency;
- new options for weed management, such as allowing flexible timing of herbicide application; and
- decrease in overall herbicide use, leading to increased use of more environmentally friendly herbicides, for example glyphosphate.[13]

2.34 The NFF also referred to potential benefits for consumers, including:

- fruit and vegetables that keep fresh for longer, reducing spoilage of food in transport and storage;
- foods which contain healthy fats and oils and cooking oils with lower saturated fat content;
- increased nutritive value such as higher expression of vitamins;
- soybeans with a higher expression of anti-cancer proteins naturally found in soybeans;
- elimination of allergy-causing substances; and
- food products which carry with them medicinal properties.[14]

Environmental

2.35 The IOGTR outlined potential benefits to the environment, including reducing the use of conventional chemicals and pesticides. This would lead to more specific targeting of pests and weeds, and reduce ground water contamination. Polluted or salt-affected land could be reclaimed by the production of genetically modified salt-tolerant crops, while higher agricultural productivity would reduce the need for land

12 Submission No.88, Attachment, p.3 (National Farmers' Federation).

13 Huppatz, JL and Fitzgerald, PA. 'Gene technology is a new form of biotechnology with much greater potential applications', *MJA*, 2000, 172: 170-173.

14 Submission No.88, Attachment, p.3 (National Farmers' Federation).

clearing. Other potential benefits of gene technology are the cost-effective production of biodegradable plastics and biodiesel, as well as the use of GMOs for bio-remediation, for example, using micro-organisms to decompose toxic substances and clean-up industrial sites or environmental accidents.

Health and medical

2.36 As described earlier in the chapter, gene technology also has been used in the areas of public health and medical applications. A number of products are already being used in Australia, including enzymes, hormones, blood coagulation factors, a Hepatitis B vaccine, and a treatment for flu symptoms. IOGTR claimed that the advantages of these products are improved efficacy, greater availability, cheaper production, reduced allergenicity, and reduced risks of transmission of infectious agents.

2.37 Living GMOs have yet to be introduced for therapeutic use in humans, however, it is claimed that they have the potential to provide vaccines for cholera, malaria and HIV, and treatment for cancer and diabetes.[15]

Risks associated with gene technology

2.38 While many potential benefits of gene technology have been identified, evidence presented to the Committee also highlighted a range of potential risks associated with genetically modified organisms.

2.39 The IOGTR and others identified risks arising from modern genetic manipulation techniques, especially transferring genes from one species into a different species, including:

- introduction of unidentified allergens into GM food;
- contamination of traditional or organic crops by neighbouring GM crops;
- the inability to eliminate a GMO once it is released and found to have an adverse impact, as observed by the Organic Federation of Australia (OFA):

  > Unlike chemicals in agriculture which are recallable and have a half life and then eventually cease to be biologically active, GEO's are live replicating organisms that once released, are likely to be [un]controllable;[16]

- increased environmental damage due to increased use of chemicals;
- increased environmental competitiveness of GMOs creating weeds, in the case of plants, or pests in the case of animals;

15 Biotechnology Australia, *Background Information: Biotechnology in Medicine*, June 2000.

16 Submission No.54, p.3 (Organic Federation of Australia Inc).

- insect-resistant crops adversely affecting non-target insects, exemplified by study of the impact of transgenic cotton on the Monarch butterfly;[17] and
- the transfer of genes for herbicide tolerance from GM crops to related species resulting in herbicide-resistant weeds.[18]

2.40 In relation to the latter point, Mr Scott Kinnear from the OFA advised:

> …in Canada…farmers have found cross-pollination, three canola crops resistant to three types of chemicals…It will lead to increased use of that herbicide, and it has to lead to increased use of that herbicide.[19]

2.41 Opponents have argued that while the products of gene technology, such as herbicide resistant crops, long shelf life melons and delayed ripening tomatoes, are likely to bring some benefits to consumers, these products have been mainly developed to meet the needs of those in the food supply system, growers, transporters, wholesalers and retailers.

2.42 Notably, the crops that have been subject to genetic engineering are those that are economically important in the industrialised not the developing nations, for example maize, oilseed rape (canola), sugarbeet, tomato and potato. Nevertheless some research and trials have been conducted on wheat, rice, and cassava, an important food source in African and South American countries.[20] Additionally, the main applications of genetic modification are producing herbicide and pesticide resistant plants, with much of the benefit going to the producers rather than consumers.

2.43 In referring to claims about the potential environmental benefits of GM plants, Mr Phelps of the ACF GeneEthics Network, stated:

> There are none with the existing crop on offer. Of all the releases to date, 70 per cent have been for herbicide tolerance by companies which also sell the chemicals. They are selling farmer seed chemical packages, which intensify the destruction being done to our environment. Our land and water are making us so unsustainable that we are likely to have to be net importers of food and fibre before long rather than exporters.[21]

2.44 The transfer of herbicide-resistant genes from transgenic to wild or weedy relatives does occur through cross pollination. The solution could require farmers to

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17 See also *Committee Hansard*, 24.08.00, p.265 (National Genetic Awareness Alliance) who advised that 'there is evidence that GM crops with BT toxins–that is, *Bacillus thuringiensis*–kill beneficial insects such as bees and lacewings.'

18 Submission No.77, p.17 (IOGTR).

19 *Committee Hansard*, 23.08.00, p.155 (OFA).

20 Ruibal-Mendieta, NL and Lints, FA (1998). 'Novel and transgenic food crops: overview of scientific versus public perception', *Transgenic Research*, 1998, 7: 379-386.

21 *Committee Hansard*, 24.08.00, p.331 (ACF GeneEthics Network).

resort to alternative, environmentally less friendly herbicides, and this would reduce the attractiveness of growing the transgenic varieties. It has been argued that 'controlled experiments cannot predict whether unexpected consequences will occur'.[22]

2.45 The role of viruses in genetic modification, was also raised in evidence to the Committee. Dr Dalling, from the companies Florigene and Nugrain, indicated that viral 'switches' are used in the genetic modification of carnations to produce violet varieties. He stated:

> The genes came from a range of other flowers in the first place–petunia or pansy. Pansy was an important source of intense blue. There are genes in there though that, from memory, have come from a construct or a part of a gene from a virus. You might have picked up the term '35S', which is a well-known regulator of gene expression. To get genes to work you have to have a switch. One of the more ubiquitous switches that is used commercially is 35S. It was isolated from a virus back in the early 1980s. It has been the basis of a very large number of constructs that have been used, not just by our company, but by other companies around the world with currently released corn, soybean, cotton, canola.[23]

2.46 However, virologist, Professor Adrian Gibbs, expressed concern at the lack of research currently being conducted into the consequences of using viruses for genetic modification purposes. He cited two cases which he considered may cause serious problems:

> I put down two examples to mention to the committee: one is the development of viruses for controlling mice by CSIRO division of wildlife research; and another is putting virus genes into potatoes to try to control infection by other viruses. Both of those technologies could result in major problems and, as far as I know, there is no scientific work being done at present on the safety to the environment of either of those developments. So I am worried about the lack of research.[24]

Food

2.47 While there is greater community acceptance of the use of gene technology in pharmaceuticals and medicine, public concern related to GMOs in food remains high and increasing. This has been expressed in calls for a ban or moratorium on all general releases of GM crops and for clearer labelling of food products containing GMOs or GM products.

2.48 The risks to human health of greatest concern are:

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22 Rubial-Mendieta & Lints (1998).

23 *Committee Hansard*, 24.08.00, p.337 (Florigene Ltd).

24 *Committee Hansard*, 25.08.00, p.429 (Professor A Gibbs).

- transfer of allergens to new food products; and
- the possibility of delayed effects similar to CJD.

Antibiotic resistance markers

2.49 The use of antibiotic resistance markers in gene technology are controversial because of public fears about the resistance trait transferring to bacteria in human and animal stomachs. While studies have indicated that antibiotic resistance genes in crops or crop products will have a negligible impact on food safety, there is still a concern that the use of antibiotic resistance as a selectable marker will 'compromise the therapeutic use of antibiotics in humans and animals'. Studies on the effect on food safety have shown, however, that 'such transfer occurs, if at all, at extremely low frequency'.[25]

2.50 Despite the conclusion of a 1996 report to the Nordic Council responsible for directing food policy issues in five nordic countries, that 'the overall risk is effectively zero, and that the therapeutic use of antibiotics in humans or animals will not be affected by commercialisation of transgenic crops containing antibiotic-resistance selectable marker genes', the London Royal Society in 1998 recommended that antibiotic resistance markers should no longer be used in GM food crops.[26]

2.51 In evidence to the Committee, Dr Tribe of the Australian Biotechnology Association, was critical of what he considered to be an 'overstated' problem of antibiotic resistance markers.[27]

2.52 One of the reasons advanced for using antibiotic resistance selectable markers is because of the inefficiency of the techniques used to transfer DNA into host organisms, and the need to be able to identify whether the target gene has actually been inserted into the host cell. These markers can now be 'zipped out' leaving only the desired gene in place.[28]

2.53 The Committee considers that the potential risks associated with the transfer of antibiotic resistance genes to other bacteria is another reason for ensuring extreme caution in the regulation of GMOs, and this is discussed in detail in Chapter 4.

Allergens

2.54 The possibility that an allergy-causing protein may inadvertently be transferred during the genetic modification of a food product was raised in evidence to

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25 Huppatz and Fitzgerald (2000).

26 Huppatz and Fitzgerald (2000).

27 *Committee Hansard*, 24.08.00, p.242 (Dr Tribe). Dr Tribe referred to ANZFA's Occasional Paper Series– No. 1: *GM Foods and the Consumer–ANZFA's Safety Assessment Process for Genetically Modified Foods*, June 2000 which, he argued, presents 'a much more reasoned and understandable description of the antibiotic resistance issue' [see ANZFA website: http://www.anzfa.gov.au/].

28 *Committee Hansard*, 25.08.00, p.419 (CSIRO).

the Committee.[29] The dangers to human life that this could pose led to the question of whether GM foods should be tested to the same degree as medications. Dr Dalling from Florigene Ltd, responded:

> In principle I do not oppose it so long as all food is subject to the same testing. At the moment anything that has the word 'GM' in front of it is subject to the most unbelievable scrutiny. Long ago the concept of substantial equivalence was well and truly established. I understand that people are debating it now. A huge amount of evidence has been gathered to support the idea, but it is an evolving process. More and more evidence may well be demanded and gathered, presumably, so long as there is no discrimination as to what the products are.[30]

2.55 Mr Buz Green of Serve-Ag, supported the stringent testing of GMOs where there is a possibility of the transfer of allergens.[31] Mr Gary Burgess representing the South Australian Farmers Federation, considered that issues of allergenicity in GM products should be part of the risk assessment process.[32]

2.56 The Committee acknowledges that there are concerns about the reliance on current scientific understanding to identify risks, particularly given past experience when it was discovered that scientific 'fact' turned out to be incorrect.

2.57 The case of the transfer of an allergen from the Brazil nut into the soybean is a major concern. The case involved the transfer of a protein gene from the Brazil nut into the soya bean to improve the quality of soya bean protein. After testing, it was discovered that the gene caused allergic reactions in humans.[33] While the Committee notes that in this case, the problem was identified before it had been commercially released, the Committee considers that this is a serious risk and that risk assessment processes must be rigorous enough to pick similar instances up early. Risk assessment processes under the Gene Technology Bill are discussed in Chapter 4 of this report.

Food labelling

2.58 One of the areas that is considered to be important in allowing consumers to make informed choices about genetically modified food is the issue of food labelling. While a meeting of New Zealand and Australian State and Territory Health Ministers in Wellington in July this year discussed labelling of genetically modified foods,

29 See for example *Committee Hansard*, 23.08.00, p.152, 157 (OFA).

30 *Committee Hansard*, 24.08.00, p.355 (Florigene Ltd).

31 *Committee Hansard*, 23.08.00, p.194 (Serve-Ag).

32 *Committee Hansard*, 22.08.00, pp.57-8 (SA Farmers Federation).

33 *Committee Hansard*, 14.08.00, pp.8-9 (Dr T J Higgins).

different views were expressed in evidence to the Committee about the extent of labelling required.[34]

2.59 The issue of food labelling is not covered by the Gene Technology Bill, however, the Committee notes the important consumer links between GM foods and labelling. One area of concern relates to the issue of substantial equivalence with respect to GM food products, and how it effects how these products may be labelled.

Substantial equivalence

2.60 Huppatz and Fitzgerald explain the concept of substantial equivalence in foods as follows:

> Substantial equivalence is established if food products are essentially the same in composition, nutritive value, functional characteristics and organoleptic properties (taste, smell, mouthfeel).[35]

2.61 If a genetically modified crop is determined to be substantially equivalent to a conventionally grown crop, 'the focus of testing becomes the introduced genes and their specific products', however, if the GM crop is not judged to be substantially equivalent, then the crop must be 'assessed for food safety on a case-by-case basis'. Thus, for example, rice with enhanced vitamin A would be considered as a 'new food'.[36]

2.62 Dr Annison of the Australian Food and Grocery Council (AFGC), explained how the concept of 'substantial equivalence' was applied in food testing:

> It essentially says that, if we accept one product as being safe, the most rational way of approaching assessing a second product it is to look for differences from one to another. The principle of substantial equivalence looks at the chemical composition and nutritive value and looks specifically for levels of toxins and allergens. It compares one with another and determines whether they are essentially the same. That seems to me to be a very practical way to go…If there are different materials in foods, we also consider the chances of their being bio-active in any way. We know that in some foods it will be classified as substantially equivalent. There would be DNA in there from the genetic modification. But there is no evidence whatsoever that DNA itself, either from a genetic modification or just as we eat it, is biologically active. In fact, we know it is not biologically active. We eat DNA all the time, and we so know it is not biologically active. If there were an expression production from that DNA present in any great quantity, it would be picked up by the substantially equivalent definition

34 See for example, *Committee Hansard*, 22.08.00, pp.109-110 (Ms E Attwood); *Committee Hansard*, 23.08.00, p.192 (Serve-Ag).

35 Huppatz and Fitzgerald (2000).

36 Huppatz and Fitzgerald (2000).

> anyway. That, on top of the tests that are done by the companies who are developing these products, I believe provides a very sound framework.[37]

2.63 A genetically modified product that is deemed 'substantially equivalent' to its non-genetically modified counterpart will not be labelled as a GMO.

2.64 In response to questions about whether the products of cattle fed with GM crops should be considered GM, Mr Downer of the AFGC replied 'I would class them as GM free'. The AFGC added that:

> …it depends on exactly what you are feeding them, but if you are feeding them a substantially equivalent GM crop–for example, if you are feeding them Roundup ready soya beans as supposed to conventional soya beans, because they are substantially equivalent; the differences between the soya beans are virtually non-existent–there will be no differences in the animals feeding on those crops. By definition, that is what 'substantially equivalent' means—there will be no difference. So when you come to analyse the meat, you will not be able to tell whether the meat came from an animal feeding on Roundup ready soya beans or an animal feeding on conventional soya beans. This will be the difficulty facing the retailers if they decide to go GM free and use that as one of the stipulations: they could have two pieces of meat side by side and be making a GM free claim about one, but there will be no way either the enforcement agencies, in terms of making sure the label statements are correct, or, indeed, the consumers buying the products, will be able to tell whether the label statements are correct.[38]

2.65 Although there may be no evidence of genetically modified DNA being transferred from GM crops through the food chain, the public perception of this risk still exists.[39] The way in which consumer confidence in gene technology can be enhanced is examined in Chapter 3.

2.66 The Committee notes that there is significant disagreement about the nature and extent of the risks associated with genetic engineering. The approach that should be taken with respect to the regulation of GMOs in the light of the uncertainties and inconclusiveness about the potential risks of gene technology are discussed in Chapter 3 of this report under the section 'the precautionary principle'.

GMOs covered by the Gene Technology Bill 2000

2.67 Another issue raised during the inquiry was the way in which the Bill defines GMOs and gene technology. The definitions of gene technology and genetically modified organism contained in the Bill were referred to at the start of the chapter.

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37 *Committee Hansard*, pp.403-4 (AFGC).

38 *Committee Hansard*, 25.08.00, pp.407-8 (AFGC).

39 *Committee Hansard*, 23.08.00, p.175 (GE-Free Tasmania).

2.68 Heritage Seed Curators expressed concern that regulations would be able to exclude organisms from the definition of a GMO under the Bill.[40] Friends of the Earth (Fitzroy) recommended that, in addition to the organisms specified as GMOs in the Bill, the following should be added:

> (d) any biological entity capable of replication or transfer of genetic information, and includes plants, animals, bacteria and all other kinds of micro-organisms, cell cultures (prokaryotic[41] or eukaryotic[42]) created and propagated as such, viruses, and plasmids[43] and other kinds of vectors, in which the genetic material has been altered in away that does not occur naturally, by means of cell or gene technology.[44]

2.69 One of the dangers in including a list of additional biological entities under the definition of GMO is that in providing such a prescriptive definition, the chance that something may slip through may increase because the definition is too specific.

2.70 Concerns were raised about the lack of regulation for stockfeed safety.[45] However, the Committee notes that the draft regulations, released on 25 August, declare that any GM product intended for use as a stockfeed is also a genetically modified organism.

2.71 Under the Gene Technology Bill, a GMO does not include:

- a human being who has undergone somatic cell[46] gene therapy; or
- 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.

2.72 The draft regulations exempt a number of organisms listed from the Bill's definition of a GMO because they:

- give rise to organisms that can occur in nature;
- are commonly used in biology; and
- have a very long history of usage in Australia and overseas.[47]

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40 Submission No.9, p.5 (Heritage Seed Curators Australia Inc).

41 Bacteria and their relatives.

42 Non-bacterial organisms, including plants and animals.

43 Circular DNA present in bacteria.

44 Submission No.51, p.2 (Friends of the Earth (Fitzroy)).

45 *Committee Hansard*, 22.08.00, p.122 (Aventis).

46 Cells of the body rather than ova or sperm.

47 A list of organisms not considered to be GMOs under the Gene Technology Bill is included in the draft regulations, p.3.

2.73 The IOGTR advised the Committee that having chosen to define gene technology in broad terms in the legislation, the exemptions in the regulations identify those techniques not generally considered to be 'gene technology' that may have unintentionally been covered by the Bill.[48]

48 Explanatory Guide to the Draft Commonwealth Gene Technology Regulations 2000, August 2000, p.19.

CHAPTER 3

OBJECTIVES OF THE GENE TECHNOLOGY BILL

Introduction

3.1 This chapter examines the adequacy of the measures in the Gene Technology Bill to achieve the Bill's objective of protecting the health and safety of people and the environment, and whether the proposed regulatory arrangements, including the public reporting provisions, will provide sufficient consumer confidence in the regulation of the development and adoption of new gene technologies.

Objective of the Bill

3.2 The objective of the Gene Technology Bill, as stated in proposed 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 genetically modified organisms (GMOs).

3.3 This objective is to be achieved through a regulatory framework that will be based on an efficient and effective system of assessment and will operate in conjunction with other Commonwealth and State regulatory schemes relevant to GMOs and genetically modified products.[1]

3.4 An important aspect for achieving such an objective is to heed the comment that a critical feature of any regulatory scheme is that it 'remains relevant to the science it oversees, the community it protects, and the industry it regulates'.[2]

The current regulatory regime

3.5 Before examining the measures contained in the Bill to achieve its objective, the current regulatory system is briefly outlined by way of background to the need for the proposed legislation.

3.6 There are a number of regulatory bodies that currently oversee the use and distribution of genetically modified (GM) products in Australia. These are:

- The Australia New Zealand Food Authority (ANZFA), established by the *Australia New Zealand Food Authority Act 1991* (Cth), develops standards for foods, including genetically modified foods, which are regulated under State and Territory food acts. ANZFA reviews current food standards and processes

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1 Explanatory Memorandum, Gene Technology Bill 2000, p.45.

2 IOGTR, *Fact Sheet 7: A National Regulatory Framework for Genetically Modified Organisms (GMOs)*, p.1.

applications and proposals to amend the Food Standards Code. In addition, it conducts research and surveys in relation to matters that may be included in a food standard and develops food education initiatives in cooperation with the States and Territories. ANZFA is a statutory authority within the portfolio of the Minister for Health and Aged Care.

- The Therapeutic Goods Administration (TGA), pursuant to the *Therapeutic Goods Act 1989* (Cth), is responsible for the regulation of therapeutic goods, including GM therapeutic goods, and human gene therapy, both clinical research and marketing of products for human gene therapy. Regulation of therapeutic goods is achieved through a risk management approach to pre-market evaluation and approval of therapeutic products intended for supply in Australia; licensing of manufacturers; and post-market surveillance. TGA also provides advice to other regulatory authorities on toxicology, pre-market assessment and public health issues relating to agricultural, veterinary and industrial chemicals. TGA is a division of the Department of Health and Aged Care.

- The National Health and Medical Research Council (NHMRC) provides for research funding and advice on all aspects of health and health care delivery in Australia. NHMRC also supervises research involving human gene therapy through its Gene and Related Therapies Research Advisory Panel. NHMRC is a statutory authority established under the *National Health and Medical Research Council Act 1992* within the portfolio of the Minister for Health and Aged Care.

- The National Registration Authority (NRA), established under the *Agricultural and Veterinary Chemicals (Administration) Act 1992*, administers a national regulatory scheme for agricultural and veterinary (agvet) chemicals, including GM agvet chemicals, pursuant to the *Agricultural and Veterinary Chemicals (Code) Act 1994* (Cth). NRA is a statutory authority within the portfolio of the Minister for Agriculture, Fisheries and Forestry.

- The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) regulates industrial chemicals under the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cth) and associated State and Territory legislation. NICNAS provides for mandatory notification and assessment for chemicals that are not covered by other Australian assessment and registration schemes. It aims to ensure that new industrial chemicals entering Australia are assessed for their health and environmental effects before they are used or released into the environment. NICNAS is a statutory scheme administered by the National Occupational Health and Safety Commission, which is a statutory authority within the portfolio of the Minister for Employment, Workplace Relations and Small Business.

- The Australian Quarantine and Inspection Service (AQIS), regulates imports and exports under the *Quarantine Act 1908* (Cth), the *Imported Food Control Act 1992* (Cth) and the *Export Control Act 1982* (Cth). AQIS administers the quarantine, agriculture and food export laws. The Australian Customs Service (ACS), under the *Customs Act 1901* (Cth) provides the primary border control of

imports and exports with the assistance of AQIS. AQIS is a division of the Department of Agriculture, Fisheries and Forestry[3].

3.7 The TGA and the NHMRC also have a research role in addition to their regulatory functions, unlike the other authorities.

The Genetic Manipulation Advisory Committee (GMAC)

3.8 GMAC is an independent committee of experts in fields including molecular biology, ecology, plant genetics, agriculture and biosafety[4] engineering. GMAC assesses potential biosafety hazards to the community or the environment and recommends appropriate safety and containment procedures for GMOs to researchers and institutions undertaking work on GMOs. GMAC is concerned with:

> any experiment involving the construction and/or propagation of viroids, viruses, cells or organisms of novel genotype produced by genetic manipulation which are either unlikely to occur in nature[5], or likely to pose a hazard to public health or the environment[6].

3.9 As noted in Chapter 1, GMAC recommendations are complied with voluntarily and it has limited capacity for independent, legally enforceable auditing and monitoring of compliance. This current system of overseeing the use of gene technology has no legislative backing.

The Interim Office of the Gene Technology Regulator (IOGTR)

3.10 The IOGTR was established as a branch of the Therapeutic Goods Administration within the Commonwealth Department of Health and Aged Care in May 1999, with GMAC acting as expert advisory committee to the IOGTR.

3.11 The function of the IOGTR is:

- to work with representatives of State and Territory Governments, other Commonwealth agencies, existing regulators, and non-government organisations to develop and implement a new national regulatory system for GMOs; and
- pending the establishment of this new system, to provide support and, where necessary, direction to the current voluntary administrative arrangements for GMOs.[7]

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3 Submission No.77, p.18 (IOGTR).

4 Safety with respect to the effects of biological research on humans and the environment.

5 Organisms that are not likely to occur through natural processes, which includes processes other than natural selection (for example, cross-breeding).

6 Submission No.77, p.19 (IOGTR).

7 *IOGTR Quarterly Report*, June 2000.

3.12 Research and development involving GMOs is monitored by GMAC from the initial design concept through each successive stage. Under current arrangements, approval for the commercial release of a GMO must be sought from the Commonwealth Minister for Health and Aged Care. The Minister considers advice from GMAC, the IOGTR, Environment Australia and other experts before making a decision.[8]

3.13 While GMAC has been able to provide reliable scientific advice on the risks posed by gene technology and how to manage those risks, the IOGTR has indicated that the current regulatory arrangements are insufficient for several reasons. Firstly, since there is no legislative backing to the current system, there is no legally enforceable way to audit or monitor the use of the technology or penalise breaches. Secondly, the range of applications for gene technology is changing very rapidly such that GMOs and GM products are now being developed that are not covered by existing regulatory bodies. These include:

- the growing of GM agricultural crops;
- the growing or breeding of GM animals or fish;
- the use of GM micro-organisms designed to decompose toxic substances (bio-remediation);
- stockfeed that may be produced from genetically modified crops, for example cotton; and
- the use of GM viruses and GM vaccines.

Although GMAC has provided advice to the proponents of these GMOs, there has been limited capacity to either monitor or enforce compliance with that advice.

3.14 A third factor is that more GMOs are approaching the commercialisation stage when the producers of the GMOs will be seeking to release the GMO into the environment either for the purposes of field trials or for commercial release.[9]

3.15 Much of the impetus behind the move from a voluntary to a regulatory system of controls has been community perceptions about the risks associated with gene technology and a belief that 'industry cannot be relied upon to be sufficiently rigorous and objective in evaluating risk and implementing appropriate management strategies'.[10]

3.16 A recent case involving breaches of GMAC recommendations in the trialing of genetically modified canola at Mount Gambier highlights the need for a new legislative approach. The investigation into this matter is discussed in Chapter 6.

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8 IOGTR, *Fact Sheet 3: About the Genetic Manipulation Advisory Committee (GMAC)*, p.2.

9 Explanatory Guide, pp.9-10.

10 Submission No.77, p.20 (IOGTR).

Measures to achieve the Bill's objective

3.17 The Gene Technology Bill is the major component of a national scheme to protect the public health and safety of people and to protect the environment from risks associated with gene technology. The Bill's objective is to be achieved through the regulation of certain dealings with GMOs based on an efficient and effective system of assessment. Measures in the Bill designed to achieve its objective include:

- the establishment of a statutory officer to be known as the Gene Technology Regulator to administer the legislation and make decisions under the legislation (discussed in Chapter 4);
- prohibiting people from dealing with GMOs except in certain circumstances (see Chapter 4);
- establishing a scheme to assess the risks to human health and the environment associated with various dealings with GMOs (discussed in Chapter 4);
- providing for monitoring and enforcement of the legislation (discussed in Chapter 4);
- the establishment of three key advisory committees (discussed in detail in Chapter 5):
    - the Gene Technology Technical Advisory Committee: to provide scientific and technical advice at the request of the Regulator or the Ministerial Council on gene technology, GMOs and GM products, applications made under the Act, the biosafety aspects of gene technology, and the need for, and content of, policy principles, policy guidelines, codes of practice and technical and procedural guidelines in relation to GMOs and GM products;
    - the Gene Technology Ethics Committee: to provide advice at the request of the Regulator or the Ministerial Council on ethical issues relating to gene technology; the development of codes of practice in relation to ethics in respect of conducting dealings with GMOs; and the development of policy principles in relation to dealings with GMOs that should not be conducted for ethical reasons; and
    - the Gene Technology Community Consultative Group: to provide advice at the request of the Regulator or the Ministerial Council, on matters of general concern in relation to GMOs, and on the need for (an content of) policy principles, guidelines, codes of practice and technical and procedural guidelines in relation to GMOs and GM products; and
- providing for a publicly available, centralised database of all dealings in Australia that involve GMOs or GM products (discussed later in this chapter).

3.18 In addition to concerns about the adequacy of measures contained in the Bill to achieve the objective of protecting the health and safety of people and to protect the

environment, many submitters to the inquiry expressed dissatisfaction with the limited scope of the objective and of the Bill in toto.

3.19 The Committee received evidence that was critical of omissions from the objective of the Bill, variously arguing for the inclusion of references to the precautionary principle rather than a precautionary approach, risk reduction rather than risk management, environmental impact and protection of biodiversity, the national interest, human medical research, the ethics of gene technology, animal welfare, and the benefits of gene technology.[11]

3.20 In addition to these concerns relating specifically to the object of the Bill, a number of other issues were raised in relation to achieving the Bill's objective and providing sufficient consumer confidence in the regulation of gene technology. These include the establishment of a moratorium, the role of multinationals, implications for trade competitiveness, trial site locations, commercial-in-confidence information, proposed full cost recovery, adequacy of public reporting procedures, and public confidence.

The precautionary principle

3.21 The precautionary principle is based on the concept of taking anticipatory action to prevent possible harm under circumstances where there is a level of scientific uncertainty, although there is much discussion and diversity of opinion as to actually defining the principle.

3.22 The principle, as currently understood, emerged in German law in the 1970s as *Vorsorgeprinzip*[12] used to distinguish between the dangers and the risks caused by human behaviour, with two different approaches required to be taken: to prevent dangers (*Gefahrenvorsorge*) on the one hand, but where there is only a risk of effects occurring, risk prevention must be investigated and if warranted preventative measures applied (*Risikovorsorge*).[13] An enunciation of the principle is that:

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11 See for example Submission No.40, p.1 (Australian Conservation Foundation); Submission No.34, p.3 (Australian Centre for Environmental Law); Submission No.54, p.4 (Organic Federation of Australia Inc); Submission No.86, p.3 (World Wide Fund for Nature and the Humane Society International); Submission No.85, p.8 (ACF GeneEthics Network); Submission No.35, p.6 (GE-Free Tasmania); Submission No.11, p.3 (Canberra Consumers Inc); Submission No.20, p.5 (Ms L McDermott); Submission No.38, p.1 (Mr J Sleeman); Submission No.75, p.1 (Ms N George).

12 The concept is said to have developed from the 1930s German concept of *Vorsorgeprinzip* (foresight planning). 'The Precautionary Principle–"Nothing ventured, nothing gained"?' *Avcare Insights* Vol.1, 2000, p.2 [website: http:www.avcare.org.au/documents/insights.pdf].

13 Wybe Th. Douma, TMC Asser Institute, The Hague, The Netherlands at website: http://www.asser.nl/EEL/virtue/precprin.htm#N_9_.
Other websites that discuss the precautionary principle include:
http://www.icclaw.com/devs/uk/ev/ukev_047.htm;
http://europa.eu.int/comm/off/com/health_consumer/precaution_en.pdf;
http://www.mem.dk/faktuelt/fak15_eng.htm;
http://ehpnet1.niehs.nih.gov/docs/1999/107-12/editorial.html;
http://www.info-france-usa.org/ppseminar/transcript.htm.

> Environmental policy is not fully accomplished by warding off imminent hazards and the elimination of damage which has occurred. Precautionary environmental policy requires furthermore that natural resources are protected and demands on them are made with care.[14]

The international context

3.23 Since the early 1980s, a number of multilateral treaties and international declarations and protocols have adopted a form of the precautionary principle. Some examples of the international use of the precautionary principle, which demonstrate a variety of interpretations, include:

> [The participants] accept the principle of safeguarding the marine ecosystem of the North Sea by reducing polluting emissions of substances that are persistent, toxic and liable to bioaccumulate at source, by the use of the best available technology and other appropriate measures. This applies especially when there is reason to assume that certain damage or harmful effects on the living resources of the sea are likely to be caused by such substances, even where there is no scientific evidence to prove a causal link between emissions and effects ("the principle of precautionary action").
> *–1987 Ministerial Declaration of the Second Conference on the Protection of the North Sea.*

> Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question…in order to avoid or minimize such potential adverse effects.
> *–Cartagena Protocol on Biosafety, 2000.*

> Where action is deemed necessary, measures should be proportionate to the chosen level of protection, non-discriminatory in their application and consistent with similar measures already taken.
> *–EU Communique 2000.*

> Where there are threats of serious or irreversible environmental damage, lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation.
> *–1992 Rio Declaration on Environment and Development.*[15]

3.24 With respect to the intentional release of GMOs into the environment, relevant legislation, directives, regulations or guidelines in the European Union,

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14 Review of the Canadian Environment Protection Act (CEPA Review) [website: http://www.ec.gc.ca/cepa/ip18/e18_01.html].

15 Quoted sections are from the CEPA Review or *Avcare Insights*. Other references to the precautionary principle in international conventions, declarations and treaties are listed in Appendix 4.

United Kingdom, United States of America, Japan and South Africa[16] make no explicit reference to the precautionary principle. Appendix 3 provides an international comparison of the regulation of gene technology. However, there is precedent for the precautionary principle to be included in legislation covering GMOs:

- section 7 of the New Zealand Hazardous Substances and New Organisms Act states that all persons exercising functions, powers and duties under this Act shall take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects; and
- the preamble to the Canadian Environmental Protection Act (CEPA) states that 'whereas the Government of Canada is committed to implementing the precautionary principle that, 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 environmental damage'.[17]

3.25 The differing forms of the precautionary principle also impact on the scope of the principle's application, with some conventions and statements limited to toxic substances control[18], while others include any government policy with the potential to cause environmental degradation.[19]

3.26 One of the areas of dispute is what should trigger the application of the principle, for example 'likely harm' or 'serious or irreversible harm', and who should make such a determination.[20] While there is greater clarity with respect to the implementation of the precautionary approach in the context of ocean dumping, in other contexts its meaning is more elusive.[21]

3.27 Underlying much of the divergence of opinions are the contrasting philosophies of those opposed to the emission of non-natural products into the environment regardless of cost, and those prepared to make environmental trade-offs where there is potential for economic and social benefits. The latter interpretation of the precautionary principle may allow for the use of the best available technology not entailing excessive costs. The 1992 Rio Declaration, for example, includes a reference to 'cost-effective measures'. The former view is summed up by Greenpeace International which emphasized:

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16 Information for Germany is not available, however, it has been argued that Germany's 'overall regulatory approach might be described as a moderate version of the precautionary principle' See CEPA Review.

17 IOGTR, *Overview of International Regulatory Systems for Gene Technology*, August 2000.

18 See for example, the Final Declaration of the Third North Sea Conference, in Appendix 4.

19 See for example, the 1990 Bergen Declaration, in Appendix 4.

20 Compare the 1972 London Convention in Appendix 4 and the 1992 Rio Declaration stated above.

21 CEPA Review.

> the need for an effective precautionary approach, with that important principle intended to safeguard the marine ecosystem by, among other things, eliminating and preventing the release of substances, especially synthetic and persistent substances, where there is reason to believe that damage or harmful effects may be caused, even where there is inadequate or inconclusive scientific evidence to prove a causal link between emissions and effects.[22]

3.28 Regardless of the local variations of the scope and interpretation of the principle, a 'conceptual core' has been described by the Director of the Foundation for International Environmental Law and Development at King's College of London:

> The precautionary principle stipulates that where the environmental risks being run by regulatory inaction are in some way a) uncertain but b) non-negligible, regulatory inaction is unjustified.[23]

3.29 Core elements or directions underlying the precautionary principle include:

- proaction, a willingness to take action in advance of formal scientific proof;
- cost-effectiveness of action, that is, some consideration of proportionality of costs;
- providing ecological margins of error;
- intrinsic value of non-human entities;
- a shift in the onus of proof to those who propose change;
- concern with future generations; and
- paying for ecological debts through strict/absolute liability regimes.[24]

The Australian context

3.30 The precautionary principle has been incorporated into Australian legislation and agreements:

> Where there are threats of serious or irreversible environmental damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation. In the application of the precautionary principle, public and private decisions should be guided by:
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> i) careful evaluation to avoid, wherever practicable, serious or irreversible damage to the environment; and

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22 CEPA Review.

23 CEPA Review.

24 CEPA Review. Similar points were made by the Wingspread Conference referred to in 'The Precautionary Principle', *Rachel's Environment & Health Weekly*, No. 586, 19 February 1998, Environmental Research Foundation [website: http://www.ratical.org/co-globalize/REHW586.html].

ii) an assessment of the risk-weighted consequences of various options.

Under the principle the "onus of proof" regarding impacts has shifted to those actions that might cause change.
–Intergovernmental Agreement on the Environment, May 1992.[25]

The Minister must take account of the precautionary principle in making a decision listed in the table in subsection (3), to the extent he or she can do so consistently with the other provisions of this Act.

The *precautionary principle* is that lack of full scientific certainty should not be used as a reason for postponing a measure to prevent degradation of the environment where there are threats of serious or irreversible environmental damage.
–Environment Protection and Biodiversity Conservation Act 1999, section 391.

3.31 The precautionary principle is included as an objective of the New South Wales *Protection of the Environment Administration Act 1991*, which states that 'If there are threats of serious or irreversible environmental damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation'.

Evidence arguing for and against including the Precautionary Principle in the Bill

3.32 Many submissions expressed the view that the major deficiency of the Gene Technology Bill was that it does not contain the precautionary principle.[26] Heritage Seed Curators Australia summed up this widely held view by suggesting that the precautionary principle should be inserted in the object of the Bill to express clearly the paramount need for caution in any releases of GMOs. They argued that 'the "precautionary principle" is a simple way of saying that "if we do not know what will happen" it is ill-advised to go ahead and do it!'.[27]

3.33 The Australian Centre for Environmental Law (ACEL) drew attention to Environment Australia's submission to the House of Representatives inquiry into primary producer access to gene technology, which stressed:

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25 Referred to in Submission No.85, p.2 (ACF GeneEthics Network).

26 See for example, Submission No.34, p.4 (Australian Centre for Environmental Law); Submission No.40, p.2 (Australian Conservation Foundation); Submission No.13, p.1 (Mr A Walker-Morison); Submission No.19, pp.1-2 (The Environment Centre of WA); Submission No.22, p.4 (Mr G Whitten); Submission No.85, p.8 (ACF GeneEthics Network); Submission No.35, p.7 (GE-Free Tasmania); Submission No.6, p.3 (Consumers' Association of SA Inc); Submission No.5, p.1 (National Council of Women of Australia); Submission No.106, p.1 (GeneEthics Network); Submission No.16, p.1 (Mr A Ward); Submission No.87, p.1 (Mr & Mrs Underwood); Submission No.66, p.1 (Strider); Submission No.31, p.1 (J Grevillea); Submission No. 30, p.1 (Mr J Langmead); Submission No. 28, p.1 (Ms P Hemsworth); Submission No.15, p.2 (Mr B Holderness-Roddam).

27 Submission No.9, p.3 (Heritage Seed Curators Australia Inc). See also *Committee Hansard*, 24.08.00, p.264 (NGAA) who stated 'Even if no adverse effects have been reported, this does not mean that these will not emerge in the future'.

> The precautionary principle has particular application to GMOs. Not only could direct damage be serious, but ongoing and extensive because of irreversibility. Once released freely to the environment, a living organism, or a novel gene that has transferred to an unintended host, cannot be "recalled". A cautious and conservative approach to risk should be followed where there is insufficient scientific confidence of safety. Successful application of the principle will mean that Australia avoids expensive failures.[28]

3.34 Although characteristic of some opponents of GMOs, support for the application of the precautionary principle in regulating GMOs did not always indicate opposition to the technology, where there was an expressed desire that the technology be a 'benefit to mankind, not…an encumbrance'.[29]

3.35 The Australian Conservation Foundation (ACF) also called for inclusion of the precautionary principle to create certainty, arguing that this can only be achieved by the 'specific mentioning' of the principle in legislation. Mr Kerr of ACF added: 'I would not like to see someone forget that the precautionary principle applies simply because we have not taken five minutes to draft it into the legislation'.[30]

3.36 However it was argued that confusion about how to interpret the principle may itself lead to uncertainty in the operation of the legislation, with the wording in the Biosafety Protocol cited as an example of where the precautionary principle was 'almost grammatical nonsense and extremely difficult to understand'.[31]

3.37 It has also been argued that the terms used in statements of the precautionary principle, such as 'risk', 'uncertainty' and 'serious' have not been defined. Consequently, there is little agreement on the circumstances which warrant the use of the precautionary action or what those actions should be. Opinions have thus polarised: some seeing it as a means for protecting future generations while others a means of stopping research and development.[32]

3.38 The differing view of the precautionary principle was reflected in the Committee's evidence. For some the principle was a general one analogous to the removal of land mines.[33] Others however, understood it to mean that a technology could not be progressed unless there was certainty about its future risks:

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28 Cited in Submission No.34, p.4 (Australian Centre for Environmental Law).

29 *Committee Hansard*, 22.08.00, p.78 (Mrs L Huebner). See also, *Committee Hansard*, 23.08.00, p.162 (Mr A Macintosh).

30 *Committee Hansard*, 24.08.00, p.315 (ACF).

31 *Committee Hansard*, 24.08.00, p.246 (Australian Biotechnology Association).

32 *Avcare Insights*, p.2. See also, for example, R Horton, 'Genetically modified food: consternantion, confusion, and crack-up', *MJA* 2000, 172:148-149 [Article published on the Internet by *The Medical Journal of Australia* website: http://www.mja.com.au].

33 *Committee Hansard*, 22.08.00, p.65 (Heritage Seed Curators Australia Inc).

> The precautionary principle, as I understand it, would mean that you do not do anything unless you are absolutely 100 per cent certain that there is no risk. I do not think we can say that there is any technology we can progress to that extent. If we take the literal meaning of the precautionary principle, I would not support it, but I would support a precautionary approach.[34]

3.39 However the precautionary principle as written in Australian environmental policy and the *Environment Protection and Biodiversity Conservation Act 1999* (Cth) (EPBC Act) applies a lesser test than 'absolute 100 per cent certainty that there is no risk'. The obligation on regulators is to consider identified risks carefully:

> where there are threats of serious or irreversible environmental damage, lack of scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation.

3.40 If the Regulator is aware of threats to the environment, then the obligation is to take action even if there is a lack of scientific certainty about the extent of the threat. There has to be sufficient evidence that the threats are credible and would result in serious or irreversible damage.

3.41 In the case of GMOs this would suggest that the Regulator should postpone approval for release of GMOs where it is believed there was a threat of serious or irreversible environmental damage. Equally the Regulator might apply the principle to decide to approve an application subject to a rigorous set of conditions to forestall or minimise any threats of damage even if there was not scientific certainty that those measures would be absolutely necessary.

3.42 Florigene Limited and Nugrain Pty Ltd argued, that while they 'are not opposed to incorporating sound science-based precaution into regulatory procedures':

> We are firmly of the view that indiscriminate use of the precautionary principle will stifle technological advancement and investment and as a consequence, reduce the capacity of agriculture to respond to future demands for its products, both in Australia and internationally.[35]

3.43 Professor Peter Gresshoff argued:

> While it is natural for our species to fear the "unknown", and while I accept that "zero risk" technology is unattainable, I believe it is essential that we as

34 *Committee Hansard*, 23.08.00, p.188 (Serve-Ag). See also Submission No.9, p.3 (Heritage Seed Curators Australia Inc). Cf. Submission No.93, p.1 (Dr K Clinch-Jones) who argued that commercial interests should come second to the protection of humans and the environment.

35 Submission No.42, p.4 (Florigene Limited and Nugrain Pty Ltd). See also, for example Submission No.105, p.1 (Australian Cotton Cooperative Research Centre).

> a society of thinking and rational individuals venture on the side of reason rather than superstition and hear-say.[36]

3.44 The possibility that a development should not proceed where the potential adverse effects were not fully understood was included in the World Charter for Nature (1982):

> Activities which are likely to pose a significant risk to nature shall be preceded by an exhaustive examination; their proponents shall demonstrate that expected benefits outweigh potential damage to nature, and where potential adverse effect are not fully understood, the activities should not proceed.[37]

3.45 Many of those arguing in favour of the precautionary principle used historical examples of 'science gone wrong' to further their argument, citing for example the adverse effects of thalidomide, DDT or the release of certain animals such as the cane toad for biological control.[38]

3.46 However, this view was countered by other cases where opposition to beneficial scientific advances was poorly substantiated, for example halting vaccination and opposition to fluoridation.[39]

3.47 The IOGTR informed the Committee that the Commonwealth, States and Territories had examined in detail the issue of including a reference to the precautionary principle in the Gene Technology Bill 2000. All jurisdictions noted that there was continuing debate both internationally and within Australia on the scope and application of the precautionary principle. The jurisdictions considered that some sectors of the community perceived the precautionary principle as being about non-action or not taking a decision, arguing instead that:

> In reality, the Precautionary Principle allows governments to take action and decide upon measures in circumstances where there is a serious or irreversible threat to the environment but the available scientific evidence may be inconclusive.[40]

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36 Submission No.100, pp.1-2 (Professor P Gresshoff). See also, *Committee Hansard*, 24.08.00, p.283 (AWB Ltd).

37 World Charter for Nature, UN GA Resolution 37/7 (1982), 11(b) [See website http://sedac.ciesin.org/pidb/texts/world.charter.for.nature.1982.html].

38 *Committee Hansard*, 24.8.00, p.264 (National Genetic Awareness Alliance). Other cases include the introduction or use of organochlorins, asbestos, and DES – diethylstilboestrol - which had been used in medicine and agriculture for 30 and 25 years respectively. *Avcare Insights*, p.1; See also Submission No.113, p.1 (Ms M Sculthorp); *Committee Hansard*, 23.8.00, p.142 (OFA); *Committee Hansard*, 23.8.00, p.165 (Mr G Whitten); C*ommittee Hansard*, 24.8.00, p.309 (ACF GeneEthics Network).

39 *Committee Hansard*, 24.08.00, p.246 (Australian Biotechnology Association). See also *Committee Hansard*, 23.08.00, p.186 (Serve-Ag).

40 Submission No.77, p.74 (IOGTR).

3.48 In recognition that an explicit reference to the precautionary principle may create potential uncertainty about its interpretation, all jurisdictions agreed that the risk assessment and risk management approach contained in the Bill embodied an appropriate precautionary approach without being directly stated. To ensure that a precautionary approach is applied by the Gene Technology Regulator, the legislation:

- empowers the gene technology regulator to obtain scientific evidence from a range of sources, including his/her own independently commissioned research;
- requires the regulator to identify risks to people or the environment posed by each dealing;
- requires the regulator to determine a risk management plan for each dealing;
- requires the regulator to reject the application if the risks cannot be managed (i.e. if the dealing presents a serious or irreversible threat);
- requires the regulator to establish a monitoring program;
- requires the regulator to take or order remedial action if required; and
- ensures that the regulator is publicly accountable for decisions.[41]

3.49 The Committee is cognisant of the potential risks associated with the release of GMOs into the environment and that this is the primary concern of most people advocating the adoption of the precautionary principle in relation to the regulation of GMOs. To avoid uncertainty, the Committee considers that any reference to the precautionary principle should be expressed in terms consistent with those used in Australian precedents including the EPBC Act.

3.50 Despite variations in defining the principle, the need for the precautionary principle to be included in the object of the Bill and to be applied by the Regulator when making decisions on licence applications, received considerable support in submissions and during the Committee's hearings.[42]

3.51 The adoption of the principle is not unprecedented, with the precautionary principle entrenched in both the EPBC Act and the Cartagena Biosafety Protocol, to which Australia is not yet a signatory.[43] It was emphasised that the push for the inclusion of the principle in the Gene Technology Bill did not stem from groundless

41 Submission No.77, p.74 (IOGTR).

42 See for example, *Committee Hansard*, 23.08.00, p.180 (GE-Free Tasmania); *Committee Hansard*, 24.08.00, p.305 (ACF); Submission No.54, p.6 (Organic Federation of Australia Inc).

43 *Committee Hansard*, 24.08.00, p.305 (Australian Conservation Foundation); *Committee Hansard*, 25.08.00, pp.357, 371 (ACEL).

fear but from a real need to exercise caution in relation to a technology for which the long-term effects are yet to be fully studied or understood.[44]

3.52 It was argued that gene technology should not merely be viewed as a scientific field but also an industrial technology and that the inclusion of the precautionary principle in the Bill should serve as a benchmark for the regulation of other new industrial technologies.[45]

3.53 The Committee supports the precautionary approach to the introduction of gene technologies at a time when much scientific research is being done around the world to quantify the extent, if any, of the risks of serious or irreversible environmental damage, or risks to human health.

3.54 The Committee notes the concern raised about the way in which the handling of BSE infected beef has influenced many people's cautious attitudes towards GMOs, particularly genetically modified foods. While it is acknowledged that this incident did not involve GMOs, it is considered to be an example of where a precautionary approach may have prevented a major public health problem.

3.55 The Committee further notes the recent decision to prevent Australians who lived in the UK during the height of the BSE scare from donating blood. This decision was made despite the extremely small risk that CJD could be passed through blood donations and represents a precautionary approach to the possible risk that has been welcomed by experts and the general public alike.

3.56 The requirement in section 391 of the EPBC Act for the Minister to consider the precautionary principle in making a range of decisions was cited by many in evidence as a valuable precedent. The Committee is concerned that legislation covering the protection of the environment provides through the inclusion of the precautionary principle a more stringent precautionary approach than that which is being proposed for the protection of human health and safety in the Gene Technology Bill. Nevertheless, the Committee welcomes the measures included in the Bill to ensure that a precautionary approach is applied, but considers that without the precautionary principle explicitly stated in the legislation, other measures such as extending standing for third-party appeal to the Administrative Appeals Tribunal (see Chapter 5) must be included to ensure that measures to protect the health and safety of people are stringent.

A precautionary approach

3.57 The overwhelming majority of submitters to the inquiry recognised the need to adopt a cautious approach in relation to the regulation of GMOs and differed only in the degree of caution required. The difference centred on the adoption of either a

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44 *Committee Hansard*, 22.08.00, p.62 (Heritage Seed Curators Inc); *Committee Hansard*, 25.08.00, p.371 (ACEL). See also *Committee Hansard*, 23.08.00, p.222 (Tasmanian Government).

45 *Committee Hansard*, 24.08.00, p.309 (ACF GeneEthics Network).

precautionary approach or the explicit statement of the precautionary principle in the legislation, notably in the object and licensing provisions of the Bill.

3.58 This view was highlighted during the First Australian Consensus Conference on Gene Technology in the Food Chain which observed:

> The potential hazards are largely unknown in the long-term and as such demand due caution during the research, development and initial use of GMOs.[46]

3.59 The Committee notes that the Cartagena Protocol's objective reaffirms the 'precautionary **approach'** enshrined in Principle 15 of the Rio Declaration on Environment and Development rather than the precautionary principle itself. The Committee also notes that CSIRO was unable to identify any legislation of similar scope and intent as the Gene Technology Bill 2000 where the precautionary principle was intended but not explicitly stated.[47]

3.60 The June 2000 report of the House of Representatives Standing Committee on Primary Industries and Regional Services *Work in Progress: Proceed with Caution*, recommended the continued use of gene technology, but only with 'stringent regulation, constant and cautious monitoring, and public reporting'.[48]

3.61 While the precautionary principle was not favoured in all evidence presented to the Committee, a precautionary **approach** was considered sufficient to ensure that risks associated with GMOs were identified and properly managed without stopping potentially beneficial research and development of GMOs, and without requiring the expectation of absolute certainty in science, an unattainable aim.[49]

> What we are saying is that a precautionary approach should be applied to risk management. Once an organism has been approved, then it has to be managed under farming conditions, and we have a lot of examples where best management practice is the tool to actually manage that risk. So we certainly believe that a precautionary approach should be applied in that area of risk management.[50]

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46 Lay Panel Report, First Australian Consensus Conference on Gene Technology in the Food Chain [website: http://www.austmus.gov.au/consensus]

47 CSIRO, Additional Information dated 25.August 2000, p.3.

48 *Work in Progress: Proceed with Caution*, Report by the House of Representatives Standing Committee on Primary Industries and Regional Services, June 2000, p.29.

49 *Committee Hansard*, 25.08.00, p.426 (CSIRO); Submission No.90, p.1 (Du Pont Technical Centre). See also Submission No.94, p.2 (Monsanto Australia Ltd); Submission No.98, p.2 (Novartis Australia Pty Ltd); Submission No.104, p.1 (Dow AgroSciences).

50 *Committee Hansard*, 25.08.00, p.381 (Avcare).

3.62 The adoption of the precautionary approach was supported by Dr Lonsdale from CSIRO, who also commented on the attitude of CSIRO scientists to the precautionary principle:

> I think you would find within our organisation there are a range of views on the precautionary principle: there are those for whom it is the very essence of science, and there are those for whom it is the antithesis of science. Ultimately, the precautionary approach is probably the one I would subscribe to, because I am aware of the very great problem facing agriculture and biodiversity in this country and overseas, and I do not think we can tie our hands behind our backs. So I would argue that moving forward cautiously, making haste slowly-the precautionary approach-is the approach to take, rather than the principle which seems to me to argue for doing nothing until absolute certainty is achieved, which in science is impossible.[51]

3.63 The Committee notes that a precautionary approach rather than precautionary principle is contained in the South Australian *Environment Protection Act 1993* which includes in its objectives (sub-section 10(1)(b)) a commitment:

> to apply a precautionary approach to the assessment of risk of environmental harm and ensure that all aspects of environmental quality affected by pollution and waste (including ecosystem sustainability and valued environmental attributes) are considered in decisions relating to the environment.

3.64 While there is clearly consensus on the need to ensure a cautious approach to the development and adoption of gene technologies, there is also acknowledgment of the need to ensure the continuation of research and development on the basis of current scientific understanding of potential risks:

> [The] Regulator's deliberations must be based on sound, consistent and reproducible scientific and technical data generated according to world best practice standards.[52]

3.65 The adequacy of science to identify all of the potential risks and detect hazardous cause and effect consequences associated with biotechnology has been questioned. Reasons for this concern include:

- limitations in scientific knowledge;
- problems of statistical power (producing false negatives);
- low-level adverse effects;

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51 *Committee Hansard*, 25.08.00, p.426 (CSIRO).

52 Submission No.42, p.4 (Florigene Limited and Nugrain Pty Ltd). See also, *Committee Hansard*, 23.08.00, p.184 (Serve-Ag Pty Ltd) for support for a 'responsible and regulated' cautious approach to use of gene technology.

- difficulties in addressing cumulative effects; and
- financial and resource limitations which make it too expensive to test all product and environmental combinations.[53]

3.66 The Committee notes the view expressed by the IOGTR about the ability of the regulatory procedures to protect the community:

> No regulatory system can guarantee absolute safety or zero risk. However, Australia already has an extremely good record on the regulation of food, chemicals and pharmaceuticals that are genetically modified.[54]

3.67 A number of organisations considered that the measures provided for in the Bill would enable the Regulator to meet the objectives of the legislation.[55] For example, the Grains Research and Development Corporation stated:

> The establishment of an independent regulator with the power to enforce decisions on GMO use should ensure the protection of health and the environment, and, importantly, the community's confidence that the protection is being provided.[56]

3.68 The National Farmers' Federation (NFF) considered that in addition to the measures outlined above, the requirement for the Regulator to report to Parliament in the event of serious breaches of the legislation and the strict liability attached to breaches of licence conditions should ensure high consumer confidence.[57]

3.69 While the Institute of Public Affairs considered that measures in the Bill were more than adequate to meet its objectives, claiming that 'there is considerable overkill since the technology poses no threat to humans and is likely to improve environmental outcomes',[58] others expressed scepticism that the objectives could be achieved given that the 'scientific discovery of DNA is less than 50 years old and the gene pool has developed and matured or diversified over billions of years'.[59]

3.70 Ms Lisa McDermott concurred, stating:

> A genetically engineered organism is uniquely different to every other organism on the planet. We cannot possibly know the consequences of

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53 *Avcare Insights*, p.5.

54 IOGTR, Gene Technology Bill 2000, Questions and Answers, p.14.

55 See for example, Submission No.89, p.3 (Tasmanian Government); Submission No.105, p.1 (Australian Cotton Co-operative Research Centre); Submission No.8, p.2 (Serve-Ag Pty Ltd); Submission No.71, p.11 (Australian Food and Grocery Council); Submission No.63, p.5 (AWB Ltd); Submission No.102, p.2 (CSIRO).

56 Submission No.41, p.1 (Grains Research and Development Corporation).

57 Submission No.88, pp.1-2 (National Farmers' Federation).

58 Submission No.78, p.1 (Institute of Public Affairs Ltd).

59 Submission No.101, p.1 (Ms F Murrell). See also, Submission No.64, p.1 (Mr P Hockey).

> restructuring living organisms which in billions of years of evolution have never crossed species boundaries. Those who realise and acknowledge this will feel a little more cautious and be more inclined to act responsibly about gene technology.[60]

3.71 The paradox of gene technology is that there is considerable uncertainty about the extent of risks at this time. Being too cautious may stifle research that might clarify the extent of such risks and unnecessarily restrict work to determine the extent of benefits that gene technology may bring. However, unless care is taken, it is possible that if problems are identified in the future the applications might be too widespread to be able to counter the harmful effects.

3.72 The Committee considers that the precautionary approach would be underpinned in the Bill if the precautionary principle appeared as one of the objects in the same form as it appears in the EPBC Act. The Committee does not support the precautionary principle being made a specific test in the licensing provisions.

3.73 The Committee considers that there is a balance between the risks to the community versus the rights of a company,[61] and strongly considers that, in keeping with a precautionary approach, the onus of proving that GMOs are not harmful should rest with the proponents of the technology.

Risk management versus risk prevention

3.74 Some submissions expressed concern at the use of 'risk management' as an object of the Bill rather than risk prevention or reduction.[62] It was argued that the onus should be on the applicant to show that the work being undertaken was not harmful or unethical,[63] and that where the outcomes may be irreversible, 'the concern of the GTR then must be to prevent and eliminate such risks'.[64]

3.75 The Committee understands concerns raised in evidence about the emphasis on risk management rather than risk prevention. The Committee considers that risk identification, assessment and management should be based on the most up-to-date and independent scientific advice available at the time of the application for a licence. The adequacy of the risk assessment processes is discussed in Chapter 4.

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60 Submission No.20, p.1 (Ms L McDermott).

61 See for example, *Committee Hansard*, 24.08.00, p.268 (NGAA) who stated that 'industry concerns should not override health and safety concerns'.

62 Submission No.34, p.3 (Australian Centre for Environmental Law); Submission No.86, p.3 (World Wide Fund for Nature and The Humane Society International); Submission No.54, p.4 (Organic Federation of Australia Inc); Submission No.79, p.1 (Mr K Healy).

63 Submission No.75, p.1 (Ms N George).

64 Submission No.73, p.1 (Ms J Ablitt).

Environmental impact

3.76 The Committee considers that while the protection of the environment is important, it should not detract from the paramount objective of protecting the health and safety of people.[65] The Committee supports the placement of the OGTR in the Health and Aged Care portfolio.

3.77 The Committee notes the concern raised by ACF that 'there is no requirement under the GT Bill that an environmental impact assessment (EIA) of a proposed GMO dealing take place'.[66]

3.78 The objective of the Bill was also considered inadequate because of its failure to refer to ecological sustainability. The ACF Gene Ethics Network recommended:

> The Objects of the GT Bill 2000 should also be amended to include the principle of ecological sustainability, to ensure GEOs do not contribute to the long term destabilisation and decline of our food and fibre production systems, the natural environment and biological diversity.

3.79 The Committee notes that the procedures for assessing the environmental impact of GMOs were considered inadequate to protect the environment as required by the objective of the Bill. Chapter 4 includes a discussion of the adequacy of risk assessment processes under the Bill.

Biodiversity

3.80 The Environment Protection and Biodiversity Conservation Act includes in its objectives (section 3) the protection of Australia's biodiversity. A number of submissions recommended that one of the objects of the Gene Technology Bill should be to protect, conserve and maintain biological diversity against threats posed by GMOs.[67]

3.81 Mr Ian Dowden and Ms Kathleen Canning argued:

> Scientists are unsure of how GMOs will react in the open environment. In particular they are uncertain as to how GMOs will interact with other species and their capacity to mutate. As in the case of exotic species (eg the rabbit, cane toad and the prickly pear), the release of GMOs into the open environment could have unforeseen and catastrophic consequences.[68]

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65 The Committee notes, for example, the recommendation that the objective of the Act should be amended to add, 'but with an overall priority being given to public health and occupational health'. See Submission No.111, p.4 (Dr I Furzier).

66 Submission No.40, p.2 (Australian Conservation Foundation). See also *Committee Hansard*, 24.08.00, p.308 (ACF).

67 Submission No.51, p.3 (Friends of the Earth (Fitzroy)); Submission No.73, p.2 (Ms J Ablitt); Submission No.79, p.1 (Mr K Healy).

68 Submission No.49, pp1-2 (Mr I Dowden & Ms K Canning).

3.82 The Committee notes the recommendation of the World Wide Fund for Nature and the Humane Society International that the EPBC Act should be amended to include GMO releases as a matter of national environmental significance, in order to ensure full environmental assessment and to give the Environment Minister power to veto GMO releases where necessary for environmental protection.[69]

3.83 Mr Anton from the ACEL observed:

> Environmental impact assessment is only "triggered" where there is likely to be a significant impact on the environment under the EPBC Act, as determined by the minister. If it is taking place in a contained, closed area-in research, if you will-and it is determined under the EPBC regime that it is not likely to have a significant environmental impact, then there is no need and no occasion to prepare an environmental impact assessment.[70]

3.84 The Committee notes the advice that if the Regulator were concerned that the release of a GMO may impact on species diversity, the Regulator would not approve the application to release the GMO.[71] Avcare Limited argued:

> It is not necessary for biological diversity matters to be included as they can be considered as part of the environmental assessment conducted by the Environment Minister. In the situation where the release is to be made onto areas of national significance could trigger the Environment Protection and Biodiversity Conservation Act (Part 3).[72]

3.85 The Committee notes that in the current Bill, the Regulator must seek advice from the Environment Minister in preparing a risk assessment and risk management plan for applications that may involve the intentional release of a GMO into the environment. This differs from the 1999 draft Bill, where the Environment Minister is not specifically mentioned. The Committee is not satisfied that this change provides sufficient strengthening of the overall risk assessment processes with respect to the impact of GMOs on the environment.

3.86 The Committee considers that, given the scope of the Bill which includes the protection of the environment, any measures needed to ensure this objective should be contained within the Gene Technology Bill itself rather than referring to another Act. The relationship between the Bill and the EPBC Act with respect to environmental risk assessments is discussed in Chapter 4.

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69 Submission No.86, p.2 (World Wide Fund for Nature and the Humane Society International). See also, Submission No.28, p.1 (Ms P Hemsworth).

70 *Committee Hansard*, 25.08.00, p.367 (ACEL).

71 IOGTR, Gene Technology Bill 2000, Questions & Answers, p.13.

72 Submission No.32, p.5 (Avcare Limited).

Recommendation

The Committee RECOMMENDS that the risk assessment provisions of the Bill should be amended to give greater weight to the consideration of the impact of the release of GMOs into the environment, especially given Australia's unique flora and fauna and the importance of maintaining Australia's biodiversity.

The national interest

3.87 The consultation draft of the Gene Technology Bill circulated in 1999 included in its object, in addition to the primary objective of protecting human health and the environment, a reference to the national interest:

> It is also an object of this Act that dealings with GMOs be regulated in a way that is consistent with Australia's national interests.[73]

3.88 The present Bill's object does not refer to the national interest, an omission criticised in evidence to the Committee.[74] It was considered important that the regulatory framework was seen to be operating in the national interest rather than a private or secular interest.[75]

3.89 Mr Gary Burgess from the SA Farmers Federation stated:

> …the national interest could mean that we wish to encourage a biotechnology industry in Australia, and it may be in our national interest not to allow certain products to come in without an Australian partner and things like that…currently, if you were to take national interest out, providing everything is hunky-dory through the rest of the act, there is then no provision to say, "No, we're not going to accept that piece of technology".[76]

3.90 The Consumers' Association of SA proposed:

> We would like to see an objective here that spells out the protection of Australia's diverse farming systems as being in the national interest. It was the term "national interest" in the first draft not being defined, that left open "matters of trade" as being seen as in the national interest to the detriment of our diverse farming systems and possibly other matters such as public or community interest.[77]

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73 Consultation Draft Gene Technology Bill 2000, sub-clause 3(2).

74 *Committee Hansard*, 22.08.00, p.48 and Submission No.81, p.1 (South Australian Farmers Federation); *Committee Hansard*, 22.08.00, p.127 (Aventis Crop Science Pty Ltd).

75 *Committee Hansard*, 22.08.00, p.50 (South Australian Farmers Federation).

76 *Committee Hansard*, 22.08.00, p.53 (SA Farmers Federation).

77 Submission No.6, p.2 (Consumers' Association of SA Inc).

3.91 As with the precautionary principle, there is lack of clarity as to how the expression 'national interest' should be interpreted.[78] The Committee notes that 'national interest' was not defined in the draft Bill but included matters that may have been specified in policy guidelines or codes of practice developed in accordance with the Gene Technology Intergovernmental Agreement. The Bill provides that the Ministerial Council may issue policy guidelines in relation to matters relevant to the functions of the Regulator.[79] The role of the Ministerial Council is examined in detail in Chapter 5.

Human medical research

3.92 Concern was expressed about the failure to include clinical research which involves gene technology within the scope of the Bill. Ms Kathy Liddell stated:

> It is claimed that these matters are dealt with by the NHMRC in much the same way that certain activities are handled by the regulatory authorities mentioned above. However, the regulatory power of the NHMRC is relatively weak. It is primarily based on Guidelines that are part of funding agreements. It does not have strong powers to monitor compliance and are only voluntarily binding on some organisations. If the Bill is not extended to cover clinical research that uses gene technology, this particularly risky application of gene technology will be regulated the least stringently of all GM dealings.[80]

3.93 Canberra Consumers stated that 'there should be some comment, perhaps along the lines that genetic modification of humans is excluded but will be picked up in other legislation'.[81]

3.94 The IOGTR advised that the original draft had defined a GMO to exclude a human being, but that this had led to concerns that trials involving the use of GMOs in humans would not be covered by the Bill. This has been clarified in the current Bill which excludes people who have undergone somatic[82] cell therapy, who may then, under the previous definition, have been required to be licensed. Under the current legislation the GTR will regulate all organisms modified by gene technology including human cell lines and tissue samples. While the TGA and the NHMRC will have the primary responsibility for overseeing somatic cell gene therapy, the GTR will

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78 See for example, *Committee Hansard*, 22.08.00, p.53 (South Australian Farmers Federation) *Committee Hansard*, 22.08.00, p.109 (National Council of Women of Australia Ltd).

79 Gene Technology Bill 2000, clause 23.

80 Submission No.45, p.3 (Ms K Liddell). See also *Committee Hansard*, 24.08.00, p.312 (ACF GeneEthics Network) who expressed concern about 'human genetic engineering' and the need for it to be regulated by the Gene Technology Bill.

81 Submission No.11, p.4 (Canberra Consumers Inc).

82 Body cells as opposed to sperm and ova.

also be involved to ensure that there are no environmental risks posed by GMOs to be used as part of the human trials.[83]

3.95 While other regulatory authorities will continue to have carriage of the regulation of GMOs relevant to their area of responsibility, the Regulator will still play an advisory role.[84] The Gene Technology (Consequential Amendments) Bill 2000 requires existing regulators to:

- seek advice from the Gene Technology Regulator in relation to any application for approval of a GM product;
- take such advice into account in decision making under relevant legislation; and
- notify the Regulator of all decisions made in relation to GM products to enable those decisions to be entered on a central, publicly available database of all GMOs and GM products held by the Regulator.[85]

3.96 The confusion over the scope of the Bill in relation to human medical research highlights a major criticism expressed in evidence to the Committee – that of the interaction between other regulatory authorities and the proposed Gene Technology Regulator backed by calls for a 'one-stop shop' approach to be adopted. This is discussed in detail in Chapter 4. The appropriateness of the advisory role of the Regulator is also examined.

3.97 The Committee notes that in a late submission, concerns were raised about the possibility that the Gene Technology Bill would permit human cloning.[86] The Committee also notes that there is disquiet about suggestions that human cloning be covered by the Bill, and concurs with the view expressed by the Queensland Government that 'human cloning raises complex and sensitive issues which are probably best dealt with in separate legislation'.[87] The Committee notes that the House of Representatives Standing Committee on Legal and Constitutional Affairs is currently conducting an inquiry into the scientific, ethical and regulatory aspects of human cloning.

Recommendation

In view of the confusion caused by the lack of clarity on the status of medical research, and particularly human medical research, under the legislation the Committee RECOMMENDS that the Bill be amended, where appropriate, to explicitly state how such research will be dealt with by the OGTR.

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83 IOGTR, Additional Information dated 25 August 2000, Attachment D.

84 IOGTR, Additional Information dated 25 August 2000, p.9.

85 Explanatory Memorandum, Gene Technology (Consequential Amendments) Bill 2000, p.1.

86 See Submission No.116 (Mr N Tonti-Filippini). Submission 65 (Mr A McKinley) also stated that the Government should legislate against human cloning.

87 Submission No.84, p.2 (Queensland Government).

Ethical considerations

3.98 According to some submitters the social, religious and ethical implications of gene technology, including transgenic organisms,[88] were issues to be considered in the regulation of GMOs.[89] It was argued that these issues should be outlined in the object rather than in guidelines or policy directives of the Gene Ethics Committee.

3.99 The Committee was reminded that these issues are held very deeply by many people:

> While the threat to human health and the environment is of vital importance, the government must be mindful of the fact that many people believe that GE involves an immoral meddling with "nature" or "God's creation".[90]

3.100 The ethical issues associated with gene technology were accorded a high priority by the First Australian Consensus Conference held in Canberra in March 1999. The Conference, which brought together a group of experts and lay people, concluded:

> There are many moral and ethical issues raised by gene technology such as:
>
> – Should life become a commercial property through patenting?
>
> – Should we create transgenic organisms, particularly those containing human and animal DNA?
>
> – Who advocates for nature?
>
> – How do we ensure that our decision-making processes respect the diverse cultural, moral and religious beliefs within our multicultural society?
>
> It would be presumptuous of us to answer these issues or to assume that we have identified all of them, however we believe that ethical considerations must assume a prominent role in decision making about gene technology.[91]

3.101 The Lay Panel's Report recommended that an ethicist be involved in the formulation of major decisions regarding GMO policies.

3.102 The IOGTR advised the Committee that:

> no statutory ethics committee is involved in providing policy guidance in New Zealand, Japan, South Africa, Canada or the United States. Likewise,

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88 Organisms that have had a foreign gene inserted into them.

89 See for example Submission No.38 (Mr J Sleeman) and Submission No.75 (Ms N George). *Committee Hansard*, 24.08.00, p.322 (ACF). See also Submission No.35, p.15 (GE-Free Tasmania).

90 Submission No.25, p.16 (Mr Andrew Macintosh).

91 Lay Panel Report, First Australian Consensus Conference on Gene Technology in the Food Chain.

> in the United Kingdom there are several advisory committees composed of a range of individuals, but there is no specific expert committee established to advise on ethics. Similarly, domestically, AQIS, TGA, NICNAS, ANZFA and the NRA all operate without the influence of an expert ethics committee.[92]

3.103 Under the Gene Technology Bill, the Regulator 'must not accept an application for a licence to deal with a GMO if it is inconsistent with a prohibitive ethical principle'.[93]

3.104 The proposed Gene Technology Ethics Committee is to be established to deal with the very issues raised by some submitters to the inquiry. The Committee notes that the Bill provides that the Ministerial Council may issue policy guidelines in relation to ethical issues relating to dealings with GMOs. The appropriateness of this provision and the relationship between the Ministerial Council and the Gene Technology Ethics Committee is discussed in Chapter 5.

Animal welfare

3.105 While the Bill's object addresses the health and safety of people and the environment, Friends of the Earth (Fitzroy) raised the issue of animal welfare, recommending that the object include a reference to the health and safety of animals.[94]

3.106 Avcare Limited, on the other hand, argued:

> It is not necessary for animal health to be included as animals can be considered as part of the environment into which the GMO is being released. Furthermore, proponents of GMOs still have to comply with other relevant legislation such as State animal welfare legislation.[95]

3.107 IOGTR advised that all States and Territories have legislation in place to protect the welfare of animals and prevent cruelty to animals, including in the context of animal research. In all jurisdictions, other than Western Australia, the animal protection legislation refers to the NHMRC's *Australian code of practice for the care and use of animals for scientific purposes* (the NHMRC code).[96]

3.108 The NHMRC code covers 'all aspects of the care and use of, or interaction with, animals for scientific purposes in medicine, biology, agriculture, veterinary and other animal sciences, industry and teaching'. This includes their use in research,

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92 Submission No.77, p.120 (IOGTR).

93 IOGTR, Gene Technology Bill 2000, Questions and Answers, p.7.

94 Submission No.51, p. 3 (Friends of the Earth (Fitzroy)). Re biological diversity, see also Submission No.73, p.2 (Ms J Ablitt).

95 Submission No.32, p.5 (Avcare Limited).

96 IOGTR, Additional Information dated 3 October 2000. [For a copy of the Code, see NHMRC's website http://www.health.gov.au/nhmrc/publicat/ea-home.htm].

teaching, field trials, product testing, diagnosis, the production of biological products and environmental studies.[97]

3.109 Additionally, guidelines for the humane conduct of scientific and teaching activities, and for the acquisition of animals and their care, including their environmental needs, are specified in the NHMRC code. All live non-human vertebrates are covered by the NHMRC code, which requires that 'eggs, fetuses and embryos must be treated in a humane manner where development of an integrated nervous system is evident'.[98]

3.110 The IOGTR advised that the Bill, when enacted, will not exclude the operation of any other State laws, and is in addition to, not a substitution for, the requirements of other Commonwealth laws. Any person undertaking research involving genetic modification and animals must comply with both the Gene Technology Bill and any other relevant State and Commonwealth legislation.[99]

3.111 The Committee notes that where issues arise in relation to gene technology and animals that are not adequately addressed under existing State legislation and the NHMRC code, the Ministerial Council may, on the advice of the Gene Technology Ethics Committee, issue policy principles or policy guidelines regarding ethical issues including animal welfare issues.

3.112 IOGTR further stated that prior to accepting an application, the Regulator will ensure that the application not only accords with any ethical guidelines issued by the Ministerial Council but also that the application is in accordance with relevant State/Territory laws for the protection of animals.[100] Any application that is not in accordance with such requirements will be rejected by the Regulator.[101] The Regulator may also prescribe certain codes of practice relating to ethics and animal welfare as a condition of a licence.[102]

3.113 The Committee notes that while there is state legislation that covers animal welfare, it is concerned that the Ministerial Council would be left to address any shortfalls in regulations covering animal welfare.

Recommendation

The Committee RECOMMENDS that relevant State and Territory animal welfare legislation and the NHMRC code of practice for the care and use of animals for scientific purposes, be examined to determine whether more

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97 Synopsis of NHMRC code (see website).

98 Synopsis of NHMRC code (see website).

99 IOGTR , Additional Information dated 3 October 2000.

100 IOGTR , Additional Information dated 3 October 2000.

101 IOGTR, Gene Technology Bill 2000, Questions & Answers, p.15.

102 IOGTR , Additional Information dated 3 October 2000.

stringent provisions need to be applied with respect to animals and genetic modification.

Benefits of gene technology

3.114 Concerns were expressed that the facilitating benefits of gene technology were not included in the object of the Bill. It was argued that this was contrary to a Commonwealth Government Ministers' announcement about the planned legislation, that the purpose of the gene technology regulatory system should be to 'realise the benefits of gene technology for the Australian community, industry and the environment, while ensuring human safety and environment protection'.[103]

3.115 The Committee acknowledges that there are potential benefits to the community and the environment from gene technology, but considers that an important purpose of the Bill is to ensure public confidence in the regulation of this technology. The Committee notes that organisations involved in the research, development and commercialisation of GMOs currently play a role in the dissemination of information and education of the community about the benefits of gene technology. However, the Committee considers that it would be more appropriate for an independent organisation to provide a balanced approach to the provision of information on the benefits **and risks** of gene technology.

3.116 In addition to the concerns just discussed relating specifically to the object of the Bill, a number of other issues were raised in relation to achieving the Bill's objective and providing sufficient consumer confidence in the regulation of gene technology. These are discussed in the remainder of this chapter.

Alternative regulatory models

3.117 The Australian Centre for Environmental Law provided the Committee with an alternative model Act for the comprehensive regulation of all activities and dealings involving gene technology.[104] A number of witnesses supported this model Act arguing that it provided a more effective regulatory framework to achieve the Government's stated object of the Gene Technology Bill.[105]

3.118 Alternative regulatory models, including the 'one-stop shop' are examined in Chapter 4.

Placement of a moratorium

3.119 A number of groups supported the placement of a moratorium on gene technology including a freeze on:

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103 Submission No. 41, pp.1-2 (Grains Research and Development Corporation).

104 Submission No.34 (Australian Centre for Environmental Law).

105 *Committee Hansard*, 24.08.00, p.305 (ACF). See also, for example Submission No.25, p.3 (Mr A Macintosh); Submission No.22, p.2 (Mr G Whitten); Submission No.35, p.6 (GE-Free Tasmania).

- the further introduction of genetically engineered crops or foodstuffs into Australia;[106]
- the release of GMOs into the environment;[107]
- GMOs until proven to be benign to humans and other life forms;[108]
- the general release of GMOs, including medical GMOs;[109]
- gene technology to allow for 'some sort of scientific consensus and the market implications of this technology to emerge';[110] and
- uncontained field trials or field crops.[111]

3.120 A moratorium was also considered essential to allow time to inquire into the need to revamp relevant legislation in the light of the uncertainty and vagueness surrounding the assessment of the risks associated with gene technology.

> I believe that if we revamp all our acts that underlie this gene technology bill we can overcome those things because we are going to put into effect greater securities and greater sureties in practical issues and these should be worked out. This is what I am saying. We need a five year moratorium in which to do that and do it appropriately, thoroughly, efficiently properly and ethically.[112]

3.121 The Committee notes that the Tasmanian Government has instituted a 12 month moratorium on the open research or trialing of GM crops during which time the Tasmanian Parliament will examine the implications of gene technology for Tasmania. Tasmania's position is discussed in Chapter 6 in the context of its support for the inclusion of an opt-out clause in the Bill.

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106 Submission No.54, p.3 (Organic Federation of Australia Inc); Submission No.51 (Friends of the Earth (Fitzroy)), p.1. See also *Committee Hansard*, 24.08.00, p.267 (NGAA) who recommended a ban on 'foods made by genetically modified organisms in artificial formulas and in baby foods' and pp.271 (NGAA) who also recommended a moratorium on patenting of GMOs.

107 See for example, Submission No.4 (Mrs S Stafford); Submission No.5 (National Council of Women of Australia); Submission No.69 (Friends of the Earth (Perth WA Group)); *Committee Hansard*, 22.08.00, pp.64, 91 (Heritage Seed Curators Australia Inc); *Committee Hansard*, 23.08.00, p.161 (GE-Free Tasmania); *Committee Hansard*, 23.08.00, p.138 (Organic Federation of Australia Inc).

108 Submission No.24 (Bio-Dynamics Tasmania), p.2.

109 *Committee Hansard*, 22.08.00, p.65 (Heritage Seed Curators Inc). See also *Committee Hansard*, 23.08.00, p.161 (GE-Free Tasmania).

110 *Committee Hansard*, 23.08.00, p.138 (Organic Federation of Australia Inc).

111 Submission No.21, p.1 (Mrs U Mueller).

112 *Committee Hansard*, 22.08.00, p.88 (Ms L Huebner). Ms Huebner also stated re the type of legislation that required amendment: 'There is the plant breeders patenting act and allied acts, and also the privacy acts…they relate to commercial confidentiality. (p.78).' See also, *Committee Hansard*, 24.08.00, p.266 (NGAA) who argued that a moratorium would allow a 'social and economic assessment, assessing of patenting, strict legal liability, can the law keep up with technology, prevention of genetic pollution, and greater public involvement and awareness of gene technology'.

The role of multinationals

3.122 GE-Free Tasmania stated that 'to date the interests of biotechnology companies have dictated the nature of the GE debate…However, this has served to stimulate considerable public concern about the safety of GE and the intentions of those involved in its development and commercialisation'.[113] Submissions pointed to public disquiet over the role of multinational companies in promoting gene technology onto an unwilling public. NT Bio Dynamic Network argued that many people 'have no confidence in science altering our food for the benefit of Multi National Companies. There are no known benefits for GM food to be forced onto consumers'.[114]

3.123 The commitment of multinational corporations to the safety of GMOs and its impact on the agricultural sector was questioned by Ms Vicki Brooke:

> The technology has the potential to undermine our whole agricultural sector as it has been built up over generations since the early nineteenth century, since it is promoted by agrichemical companies anxious to sell their product, clearly acknowledged by Monsanto when its Director of Corporate Communications said "Monsanto should not have to vouchsafe the safety of our biotech food. Our interest is in selling as much as possible. Assuring its safety is the FDA's job".[115]

3.124 Concern was also expressed about the potential misuse of gene technology by multinationals:

> Poverty and oppression contribute to famine and hunger. Gene technology could perhaps in the future promote famine and hunger if it promotes the need for cash to pay the corporations and if the corporations become oppressive.[116]

3.125 Dr Tribe commented on the dangers associated with the potential dominance of gene technology by multinational companies:

> The whole notion of having high regulatory hurdles and the whole rigour of regulation, arguably out of proportion to risks, encourages only the very strong to survive that rigorous path. So that has to be realised…If a lot more encouragement were given to more ventures, more institutes and smaller activities, and they were able to see a path forward to the market, that would be good.[117]

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113 Submission No.35, p.14 (GE-Free Tasmania). See also, for example, Submission No.114, pp.1-2 (Ms B Rosser).

114 Submission No.3, p.1 (NT Bio Dynamic Network). See also Submission No.48, p.1 (Ms S Kyriacou).

115 Submission No.27, p.8 (Ms V Brooke).

116 Submission No.68, p.3 (Ms H Swainston).

117 *Committee Hansard*, 24.08.00, p.254 (ABA).

3.126 However, according to the IOGTR concerns about the dominance of multinationals in gene technology have been addressed:

> The legislation has…been drafted so as not to impose unfair burdens on small industry nor entrench overly restrictive practices between companies and for example, contract farmers.
>
> If individual companies do…engage in unfair or restrictive trade practices, this will be a matter for consideration by the Australian Competition and Consumer Commission – the independent statutory watchdog administering the *Trade Practices Act 1974* and the *Prices Surveillance Act 1983*.[118]

Implications for trade competitiveness

3.127 The Committee received conflicting views on the impact of the proposed regulatory regime on Australian trade opportunities.[119] These included, for example, reports about loss of market share for the sugar industry, which may be recovered with the assistance of gene technology:

> CSIRO researchers…are trying to produce sugarcane which yields the lower colour sugar that attracts premium prices internationally.
>
> …the key to the research was to regulate an enzyme in the cane which causes browning in fruit and vegetables.
>
> …lowering the colour even 20 or 30 per cent…will be of benefit to the industry which has lost market share in recent years to competitors like Brazil which have produced quite a low colour sugar.[120]

3.128 The NSW Farmers' Association warned 'we do not want to see this issue being used as a weapon against industries faced with much more rigorous requirements than its competitors'.[121]

3.129 The Committee recognises the difficulties faced by the Government in ensuring the safety of people and the environment, and, at the same time, ensuring that Australia's trade and economic opportunities are not unnecessarily damaged through over regulation of this technology. However, the Committee considers that in keeping with the object of the Bill, the Government must link the health and welfare of the Australian people and protection of the environment with trade considerations in a field of science for which the long-term risks and hazards are yet to be sufficiently understood.

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118 IOGTR, Gene Technology Bill 2000, Questions and Answers, p.13.

119 *Committee Hansard*, 24.08.00, p.293 (AWB Ltd).

120 *Bid to turn sugar a whiter shade of pale*, AAP, 4 July 2000.

121 Submission No.76, p.2 (NSW Farmers' Association).

Trial site locations

3.130 Many groups and individuals criticised the secrecy associated with field trials of GMO crops and argued that information relating to trials and their site locations should be publicly available to improve confidence in the system.[122]

3.131 The District Council of Grant in South Australia expressed concern at the lack of information on trial sites made available to local councils. The Council submitted that '**No** notification is supplied to the Council or the public, regarding the location of the trial sites, duration, size, and conditions pertaining to the trialing of genetically modified crops (for example Canola)'.[123]

3.132 There was also concern that the location of dealings involving the general release of GMOs could be declared confidential commercial information:

> The argument that this is necessary to protect property and personal safety does not outweigh the great harm the gene technology industry is doing to its public image. It is worth noting that in Europe, where there is widespread opposition to gene technology, the location of GMO crops is not concealed as it is here.[124]

3.133 While Tasmanian Alkaloids was prepared to publicise future trial sites[125], the NFF drew on overseas experience to argue against this proposition, and considered that the destruction of or damage to trial sites should be made an offence under the Bill. Other companies currently involved in gene technology trials supported the NFF's position.[126]

3.134 Novartis explained that while they agreed that there was a 'genuine need for openness' with respect to the location of trial sites to support confidence in the process, their experience in the UK, where in a spirit of openness the company had supported the practice of revealing the precise location of sites, was 'that such disclosure led to trial site vandalism to such a degree that some of the current farmscale biodiversity evaluations are now in jeopardy'.[127]

3.135 Others claimed that the incidence of vandalism of GMO crops should not be used to justify the non-disclosure of trial site locations, arguing that 'security alarm

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122 See for example, Submission No.99, p.3 (Ms K Harris) and Submission No.51, p.9 (Friends of the Earth (Fitzroy)).

123 Submission No.60, p.1 (District Council of Grant).

124 Submission No.35, p.9 (GE-Free Tasmania).

125 *Committee Hansard*, 23.08.00, p.216 (Tasmanian Alkaloids Pty Ltd).

126 Submission No.88, p.2 (National Farmers' Federation). See also Submission No.32, p.7 (Avcare); Submission No.42, p.6 (Nugrain and Florigene); Submission No.76, p.4 (NSW Farmers' Association).

127 Submission No.98, p.2 (Novartis Australia Pty Ltd). See also Submission No.90, p.1 (Du Pont Technical Centre); Submission No.94 (Monsanto Australia Ltd); Submission No.104 (Dow AgroSciences); Submission No.32, p.7 (Avcare Limited). See also *Committee Hansard*, 23.08.00, p.187 (Serve-Ag).

systems may have to be put in place to protect GE crops but farmers as well as the public have a right to know this information'.[128]

3.136 The Committee condemns any acts of vandalism against GMO field trials and is concerned that such acts may themselves facilitate the dispersal of GM pollen resulting in the types of contamination that must be prevented.[129]

3.137 Avcare, an umbrella organisation of biotechnology companies, proposed an alternative approach to providing information on trial site locations:

> [that] Avcare members…make the locations of trials available to an independent third party who could be contacted by a concerned grower. The grower would then be told whether a trial was nearby and, if so, directed to the proponent of the trial for information.[130]

3.138 The Organic Federation of Australia was critical that this proposal required organic farmers to advise GMAC of the location of their crops around Australia:

> ...it is going to cost us money to do that. We have farmers who declare that they grow oilseed but, because we do not know whether they grow it in that particular year, we have to write to 1,000 or 2,000 farmers who might grow it. We have a 20,000 tonne organic canola crop, and we ask, 'Are you growing it or not?' So there is a cost involved. We have said that, if the government is willing to repay us for that cost, we will consider it.
>
> …if you do that for organic farmers, then you have to do that for beekeepers, and why shouldn't you do that for any conventional canola farmer out there around Australia?[131]

3.139 The Committee considers that Avcare's proposal may undermine confidence in the GTR and confuse the public in relation to where information on trials and other issues concerning the regulation of gene technology should be sought. The Committee supports the views of the Organic Federation of Australia and considers that it is more appropriate for GM growers to make details of trial site locations available to those who may be affected.

Commercial-in-confidence information

3.140 Environs Kimberley felt that the commercial-in-confidence provisions of the Bill would undermine the object of the Bill to protect human health and safety.[132]

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128 Submission No.20, p.2 (Ms L McDermott).

129 See *Committee Hansard*, 23.08.00, p.217 (Tasmanian Alkaloids Pty Ltd) who states that 'damaging things is not the right way to conduct a debate'.

130 Submission No.32, p.7 (Avcare Limited). See also Submission No.98, p.3 (Novartis Australia Pty Ltd); Submission No.90, p.1 (Du Pont Technical Centre).

131 *Committee Hansard*, 23.08.00, p. 146 (Organic Federation of Australia Inc).

3.141 The importance of transparency was also stressed by Professor Adrian Gibbs:

> If the public is to have faith in the regulation of gene technology, very little of the data upon which the Regulator has made a decision should be permitted to be hidden from scrutiny on the grounds that it is commercially sensitive information, and even if it is, then the type of each item of information must be declared, even though the specific details may be hidden. Thus, for example, an interested member of the public must be able to determine for an approved GMO whether a particular type of safety feature has been examined and considered by the Regulator, even though the details of the outcome of the test may be hidden. Otherwise, if there is no public record of the type of information being withheld, then the public record, in toto, is valueless.[133]

3.142 Others, while recognising that the public has a right to information about the development of GMOs, were concerned at the ramifications of revealing too much in a competitive market-place:

> sooner or later you will reach a point where all we will see in Australia is last year's technology or 10-year-old technology. It will be absolutely generic and fully disclosed. We will never see state-of-the-art, highly competitive technology–especially if we are looking for technology that will give products a competitive edge in the international marketplace.[134]

3.143 Mr Kim Healy considered that the Bill should include a 'precise definition of commercial confidentiality' and added:

> The GTR should always have the power to override the claim for confidentiality in the public interest, as when human lives or environmental damage are threatened.[135]

3.144 The IOGTR advised that the current Bill requires the GTR to refuse to declare information to be confidential commercial information if the public interest in disclosure outweighs the prejudice the disclosure would cause.[136]

Recommendation

The Committee would consider it undesirable if commercial in confidence information compromised the objectives of the Bill or the transparency of the regulatory regime, and RECOMMENDS that where an application for an intentional release of a GMO into the environment includes the size and location

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132 Submission No.82, pp.7-8 (Environs Kimberley). See also, Submission No.21, p.1 (Ms U Mueller); Submission No.95, p.1 (Mr D Adams MP).

133 Submission No.70, pp.2-3 (Professor A Gibbs).

134 *Committee Hansard*, 24.08.00, p.340 (Nugrain Pty Ltd).

135 Submission No.79, p.1 (Mr K Healy).

136 IOGTR , Additional Information dated 25 August 2000, Attachment D.

of this proposed release, the information should be made available publicly providing that the penalties for any intentional damage to that release are an effective deterrent against eco-terrorism.

3.145 The issue of the information to be taken into account by the Regulator when making a decision on whether a licence should be granted is discussed in Chapter 4.

Cost recovery

3.146 The proposed full cost recovery to fund the OGTR was identified as one of the measures that could potentially undermine the objective of the Bill.[137] The Committee notes that this proposal has recently been assessed by KPMG. The issue of cost recovery, the KPMG report and implications for parliamentary accountability, are discussed in Chapter 4.

Adequacy of public reporting provisions

3.147 The Bill includes a number of public reporting provisions that must be observed by the Regulator. These include requirements to:

- report to Parliament annually, and on other occasions as may be required, about matters relating to the function of the Regulator;[138]
- establish a GMO Register;[139] and
- provide a Record of GMO and GM Product Dealings.[140]

3.148 The IOGTR advised that the Record of GMOs and GM product dealings would list all dealings with GMOs and GM products approved for use in Australia, regardless of whether they were produced domestically or imported. Approval must be sought from the Australian Quarantine and Inspection Service (AQIS) for the importation of a live or viable GMO, to ensure there are no pest and disease or quarantine risks. Approval must also be sought from the Regulator who is required to check the biosafety of the GMO. If either AQIS or the GTR considers that the risks of import are too high, on either quarantine or biosafety grounds, the GMO cannot be imported. In the event that the importation of the GMO is approved, details of the approval will be entered on the Record.[141]

3.149 GE-Free Tasmania argued that the Record should also include the location of all dealings. They further suggested that:

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137 See for example, Submission No.58, p.1 (Australian Biotechnology Association); Submission No.71, p.11 (Australian Food and Grocery Council).

138 Gene Technology Bill 2000, ss.136-7.

139 Gene Technology Bill 2000, s.76.

140 Gene Technology Bill 2000, s.138.

141 IOGTR , Additional Information dated 5 October 2000.

- the wording of sub-clause 138(3) should explicitly provide that 'the information regarding licences must include all variations, cancellations and suspensions made to licences';
- information about exempt dealings should also appear on the Record;
- the scope of the Record should include all accredited organisations and certified facilities; and
- the term 'GM product dealings' be clarified for the purpose of clause 138.[142]

3.150 The Australian Conservation Foundation was also critical of information that would not be available on the Record and recommended the inclusion of the following information:

> (a) the application for the licence, and if the application is denied, the reasons why the Regulator decided to refuse the licence;
>
> (b) all information submitted in support of an application for a licence authorising dealings with GMOs issued under Part 5 of the GT Bill;
>
> (c) the name of the licence holder;
>
> (d) the persons covered by the licence;
>
> (e) the activities or dealings authorised by the licence;
>
> (f) licence conditions;
>
> (g) the date on which the licence was issued, and the reasons why the Regulator decided to issue the licence;
>
> (h) all information collected in the course of monitoring and/or auditing of the licence; and
>
> (i) any variations, suspensions or cancellations of the licence.[143]

3.151 The IOGTR advised that, in the 1999 draft Bill, the Record of GMOs and GM product dealings would only have included information about the licences issued by the GTR. However, after the consultation process, this had been expanded to include information about:

- notifiable low risk dealings; and
- all approvals granted by any other regulatory agency in relation to GM products.

3.152 The IOGTR also advised the Committee that the Record of GMOs will not include a list of failed applications for approvals to deal with GMOs and GM products. It stated that the purpose of the Record is to provide the Australian public with easy and immediate access to a comprehensive list of those dealings with GMOs and GM products that have been approved in Australia, and which may directly affect

142 Submission No.35, pp.10-11 (GE-Free Tasmania).

143 Submission No.40, pp.6-7 (ACF).

them, including approvals of GM products made by other regulators, which must be notified to the Gene Technology Regulator.[144] The Record will take the form of a comprehensive publicly available database on the GTR's website.

3.153 The IOGTR indicated that while the Record will not contain a list of failed applications, the public will have access to the failed applications through the public consultation process. For example, in the case of applications involving intentional release of a GMO into the environment, the GTR will consult the public on the application and the draft decision. As such the public will have access to, and be able to comment on, the full reasons for non-approval as set out in the GTR's draft decision (risk assessment and risk management plan).[145]

3.154 Mr Greg Whitten was critical of the Register of GMOs, claiming that 'there is no public consultation process involved - the Regulator can make a decision on whether a GMO is listed on the Register without consulting anyone'. He also expressed concern that such a Register would allow 'easy access of these GMOs into GE free zones'.[146]

3.155 There was also a suggestion that a register of accidental releases of GMOs into the environment should be established.[147]

3.156 Mr Anton from the Australian Centre for Environmental Law noted that the Register required under the EPBC Act was more comprehensive than the one proposed under the Gene Technology Bill, and argued that the Register of GMOs should include 'as a minimum…details involving the application, where the release is going to take place, and those things for public protection'.[148]

3.157 However, Mr Burgess, representing the SA Farmers Federation, argued against the Register containing details of a licence, stating:

> …while supporting the need for transparency in the licensing system, there is also a need to protect those seeking and who have been granted a licence to utilise gene technology.[149]

3.158 The 1999 draft of the Gene Technology Bill did not include a provision for a Register of GMOs. The Register was included in the current Bill following concerns raised during public consultations. It had been argued that in cases where a GMO, for example a cut-flower, was considered to be safe and dealt with (as defined by the Bill)

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144 IOGTR , Additional Information dated 3 October 2000.

145 IOGTR , Additional Information dated 3 October 2000.

146 Submission No.22, p.14 (Mr G Whitten). See also Submission No.35, p.8 (GE-Free Tasmania).

147 Submission No.96, p.1 (Ms F Murdoch).

148 *Committee Hansard*, 25.08.00, p.363 (ACEL).

149 *Committee Hansard*, 22.08.00, p.48 (SA Farmers Federation).

by millions of people, that a single company should not be required to hold a licence for that product.

3.159 The IOGTR advised that the GTR would be able to enter GMOs on the Register after a period of licensing and demonstration of the absence of risk, which would allow anyone to deal with the GMO without the need for a single licence holder.[150]

3.160 Both the Record and the Register will be accessible via the GTR's website and the public will also be able to request that extracts from the Record or the Register be mailed to them.[151]

3.161 There was also some misunderstanding as to the frequency of reports to be made and to whom, whether the Minister or the Parliament directly.[152] Under clause 136 of the Bill, the Regulator must prepare for the responsible Commonwealth Minister a report on the operations of the Regulator as soon as practicable after the end of the financial year. The Minister must table the report to each House within 15 days of receipt of the report. The Regulator must also provide a copy of the report to each State.

3.162 Under clause 137 of the Bill, the Regulator may cause a report about matters relating to the Regulators' functions to be tabled in either House of the Parliament, and must give any such report to the Minister for Health and Aged Care and the States.

3.163 The Committee understands this clause to mean that where a report on a matter was requested by the Parliament, the Regulator must provide such a report directly to the Parliament. The Committee considers that the clause would benefit from clarification to ensure that any such report is provided to **both** Houses of Parliament. The Committee also considers that the Regulator must report on any breaches of licence conditions or guidelines which have caused serious environmental damage or harm to human health or safety as soon as practicable after the breach.

3.164 The Committee considers that annual reporting by the Gene Technology Regulator is insufficient. The Committee notes that in May 2000, the IOGTR advised the Minister for Health and Aged Care that it would, in future, report on a quarterly basis in line with the it's aim of providing interested people with more timely and comprehensive information about current oversight of GMOs.[153]

3.165 The Committee believes that the Bill should be amended to add a requirement for quarterly reports on compliance with the legislation which includes information on

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150 IOGTR, Additional Information dated 25 August 2000, Attachment D.

151 IOGTR, Additional Information dated 25 August 2000, p.3.

152 See for example, *Committee Hansard*, 25.08.00, p.392 (Avcare) and pp.405-6 (AFGC).

153 *IOGTR Quarterly Report*, June 2000.

who received licences and for what purposes, and details of any investigations into breaches of licence conditions (see Chapter 4).

3.166 The Committee supports the extended use of the OGTR's website to provide timely information, in addition to the publication of quarterly and annual reports.

Public confidence

3.167 Many of the concerns about the Bill's object are tied to the ability of the Regulator to deliver a system that will restore and maintain public confidence in the proposed regulatory arrangements. Two of the most important factors bearing on the public acceptance of the proposed regulatory regime are the transparency of the assessment process and the independence of the Regulator.[154]

3.168 The Australian Food and Grocery Council stated:

> …for the maximum benefit and confidence of consumers we require a regulatory framework which is transparent, fully accountable, and, very importantly, independent of commercial, political and sectoral influence. Consumer confidence in the application of gene technology and the safety of its products is fundamental to investment in, and the subsequent commercialisation of, the technology.[155]

These issues are discussed in detail Chapters 4 and 5 of this report.

3.169 The Committee received evidence from those who want greater regulation in order to meet the objective of the Bill and ensure consumer confidence in the regulation of GMOs, and those who feel that the problem lies with insufficient public education.[156] Others considered that the Bill had been drafted with public safety in mind and provided adequate safeguards designed to enhance consumer confidence.[157]

3.170 CSIRO stated that, in addition to ensuring 'rigor and scientific underpinning' of the Regulator's decision-making:

> Ensuring consumer confidence will require significant attention to implementing the broader strategic issues as encompassed in the recently launched National Biotechnology Strategy and, in particular, urgent and decisive action on enhancing public awareness by unbiased information being provided by community, industry and government organisations. Without such information, the public acceptance and adoption of gene

154 See for example, Submission No.109, p.1 (Dr A Campbell).

155 *Committee Hansard*, 25.08.00, p.397 (Australian Food and Grocery Council).

156 See for example, Submission No.36, p.3 (Valley Seeds Pty Ltd). See also, *Committee Hansard*, 23.08.00, p.236 (Tasmanian Government).

157 See for example, Submission No. 32, pp.6-7 (Avcare Limited); Submission No.88, p.7 (National Farmers' Federation); Submission No.89, pp.3-4 (Tasmanian Government); Submission No.91, p.1 (Western Australian Government).

> technologies and their products into Australia could be delayed or even prevented in the immediate future.[158]

3.171 Valley Seeds also considered public education important despite other measures included in the Bill aimed at ensuring consumer confidence in the regulation of GMOs:

> All these measures, however will account for little if the public is not educated about the process. A high level of education is more likely to prevent public concern than any level of reporting on its own.[159]

3.172 This view was supported by Mr Buz Green of Serve-Ag Pty Ltd:

> I am finding that there is a profound lack of knowledge and understanding of the technology and the science behind it in the community. I think that if more effort were made to educate the public, then that would, I am sure, improve their confidence. Over history fear is one of the first things with any new technology, but as knowledge is increased, fear tends to be reduced.[160]

3.173 The assumption that more information will automatically ensure greater public acceptance of gene technology was criticised:

> …attempts to cast the debate as a battle of beneficent and knowledgeable cleverness versus ignorant and superstitious anxiety should be resisted. Regulators need to acknowledge that the public has well founded grounds to be ambivalent about genetic technology. No amount of instruction in molecular biology, education on the economic benefits of research and innovation, and the need to be internationally competitive can allay legitimate human concerns.[161]

3.174 This view was supported by Mr Hankin from Heritage Seed Curators Australia who argued that a lack of technical understanding of gene technology should not be used to disparage the opinions of people opposed to GMOs.[162]

3.175 The Committee notes the Commonwealth Industry Minister's strategy for responding to the concerns held by some in the community about gene technology:

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158 Submission No.102, p.3 (CSIRO). See also *Committee Hansard*, 24.08.00, p.242 (Dr Tribe) who argued consumer confidence in GMOs was low because 'there is a huge amount of misinformation being spread by people who are against GMOs for reasons that are not really scientifically well explained and who wish to portray, in order to achieve their political objectives, this technology as being morally dubious'.

159 Submission No.36, p.3 (Valley Seeds Pty Ltd).

160 *Committee Hansard*, 23.08.00, pp.190-1 (Serve-Ag).

161 Submission No.95, p.44 (Mr D Adams, MP).

162 *Committee Hansard*, 22.08.00, p.63 (Heritage Seed Curators Australia Inc). See also *Committee Hansard*, 25.08.00, pp.429-430 (Professor A Gibbs).

> …we have an obligation to demonstrate the opportunities for improvements to our health, in benefits to the environment and in enhancing the competitiveness of our industries as a result of biotechnology.[163]

3.176 The CSIRO noted that the pace of technological change also affected public confidence:

> What we see…is that some citizens in countries around the world feel very uncomfortable with technological change. It happens that biotechnology is one raft of technological change which is currently moving past us. One hundred years ago we felt equally uncomfortable in societies about the advent of the internal combustion engine and the loss of horses and carriages; we do not bemoan that now.[164]

3.177 The Committee considers that there is more substance to the concerns of opponents for them to be dismissed as the views of a 'noisy minority'.[165] While acknowledging the complexity of concepts and techniques used in gene technology and understanding the need to provide explanations in a way that lay-people can understand them, the Committee considers that it is time to move from the provision of overly simplistic descriptions to more detailed and objective accounts of the processes associated with the development of GMOs, particularly those likely to enter the food chain.

3.178 The Committee notes the observations of GE-Free Tasmania:

> To date, the interests of biotechnology companies have dictated the nature of the GE debate and the actions of the Federal government. However, this has served to stimulate considerable public concern about the safety of GE and the intentions of those involved in its development and commercialisation. The GT Bill must facilitate public involvement in the application of gene technology so as to ensure that it can be applied in an effective and prosperous manner. The current provisions of the GT Bill will only add to the public distrust and scepticism and potentially stifle the adoption of beneficial uses of gene technology.[166]

3.179 Concern over the involvement of biotechnology companies in the dissemination of public information was emphasized Ms Herminie Swainston, who stated:

> The electorate needs to have enough balanced information about gene technology to make informed decisions. This may reduce the extent to which people are manipulated and indoctrinated by vested interests who have lots of money to spend on persuading us that their GMOs are OK, safe

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163 Quoted in *Government launches national biotech strategy*, AAP, 3 July 2000.

164 *Committee Hansard*, 25.08.00, p.421 (CSIRO).

165 See Submission No.61, p.5 (Aventis CropScience Pty Ltd).

166 Submission No.35, p.14 (GE-Free Tasmania).

> and fully tested, even if they aren't. We need protection by responsible government that has not done deals with the corporations.[167]

3.180 In Europe, information on gene technology is disseminated by consumer and environmental organisations, schools/universities, industry and government. In most cases, the most widely trusted information sources are those provided by consumer and environmental groups. The issue is not one of robustness or accuracy of information, but trust. The role of the media in influencing public perceptions is also significant. Information provided by a range of media is 'often misleading, inaccurate, and incomplete'.[168] The role of the media in the dissemination of information on gene technology was also criticised in evidence to the Committee:

> I would urge the committee to give weight to the evidence which has proper scientific basis and reject the myth and misinformation that is being perpetuated in this debate…If you go around the world…you see the same messages coming out. The media obviously perpetuates a lot of it, but where it emanates from I am not too sure.[169]

3.181 Another approach, first developed and used in Denmark in the mid 1980s, is the consensus conference which brings together relevant experts and lay people. Other European countries have adopted the model, modified to fit the local political culture.[170]

3.182 Australia held its first consensus conference in March 1999 on gene technology in the food chain. Over nine days, a Lay Panel comprising people with no prior knowledge of the topic and representing a range of attitudes and values, set questions for a panel of experts who came from science, industry, environment, religion and public health. A number of concerns were highlighted as a result of the conference, including:

- consumers are mistrustful and cynical;
- people feel excluded from decision-making;
- ethical and moral considerations are major issues;
- while recognising the perceived benefits people see technology as serving the interest of a privileged few, that is, multinational companies;

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167 Submission No.68, p.2 (Ms H Swainston).

168 Mendiata, NL and Lints FA. 'Novel and transgenic food crops: overview of scientific versus public perception', *Transgenic Research*, 1998, 7:379-386.

169 *Committee Hansard*, 23.08.00, p.185 (Serve-Ag).

170 Mendiata, NL and Lints FA (1998). For information on public consultation on biotechnology in OECD countries, see [http://www.oecd.org/dsti/sti/s_t/biotech/act/consultations.htm].

- that there should be more caution and less haste in applying new technologies.[171]

3.183 The Committee notes that the Lay Panel recommended that better processes to allow public access to information, which includes varying perspectives, should be established at many levels, including:

- the establishment of a gene technology information office;
- government sponsored advertising campaigns;
- toll-free phone lines and Website for consumer information;
- public notices on GM issues;
- information fact sheets; and
- focused education information and CD Roms.

3.184 The Lay Panel also recommended that increased consumer representation on existing and future decision making bodies 'is absolutely necessary'.[172]

3.185 The Gene Technology Bill provides for extensive community participation in GMO assessment processes. The role and composition of the proposed Gene Technology Community Consultative Group is discussed in Chapter 5.

3.186 In referring to the impact on public perception of genetic modification with respect to fresh fruit and vegetables, Australian United Fresh Fruit & Vegetable Association and Fresh Produce Watch considered that:

> Consumer reassurance about safety and environmental effects of GM fresh produce is the role of Government which has to ensure adequate and thorough assessment, control, monitoring and the provision of unbiased information.[173]

3.187 In 1999, the Australian Government announced the establishment of Biotechnology Australia (BA) with the aim of consolidating information on, and increasing public awareness about, biotechnology. The Committee notes that the goal of Biotechnology Australia is to ensure that Australia captures the benefits arising from the medical, agricultural and environmental application of biotechnology, while protecting the safety of people and the environment.[174]

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171 *Gene technology and food*, National Science & Industry Forum Report, Australian Academy of Science, April 1999, p.10.

172 Lay Panel Report, First Australian Consensus Conference on Gene Technology in the Food Chain.

173 Submission No.56, p.1 (Australian United Fresh Fruit & Vegetable Association Ltd and Fresh Produce Watch).

174 See Biotechnology Australia's website [http://www.isr.gov.au/ba/].

3.188 Biotechnology Australia developed the National Biotechnology Strategy which was launched in July 2000, which encapsulates the Commonwealth's vision for biotechnology:

> Consistent with safeguarding human health and ensuring environment protection, that Australia capture the benefits of biotechnology for the Australian community, industry and the environment.

3.189 In acknowledging the purpose for which Biotechnology Australia was established, the Committee accepts that BA is perceived to have a pro-gene technology bias, notwithstanding its fact sheet *The Arguments For 'n' Against Genetic Manipulation*[175] and other general information provided for the public. A brochure produced by BA for distribution to Australian supermarkets entitled *Genetically Modified Foods – Information and answers to your questions* was described by the Australian Consumers' Association as a 'sales brochure for GM foods'.[176]

3.190 The Committee notes the conclusions drawn by the recent House of Representatives report, *Work in Progress: Proceed with Caution*, which recommended that Biotechnology Australia be established as a statutory authority to ensure that it is, and is seen to be, independent to overcome the distrust the consumers have of government agencies.

3.191 The need for a source of objective information on the benefits and risks of gene technology that presents both sides of the debate is becoming increasingly urgent.

3.192 The Committee notes that a 1998 postal survey of attitudes to genetic engineering and food conducted by the Consumer Science Program at CSIRO Health Sciences and Nutrition, Adelaide, found that most respondents would trust information provided to them by CSIRO scientists. Among the least trusted were government agencies, food manufacturers and the companies using the new technologies, with the news media rated last.[177]

3.193 The Committee acknowledges the valuable contribution that CSIRO is making to gene technology research and awareness. CSIRO currently conducts three main gene technology public awareness activities:

Gene Technology Information Program

3.194 This program was established in 1998 to provide balanced and factual information on the benefits and risks of gene technology, which brought together a

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175 See the BA website under Education, Factsheets. See for concerns about BA's pro-GM bias, see for example, *Committee Hansard*, 24.08.00, p.280 (NGAA).

176 Submission No.95, p.44 (Mr D Adams, MP).

177 National Science & Industry Forum Report, April 1999, p.15.

number of activities previously run by individual Divisions of CSIRO as well as initiating new activities including:

- participating in the Biotechnology Australia public awareness program (since 1999) [BA website: http://www.isr.gov.au/ba/];
- providing background scientific information to the media;
- producing radio interviews with scientists in the *Sci Files* CSIRO radio series [CSIRO education website: http://www.csiro.au/];
- sponsoring and helping organise Australia's First Consensus Conference on Gene Technology in the Food Chain, Canberra, March 1999 [website: http://www.austmus.gov.au/consensus/];
- organising National Science Briefings for members of parliaments in Canberra, Adelaide and Melbourne on the subject of gene technology;
- producing six short video clips about gene technology research as part of CSIRO's Australia Advances television series (funded by BA);
- organising a special gene technology feature in the science magazine *The Helix* [magazine website: http://www.csiro.au/helix/dhthehelix.html];
- launching a website providing scientific information about gene technology in Australia [http://genetech.csiro.au/] (funded by BA); and
- piloting a public telephone enquiry service for Biotechnology Australia (funded by BA).

CSIRO Plant Industry communication activities

3.195 In 1993 the CSIRO Division of Plant Industry coordinated the production of 'Will Pigs Fly?', an exhibition that toured eastern Australia for two years explaining the potential uses of gene technology in Australia. An associated teachers education kit was also produced and distributed to schools. Other activities include:

- organisation of the Australian Academy of Science's Science and Industry Forum on Gene Technology at the Maritime Museum, Sydney [Science and Industry Forum web site: http://science.org.au/industry/industry.htm];
- organisation of the inaugural *Discovery* Lecture 'Frontiers of Plant Biology' [website: http://www.pi.csiro.au/Events/Events.htm];
- hosting gene technology briefing sessions;
- preparation of the paper *Future Opportunities for Biotechnology in Australia: Field Crops, Horticulture and Forestry* (commissioned by BA);
- coordination of a series of seven *Cross Country* stories on gene technology covering major CSIRO sectors, which form the basis of CSIRO's *Australia Advances* series 7 [website: http://www.csiro.au/promos/ozadvances/];

- provision of speakers at major forums/events including Australian Science Communicators 'Science in the Pub', the First Australian Consensus Conference on Gene Technology in the Food Chain, the National Farmers Federation Annual Horticulture Conference, University of the Third Age, Food Congress 2000, Seed Industry Association of Australia; and
- coordination of the CSIRO *Discovery Centre* Gene Technology Exhibit.

The Green Machine Science Education Centre

3.196 The Green Machine opened in mid 1993 and is part of a national network of CSIRO Science Education Centres. It is currently operated as a joint venture between the ACT Department of Education and Community Services, the Australian National University and CSIRO Education, with support from CSIRO Plant Industry and the Catholic Education Office. Its flagship program is *Gene Technology in Australia* – a workshop presented during Science Festival Week which enables school students and adults to extract DNA from peas and ask questions about the technology [website: http://www.csiro.au/greenmachine/main.html].

3.197 Another program run under the auspices of the Green Machine is the *Industry Link* program, a joint initiative of CSIRO Education and CSIRO Plant Industry. Laboratory and lecture sessions aim to give industry groups and the general public an understanding of fundamental concepts in science. It currently has one course, the Industry Link Plant Gene Technology Workshop, which focuses on explaining plant gene technology in simple terms.

3.198 The Committee is cautious about suggestions that the CSIRO should be the primary Australian disseminator of public information on gene technology,[178] noting that Biotechnology Australia has utilised CSIRO's expertise as part of its public awareness program.

3.199 The Committee is concerned that CSIRO's objectivity may have been compromised by its increasing reliance on funding from industry to support its research, and perceived vested interest in, and enthusiasm for, biotechnology. It concurs with the view that there must be substantial consumer and medical input, as well as the inclusion of a range of other views, regardless of who ultimately issues the material.[179]

3.200 Ms Lisa McDermott observed:

> Many people don't get a chance to read newspapers or read notices of submissions but if the information is brought to people's attention, they will get involved…All opportunities for public input…on GE as well as other

178 See for example, *Committee Hansard*, 25.08.00, p.410 (Australian Food and Grocery Council).

179 *Committee Hansard*, 24.08.00, p.280 (Australian Lactation Consultants Association). See also, *Committee Hansard*, 25.08.00, p.436 (Professor A Gibbs) who argues for a 'plurality of sources of information'.

> matters that effect consumers should be made by way of an announcement on ABC Radio, Triple J (for younger audiences) and ABC television during prime time. It would only take a few minutes of broadcasters' time and it is important community information that I'm sure everyone would wish to know.[180]

3.201 The Committee also notes comments made by virologist, Professor Adrian Gibbs, who considered that universities would be better placed to provide information on gene technology:

> That is their role. I think that is why the public pays taxes for universities to be established. They rely upon universities to try and tell them exactly what the truth is, even if it hears a thousand voices all telling different versions of the truth. CSIRO is very much a corporate body. It is a single body. It has a long history of looking after itself. I believe that, therefore, it is not the only appropriate body and funding should be supplied to other bodies. I believe, in fact, there should be a plurality of sources of information, and that will keep everybody honest.[181]

3.202 The Committee is aware that various organisations[182] provide information on different aspects of gene technology, but considers it vital to establish a 'one-stop' shop for independent, objective and factual information on what is an increasingly controversial issue.

3.203 The Committee considers that measures in the Bill will improve consumer confidence in the regulation of GMOs, but suggests that information on the pros and cons of gene technology must be disseminated to the public by a body that is, and is seen to be, independent from the commercial interests associated with the biotechnology industry.

3.204 In this regard, both CSIRO, although widely and highly respected as a research and education organisation, and the newly established Biotechnology Australia, should be provided with additional support to ensure that the widest possible views are incorporated into publications and other information made available to the public on gene technology.

3.205 The Committee also supports the use of other forms of communication, including television, radio and the Internet, to ensure the widest possible exposure to

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180 Submission No.20, p.4 (Ms L McDermott).

181 *Committee Hansard*, 25.08.00, p.436 (Professor A Gibbs).

182 See for example Agrifood Awareness Australia [http://www.afaa.com.au/], an industry initiative with the following members: the Australian Biotechnology Association, Avcare, the Grains Research and Development Corporation, the National Agricultural Commodities Marketing Association, the National Farmers' Federation and the Seed Industry Association of Australia; See also the Food Science Bureau [http://www.foodsciencebureau.com.au/], an initiative of the Australian Food and Grocery Council. See http://genetech.csiro.au/sites.htm for a listing of Australian and overseas gene technology sites and http://www.icgeb.trieste.it/~bsafesrv/ for biosafety webpages].

arguments both in favour and against the developing technology. The importance of these arguments being presented in an understandable format was also emphasised in evidence:

> I also think those up-to-date scientists… must be prepared to communicate [information] in the language that ordinary people can understand. If they do not, they will never win the trust of the Australian people.[183]

3.206 The Committee agrees with the view expressed by the Tasmanian Government that 'it is essential that the GTR continue to monitor consumer and public confidence in the Office of the GTR and that the Government respond to any emerging concerns with regard to the regulation'.[184]

Recommendation

The Committee RECOMMENDS that an independent organisation conduct a national public education campaign to provide information on the benefits and risks of gene technology, drawing on, but not limited to, the expertise of scientists, primary producers, academics and consumer organisations.

3.207 While the Bill covers the regulation of all GMOs, by far the greatest concern expressed in evidence was in relation to the regulation of GMOs that were or may become part of the food chain. An AC Nielson Futures study conducted in April 2000 found that 68 per cent of respondents were not happy about eating GM food.[185]

3.208 The Institute of Public Affairs argued, however:

> With regard to the protection of people's health and safety, the new products have undergone greater testing prior to release than any previous food technology. Indeed, although all plant and animal food we now consume has been the creation of human induced cross breeding, no previous food has ever been subject to the oversight required of GM foods.[186]

3.209 The NSW Farmers' Association also pointed to recent safety measures announced by ANZFA:

> …we believe that the measures recently announced by ANZFA…and used by it to assess five genetically modified products are adequate to address consumers' food safety concerns. ANZFA measures carefully assess whether genetic modification gives rise to products containing residual DNA and whether that residual DNA or any other alteration in the

183 *Committee Hansard*, 24.08.00, p.280 (NGAA).

184 Submission No.89, p.4 (Tasmanian Government).

185 Submission No.107, p.20 (Food Industry Council of Tasmania).

186 Submission No.78, p.1 (Institute of Public Affairs Ltd).

> composition of the GM product give rise to additional allergenic or toxicity problems.[187]

3.210 Surveys conducted by Consumer Science Program between 1994 and 1999 show little change in community attitudes over the period with a slight lessening of support for genetically engineered foods based primarily on:

- concerns with the involvement of large corporations;
- increased availability of information on the subject;
- fear of science and technology taking over; and
- concern with environmental and health effects.[188]

3.211 Australian consumer concerns about GM food is mirrored overseas, particularly in the United Kingdom, Western European countries and Japan, with similar trends emerging in New Zealand, South Korea and the United States.[189]

3.212 The National Farmers' Federation observed public confidence, may in part, be lacking because of less than obvious benefits to the consumer:

> One of the barriers to consumer acceptance at this stage appears to be the fact that there is currently little discernible benefit to consumers in the products on shelves. Many of the biotechnological characteristics developed so far benefit agricultural inputs, for example they may be drought resistant or salt tolerant. However, it is difficult for those benefits to be extrapolated to the finished product, so that consumers can see [and taste] the benefits as well.[190]

3.213 However, Dr Tribe of the Australian Biotechnology Association argued that acceptance of GM food will follow the same path as genetically modified pharmaceuticals. In relation to the acceptance of GM pharmaceuticals, he stated:

> Perhaps it is related to the fact that, once tangible benefits from gene technology became obvious around 1982, the anti-GMO people gave up claiming that medicine was dangerous in this area because the record showed that tangible benefits would occur. And I hazard a guess that, since agriculture is lagging behind by about 10 years in the implementation of this technology, once clear-cut examples of obvious benefits to the consumer– such as golden rice–reach the market place, you might see quite different attitudes. The historical snap shot we are looking at at the present time may

187 Submission No.76, p.3 (NSW Farmers' Association).

188 Submission No.107, pp.20-1 (Food Industry Council of Tasmania).

189 Submission No.107, p.12 (Food Industry Council of Tasmania). Concerns were also expressed about US GM wheat in Japan, the Philippines, Vietnam, Malaysia, Singapore, Thailand, Bangladesh and Egypt, reported in *Wheat industry promises to segregate biotech wheat*, AAP, 30 June 2000.

190 Submission No.88, Attachment 3, p.17 (National Farmers' Federation).

> change when demonstration of what is going to happen takes place. So that is one factor.[191]

3.214 Some applications of genetic engineering do appear to have greater public acceptance including in the areas of pharmaceuticals, pollution control, waste management and cut flowers.[192] Public confidence in the regulation of pharmaceuticals is also perceived by the public to be more stringent and the benefits more tangible than the current regulatory arrangements for GM food. An explanation of this view was expressed by the Organic Federation of Australia:

> …we see pharmaceutical [gene technology] as not involving the release of live organisms, so the risk is much less; it provides medicines which are taken in small quantities for short periods of time when people are in a compromised position. We believe that the use of gene technology in those circumstances is warranted. In terms of food, it does involve the release of live organisms…[193]

3.215 While public acceptance is higher where either the exposure of an individual to a GMO has been for medical treatment or where genetically modified plants are not destined for the food chain, particular concerns are felt in relation to the use of bacteria and viruses in gene technology, and transgenic organisms, that is, cross species transfer of genes, for example transferring fish genes into tomatoes.[194]

3.216 Mr Kinnear of the Organic Federation of Australia stated:

> When we insert a piece of DNA somewhere, there are other consequences in doing that. We may disrupt other genes on either side, we may turn on or off, or…you actually cause other genes that are already there to express proteins or cause proteins to build up in much higher concentrations than have ever existed before in that tomato plant, for example. So that tomato which we are used to is changing in its protein nutrient status…we are dealing with unknown quantities here. Perhaps 999 out of 1,000 of these products might be fine, and history may tell us that they are fine, but we have to really carefully consider our duty of care. How many generations should we think down the track? Are we here for another 100 years, or are we here for 1,000 years, and what are the implications of our activities?[195]

3.217 Mr Burgess from the SA Farmers Federation indicated that while the organisation did not, as yet, have a policy position on cross species genetic modification, for example, the transferring of a salmon gene into a strawberry:

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191 *Committee Hansard*, 24.08.00, p.259 (ABA).

192 See for example results of 1998 Consumer Science Program survey discussed in the National Science & Industry Forum Report, April 1999, p.15. See also, *Committee Hansard*, 24.08.00, pp.258-9 (ABA).

193 *Committee Hansard*, 23.08.00, p.138 (Organic Federation of Australia). See also *Committee Hansard*, 23.08.00, p.233 (Tasmanian Government); C*ommittee Hansard*, 24.08.00, p.276 (NGAA).

194 See for example, *Committee Hansard*, 23.08.00, p.174 (GE-Free Tasmania); p.193 (Serve-Ag).

195 *Committee Hansard*, 23.08.00, p.158 (OFA).

> …if the scientific evidence supports it, given that there are, say, three million genes in a single strand of DNA, to introduce a minor amount of 15 to 20 genes from another species is not going to change the whole organism so dramatically as to be a major problem. But there are ethical issues…that will need to be handled.[196]

3.218 The National Farmers' Federation commented that 'more needs to be done to ensure consumers are exercising informed choice and are not being led by media scare campaigns, for example "Frankenstein foods"'.[197]

3.219 The Committee considers that a combination of tighter regulation provided by the Gene Technology Bill and a national education campaign to inform the community about the benefits, risks and measures designed to control the development and adoption of new gene technologies, will improve consumer confidence.

3.220 The Committee is also conscious that any proposed changes to the Bill made at this stage would require agreement from the States and Territories to ensure a truly national scheme, and that anything less may adversely impact on consumer confidence in the regulatory process.[198]

3.221 The Committee considers that the Gene Technology Bill provides an adequate regulatory regime to ensure the protection of the health and safety of people and the environment, and includes public reporting provisions that should help to enhance consumer confidence in the regulation of the development and adoption of new and existing gene technologies. However, the Committee considers that some of the proposed regulatory arrangements and reporting provisions require strengthening, and has made recommendations to improve the Bill in this and subsequent chapters.

Review of gene technology legislation

3.222 While the Committee supports the Bill, it is likely that in establishing the new national regulatory scheme, the Regulator will experience problems in implementing certain aspects of, and ensuring compliance with, the new regulatory system. The IOGTR advised the Committee that it is proposed that the Ministerial Council undertake a comprehensive review of the legislative scheme no later than 5 years after the commencement of the scheme.[199] However, the Committee considers that given the fundamental importance of the issues involved, the timeframe, in which the proposed review is to take place, is too long.

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196 *Committee Hansard*, 22/08/00, p.57 (SA Farmers Federation).

197 Submission No.88, Attachment 3, p.17 (National Farmers' Federation).

198 See for example, the comments in Submission No.115, p.1 (Victorian Government). See also Submission No.110, p.2 (South Australian Government) which also refers to the opportunity for future review of the legislation.

199 Submission No.77, p.132 (IOGTR).

Recommendation

The Committee RECOMMENDS that the operation of the Act should be independently reviewed after three years to ensure that its objects are being met.

CHAPTER 4

OFFICE OF THE GENE TECHNOLOGY REGULATOR

4.1 This chapter discusses the structure of the Office of the Gene Technology Regulator (OGTR) and its risk assessment processes compared with other stakeholder models. In addition, the chapter analyses whether the powers and investigative capability of the OGTR are adequate to ensure compliance with conditions imposed in licences. Finally, the chapter discusses the extent to which the proposed cost recovery and funding measures for the OGTR are appropriate and will allow for adequate resourcing of the Office.

Structure of the Office of the Gene Technology Regulator

4.2 The Bill proposes the establishment of the Gene Technology Regulator (GTR) as an independent statutory office holder with responsibility for implementing the legislation (clause 26). The Regulator is not subject to direction from anyone in relation to his or her performance, in particular whether or not to grant a GMO licence with or without conditions (clause 30).

4.3 The Regulator is appointed by the Governor-General, who is advised by the Commonwealth Minister for Health. In turn, the Minister for Health will be advised by the Ministerial Council. Before advising the Governor-General on the preferred appointee, the Health Minister must be satisfied that a majority of State and Territory Ministers support the appointment (clause 118). The Regulator will hold office for a fixed term of between three to five years (sub-clause 118(2)). The Regulator's appointment may also be extended for a further fixed term.[1]

4.4 The Regulator must disclose to the Minister all interests, pecuniary or otherwise, that could conflict with the performance of his or her functions (clause 120).

4.5 The functions of the Regulator (as set out in clause 27 of the Bill) include the following:

- determining applications for GMO licences;
- developing draft policy principles and policy guidelines to be issued by the Ministerial Council;
- developing codes of practice, technical and procedural guidelines in relation to GMOs;
- providing information and advice to other regulatory agencies and to the public;

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1 IOGTR, Additional Information dated 26 September 2000.

- undertaking or commissioning research in relation to risk assessment and biosafety of GMOs; and
- promoting the standardisation of risk assessment relating to GMOs and GM products by regulatory agencies.[2]

4.6 The Regulator may delegate any of his or her powers or functions to an employee of the Department of Health and Aged Care (DHAC), or an employee of another Commonwealth Department, authority or State agency whose functions relate to GMOs and GM products (clause 29). This enables the Regulator to delegate to a relevant agency such as the National Registration Authority (NRA) or the Australia New Zealand Food Authority (ANZFA).

4.7 The Bill also establishes the Gene Technology Account, over which the Regulator will have complete responsibility, and it allows for staff to be recruited by the Regulator.[3]

4.8 The Regulator has discretion in the performance of his or her functions, and has the ability to obtain scientific, ethical and other advice from the three advisory committees established by the Bill. The Regulator, is however, bound by policy principles issued by the Ministerial Council not to issue a licence if to do so would be inconsistent with a policy principle (clause 57).[4] Policy principles are discussed in Chapter 5. The Regulator must report to the Minister annually and also has the discretion to table a report in either House of Parliament about matters relating to his or her functions at any time (clause 137).[5]

Independence and accountability

4.9 Evidence to the Committee emphasised the necessity for the Regulator to be independent and also to be seen to be independent in its important regulatory role.[6] The Australian Food and Grocery Council (AFGC) stated that 'to be effective, the office must be independent…the operational framework must ensure that the office is independent of commercial, political and sectoral influence'.[7]

4.10 Some submissions argued that the Bill fails to establish adequate safeguards to ensure the independence of the Regulator. As noted above, the Regulator must disclose to the Minister all interests, pecuniary or otherwise, that could conflict with the performance of his or her functions (clause 120).

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2 Explanatory Memorandum, Gene Technology Bill 2000, p.55.

3 Submission No.77, p.53 (IOGTR).

4 Submission No.41, p.6 (Grains Research & Development Corporation).

5 Department of the Parliamentary Library Bills Digest No 11 2000-01, Gene Technology Bill 2000, dated 16 August 2000, p.11. See also Submission No.77, pp.53-7 (IOGTR).

6 Submission No.110, p.2 (South Australian Government); Submission No.70, p.1 (Professor Gibbs); *Committee Hansard*, 25.8.00, p.399 (AFGC).

7 *Committee Hansard*, 25.8.00, p.399 (AFGC).

4.11 The Australian Centre for Environmental Law (ACEL) argued that the provisions needed to be strengthened and that an individual with an interest (financial or otherwise) in a regulated entity should be precluded from holding the office of Regulator. Likewise, an individual who has worked in a regulated entity should be barred from holding the office until the expiration of an adequate amount of time, such as two year, to ensure propriety and the appearance of propriety in impartial decision making. The Centre argued that disclosure of interest 'is clearly not sufficient' in these areas.[8]

4.12 The Committee believes that given the importance of the Office of the Regulator and the necessity of ensuring community confidence in its independence and impartiality strict eligibility criteria to the appointee should apply.

Recommendations

The Committee RECOMMENDS that an individual with a financial or other interest in a regulated entity be precluded from holding the office of Regulator.

The Committee RECOMMENDS that an individual who has worked for a regulated entity be precluded from holding the office of Gene Technology Regulator until the expiration of a two-year period.

4.13 Submissions also noted that the proposed requirement that the Regulator be 100 per cent self-funded imposes a very significant restriction on his or her independence. Submissions noted that the proposed cost recovery arrangements can give rise to the perception that the Regulator is a 'captive' of industry. This in turn can reduce the public's trust in the Regulator's decisions.[9] The Committee is not persuaded as to the need for a system of full cost recovery. This issue is discussed later in this chapter.

4.14 Several submissions noted the importance of the establishment of a fixed term of tenure for the Regulator to ensure his or her independence under the Bill.[10] Professor Gibbs also argued that the term of tenure should not be renewable – 'the person in this position will have great responsibility and power'.[11] The Committee considers that the office should be renewable especially given that the proposed term of office is relatively short (between three to five years), and that similar officeholder positions are usually renewable.

4.15 The Committee notes that the Regulator will be required to report annually to the Parliament. The Committee believes that the transparency of the operations of the Regulator would be enhanced if the Regulator reported more frequently than annually.

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8 Submission No.34, p.6 (ACEL); *Committee Hansard*, 25.8.00, pp.358-9 (ACEL) See also Submission No.9, p.7 (HSCA).

9 Submission No.32, p.9 (Avcare Ltd); Submission No.71, p.9 (AFGC).

10 Submission No.85, p.13 (ACF GeneEthics Network); Submission No.70, p.1 (Professor Gibbs).

11 Submission No.70, p.1(Professor Gibbs).

The Committee notes that the recent House of Representatives report into gene technology recommended that the Regulator report at least quarterly for the first three years.[12]

4.16 The Committee believes that the Regulator should be required to report quarterly with regard to compliance with the legislation. The Australian Radiation Protection and Nuclear Safety Authority, which has similar regulatory functions to that proposed for the Regulator in the Gene Technology Bill, provides for quarterly reporting. Section 60 of the *Australian Radiation Protection and Nuclear Safety Act 1998* provides that the agency must include, *inter alia*, details of any breach of licence conditions by a licensee and a list of all facilities licensed during the quarter in its quarterly reports. The Committee considers that this type of information provides a useful model for the reporting requirements that should be provided by the Regulator under the Gene Technology Bill in its quarterly reports.

Recommendation

The Committee RECOMMENDS that the Bill be amended to include a requirement for quarterly reporting by the Regulator and that these reports include relevant information on the functions and operations of the Regulator including facilities licensed and breaches of licence conditions.

Establishment as a statutory authority

4.17 Some evidence suggested that the independence of the office would be increased if the Regulator were established as an independent statutory authority.[13] The Consumer Food Network of the Consumers' Federation of Australia (CFN) argued for the establishment of a statutory authority governed by an independent board and reporting to a Cabinet Minister, preferably the Minister for Health or the Minister for the Environment.[14]

4.18 The Interim Office of the Gene Technology Regulator (IOGTR) noted that initially some jurisdictions expressed a preference for the Regulator to be established as a statutory authority, however, following consideration of the issue, 'all jurisdictions agreed that a statutory office holder with budgetary control, control over staffing and control over decision making in respect of individual applications would deliver the essential outcomes'.[15] The South Australian Government while supporting this position, however, expressed the view that the independence of the Regulator would be further enhanced if constituted as a statutory corporation established jointly

12 *Work in Progress: Proceed with Caution*, Report by the House of Representatives Standing Committee on Primary Industries and Regional Services, June 2000, p.139.

13 Submission No.88, p.3 (NFF); Submission No.71, p.6 (AFGC).

14 Submission No.50, p.2 (Consumer Food Network). See also Submission No.6, Appendix 1 (Consumers' Association of SA).

15 Submission No.77, p.53 (IOGTR).

by the Commonwealth and States – 'further, we believe that such an authority may provide a more secure constitutional basis for the administration of the scheme'.[16]

4.19 The IOGTR noted that the proposed option of a statutory office holder will provide a high level of independence, transparency and accountability.[17] The IOGTR noted that the Bill provides that Regulator as a statutory office-holder with a high level of autonomy in administering the legislation, and in financial and staffing matters.[18] AFGC also noted that although not established as a statutory authority – the Council's preferred approach – the status afforded the Regulator 'being appointed by the Governor General and reporting directly to Parliament, should provide industry and consumers with considerable confidence in the independence and apolitical nature of the office and the system'.[19]

4.20 The Committee believes, however, that the need for all decisions made by the Regulator to be not only scientifically based but entirely independent is crucial to ensuring public confidence in the regulatory system. The fact that under the current proposal the final decision rests with one person is of concern in terms of the level of responsibility and pressure this one person will have and perceptions that one person may not be able to resist pressure from outside influences, industry or Government. This being the case the Committee recommends that the independence and impartiality of the office will be enhanced by the establishment of the Regulator as a statutory authority, where a board of three people will take ultimate responsibility for decision-making.

Recommendation

The Committee RECOMMENDS that the Regulator be established as a statutory authority consisting of a board of three people who will take ultimate responsibility for decision-making.

Interface with existing regulators – 'one-stop shop' model

4.21 Under the proposed Bill, the Regulator operates as a 'gap filler' regulating all dealings with live viable GMOs and also GM products not regulated by existing regulators. The Bill regulates all 'dealings', including research, manufacture, production, propagation, commercial release and import, with live viable GMOs that have been modified by techniques of gene technology. This recognises that at present most of the 'gaps' in legislative oversight exist in relation to dealings with live viable organisms. The legislation will also regulate GM products – non-live or non-viable products – where they are not regulated by an existing regulatory regime. This recognises that most GM products are regulated by existing regulatory regimes, for

16 Submission No.110, p.2 (South Australian Government).

17 Submission No.77, p.73 (IOGTR).

18 Submission No.77, p.53 (IOGTR).

19 Submission No.71, p.6 (AFGC).

example, GM medicines, foods and chemicals, but there may be some products that are not currently regulated, for example, stock feed.[20]

4.22 Evidence from consumer, environmental and primary producer groups argued that the Gene Technology Regulator should be a 'one stop shop' for the regulation of GMOs and GM products.[21] Under this approach, all GMOs and GM products would be regulated by a single agency or through a centralised process regardless of whether the GMOs or GM products were also therapeutic goods, foods, agricultural and veterinary chemicals or industrial chemicals.

Scope of the scheme

4.23 Some submissions argued that the proposed scheme should subject every activity, application and use of GMOs or products derived from GMOs to a unified regulatory control, administered by one independent regulator. ACEL argued that the activities regulated should include all applications and uses of GMOs; the development, breeding, propagation, production and manufacture of GMOs; deliberate releases into the environment; marketing of GMOs; contained use of GMOs; and import and export of GMOs.[22] Friends of the Earth (Fitzroy) also stated that the regulatory system should have the powers to consider all GMO and GM products.[23]

4.24 Other submissions argued that the establishment of a 'one-stop shop' would not necessarily mean that the Regulator would have to be a 'super-regulator'. The Consumer Food Network argued that much of the assessment work could be done by particular agencies such as ANZFA, NRA, the Therapeutic Goods Administration (TGA), the Australian Quarantine and Inspection Service (AQIS) and the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). The Network argued that the Regulator should, however, have ultimate responsibility for coordinating the assessments and licensing of GMOs and their products.[24]

4.25 Other submissions also discussed possible structures for a 'one-stop shop' arrangement. ACF GeneEthics Network argued that that the OGTR should be the lead agency in all GE-related matters. In the first instance, all applications would pass through a single entry point to the OGTR. In addition to doing its own assessments, the OGTR would commission its subcommittees and other authorities, such as Environment Australia, to assess particular applications from their perspectives – 'this

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20 Explanatory Memorandum, p.18.

21 *Committee Hansard*, 24.8.00, p.265 (NGAA); *Committee Hansard*, 24.8.00, p.287 (AWB Ltd); *Committee Hansard*, 24.8.00, p.306 (ACF); Submission No.6, p.3 (Consumers' Association of SA); Submission No.85, p.10 (ACF GeneEthics Network); Submission No.34, p.3 (ACEL); Submission No.54, p.22 (OFA); Submission No.88, Attachment 2 (NFF); Submission No.63, p.7 (AWB Ltd); Submission No.59, p.2 (MLA).

22 Submission No.34, pp.3-4 (ACEL).

23 Submission No.51, p.10 (Friends of the Earth (Fitzroy)).

24 Submission No.50, p.1 (Consumer Food Network).

would provide broad advice, and robust, credible assessments which would have a much better chance of winning public confidence'.[25]

Advantages of a 'one-stop shop' approach

4.26 Proponents of a 'one-stop shop' approach argued that this model would ensure comprehensive regulation of all activities and dealings involving GMOs or GM products and a streamlined assessment process requiring approval from only one regulator.[26] The ACF GeneEthics Network argued that:

> The GT Bill does not fundamentally reform the existing voluntary system of advice and unenforceable guidelines. It creates an irrational situation where many authorities assess applications for some dealings with, and products of GEOs, under a variety of laws and powers. Each application may go separately to several bodies, but in some cases may never need to be notified to, or be considered by, the OGTR.[27]

4.27 Meat and Livestock Australia Ltd (MLA) also argued that the 'relative complexity of the current and proposed regulatory systems add cost and uncertainty, which discourages investment in gene technology'.[28] In some cases, businesses will require approval from a number of regulators in order to market a GM product. For example, GM crops will be regulated as they are growing in the field by the Regulator and also by ANZFA if they are intended to enter the food chain.[29]

4.28 Evidence also suggested that a 'super-regulator' may provide more transparency and certainty for community members who have serious concerns regarding gene technology. Community concerns and input about the impacts of GMOs on human health and safety and the environment could have maximum effect as they would be focussed on a single regulatory system.[30]

The 'gap-filler' approach

4.29 As noted above, the Bill regulates all dealings with live viable organisms that have been modified by techniques of gene technology (regardless of whether these are also examined by other regulators). In relation to GM products, that are not live and viable, and:

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25 Submission No.85, p.10 (ACF GeneEthics Network). See also Submission No.35, p.7 (GE-Free Tasmania).

26 Submission No.34, p.3 (ACEL); Submission No.54, p.22 (OFA).

27 Submission No.85, p.10 (ACF GeneEthics Network).

28 Submission No.59, p.2 (MLA).

29 Explanatory Memorandum, pp.18-19.

30 Submission No.85, pp.9-11 (ACF GeneEthics Network); Submission No.6, pp.1-4 (Consumers' Association of SA). See also Explanatory Memorandum, p.20.

- are not regulated by any other regulatory agency – the Regulator will directly regulate those GM products (for example, stock feed); and
- are regulated by other regulatory agencies – the regulatory agency must seek, and take into account, the Gene Technology Regulator's advice and must notify the Regulator of the decision regarding the GM product so that the GTR can include the information on a comprehensive database of GMOs and GM products approved for use in Australia.[31]

4.30 The IOGTR stated that the Gene Technology (Consequential Amendments) Bill 2000 'creates a statutory requirement for each of the other regulators of GM products to seek advice from the Gene Technology Regulator in respect of any biosafety matters arising from a GM product'.[32]

4.31 The Consequential Amendments Bill amends the current Commonwealth regulatory schemes to require the relevant regulatory agency to request advice from the Regulator, and to consider that advice when making decisions in relation to products which are GM products or contain GM products. The regulatory agencies must also notify the Regulator of decisions made in relation to GM products, so that these decisions can be included on the Record of GMO and GM Product Dealings.

4.32 The Consequential Amendments Bill amends:

- the *Agricultural and Veterinary Chemicals (Administration) Act 1992* and the *Agricultural and Veterinary Chemicals (Code) Act 1994*;
- the *Australia New Zealand Food Authority Act 1991*;
- the *Industrial Chemicals (Notification and Assessment) Act 1989*; and
- the *Therapeutic Goods Act 1989*.[33]

4.33 These amendments give the formal legislative basis for the interaction between the existing regulators and the Gene Technology Regulator in terms of requesting and providing information, making decisions and establishing publicly available information systems. This approach requires amendments to the above-mentioned primary legislation and the implementation of formal channels of communication between the regulators and the Gene Technology Regulator.[34]

4.34 The Parliamentary Library stated that the regulatory agencies do not have to follow the Regulator's advice, although they must have regard to it. If a regulatory

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31 Submission No.77, p.71 (IOGTR).

32 *Committee Hansard*, 14.8.00, p.31 (IOGTR).

33 The Attorney-General's Department operates a database of Acts which is updated regularly. There are also legal updating services that update legislation and there are tables that accompany Acts indicating where amendments to the relevant Acts have been made.

34 Explanatory Memorandum, Gene Technology (Consequential Amendments) Bill 2000.

agency approves a licence or registration or other dealing with GM product, in contravention of the Regulator's advice, there is no provision requiring this fact to be made public. The Record of GMO and GM Product Dealings contains information relating to the person authorised, and any conditions specified in the licence or authority, but does not contain copies of documents such as the Regulator's written advice or any risk management plans.[35]

4.35 The impact of the proposed changes as it applies to agricultural and veterinary chemicals, food, industrial chemicals, therapeutic goods and the import of GMOs is discussed below.

Agricultural and Veterinary Chemicals

4.36 The Consequential Amendments Bill would require the National Registration Authority to consult the Regulator if an active constituent or a chemical product is or contains a GM product. The NRA must give written notice to the Regulator that an application has been made involving a GM product, and seek the advice of the Regulator, in relation to decisions concerning the:

- approval, variation or reconsideration of an approval of an active constituent;
- registration, variation or reconsideration of the registration of a chemical product;
- approval, variation or reconsideration of an approval of a chemical product's container label; or
- issue of a permit to allow a person to do something with an active constituent or a chemical product that would otherwise be prohibited.

The Regulator must provide the advice requested, in writing, within a specified time period, and the NRA must take that advice into account in determining the application. The NRA is not obliged to follow any advice given by the Regulator, but must inform the Regulator of the NRA's final decision.[36]

Food

4.37 The Consequential Amendments Bill would amend the *Australia New Zealand Food Authority Act 1991*. The effect of this change would require that ANZFA, after accepting an application for the development and variation of food regulatory measures in relation to GMOs or GM products, give written notice to the Regulator inviting written advice from the Regulator on the application. The Authority must then have regard to such advice in making an assessment of the application. The Authority is required to advise the Regulator of the nature of the recommendations

35 Department of the Parliamentary Library Bills Digest No 10 2000-01, Gene Technology (Consequential Amendments) Bill 2000, p.2.

36 Parliamentary Library, pp.2-3.

made to the Australia New Zealand Food Standards Council. The final decision of the Council is publicly notified in the Government Gazette. The decision, as it relates to GMOs or GM products, would then be entered on the Regulator's Record of GMOs and GM products.[37]

4.38 ANZFA is only required to give notice to the Regulator if the food regulatory measure relates to food which is or contains a GMO or a GM product. The effect of the changes to the *Australia New Zealand Food Authority Act 1991* is that food containing GM products will undergo the normal approval processes followed by ANZFA, including obtaining comments from the Regulator as well as other agencies. Food that is a GMO (such as sale of raw GM tomatoes) will be subject to the licensing regime prescribed in the Gene Technology Bill 2000, as well as to ANZFA's usual consultation and approval process. The manufacture of food containing GMOs may also be subject to licensing under the Gene Technology Bill 2000 in addition to approval by ANZFA.[38]

Industrial Chemicals

4.39 The Consequential Amendments Bill amends the *Industrial Chemicals (Notification and Assessment) Act 1989*. It would require the Director of Chemicals Notification and Assessment to consult the Regulator in relation to the assessment of, and application for, a permit for any industrial chemical that is or contains a GM product. As with agricultural and veterinary chemicals, the Director must give written notice to the Regulator that an application has been made involving a GM product, and seek the advice of the Regulator. The Regulator must provide written advice within a specified time period, and the Director must take that advice into account in making the ultimate decision on the application, and inform the Regulator of the decision. However, the Director is not obliged to follow any advice given by the Regulator.

4.40 The Director also has the ability to seek advice from the Regulator about an entire class of industrial chemicals containing a certain class of GM products If an advice from the Regulator about a class of GM products is in force, the Director does not need to seek advice from the Regulator in relation to applications for assessments and permits for industrial chemicals containing those GM products However, the Director still has to take the class advice into account in making individual decisions, and must notify the Regulator of each individual decision made.[39]

Therapeutic Goods

4.41 The Consequential Amendments Bill would require the Secretary of DHAC to consult the Regulator in relation to applications for registration or listing of any

37 Explanatory Memorandum.

38 Parliamentary Library, p.2.

39 Parliamentary Library, pp.3-4.

therapeutic good which is or contains a GM product. Consonant with the proposed amendments to the schemes for agricultural and veterinary chemicals and industrial chemicals, the Secretary must give written notice to the Regulator that an application has been made involving a GM product, and seek the advice of the Regulator. The Regulator then provides written advice within the specified time period. The Secretary must take that advice into account in making the decision whether to register or list the therapeutic good, and must inform the Regulator of the decision. However, the Secretary is not obliged to follow any advice given by the Regulator.

4.42 There is also a process for the Secretary to seek advice from the Regulator about an entire class of therapeutic goods containing a certain class of GM products which duplicates the amendments to the industrial chemicals scheme. If an advice from the Regulator about a class of GM products is in force, the Secretary does not need to request advice from the Regulator in relation to applications for registration or listing of therapeutic goods containing those GM products. However, the Secretary still has to take the class advice into account in making individual decisions, and notify the Regulator of each individual decision made.

Import of GMOs

4.43 GMOs are prohibited from being imported, and will therefore require a licence under the Gene Technology Bill, and as such, it is not also necessary to make them prohibited imports under the *Customs Act 1901*. In addition, AQIS will have to approve the import of any live viable organism.[40]

4.44 In relation to imported GMOs, the IOGTR stated that if the GMO was to be released into the environment, the GTR would have to assess the risks associated with that release and would require field trials – 'you could not ever import a live viable genetically modified organism into Australia and just start growing it or releasing it into the environment without field trials being conducted to assess any unique risks to the unique Australian environment'.[41] The IOGTR also stated that if a GMO was for processing food, for example, the GTR would have to assess the risks and approve the dealing but would not require field trials because the purpose of the import is for processing. AQIS would also have to approve the GMO import.[42]

Conclusion

4.45 The Parliamentary Library stated that the Consequential Amendments Bill does not alter the substance of the existing Commonwealth regulatory schemes in relation to food, therapeutic goods, agricultural, veterinary and industrial chemicals. The Bill merely adds an additional element to the existing structure of regulation, requiring advice from the Regulator to be sought and considered in relation to certain

40 IOGTR, Additional Information dated 11October 2000.

41 *Committee Hansard*, 14.8.00, p.32 (IOGTR).

42 *Committee Hansard*, 14.8.00, p.32 (IOGTR).

applications for products containing GMOs. The Regulator's advice on GM products used in all four areas is intended to provide some measure of consistency of treatment of GM products.[43]

4.46 Although provision is made for the Regulator to provide advice about a class of GM products in relation to both therapeutic goods and industrial chemicals, no such provision for class advice is made in relation to agricultural and veterinary chemicals. The Parliamentary Library stated that the reason for this omission is 'not immediately apparent'.[44] The Committee believes that this omission needs to be addressed in the legislation.

Advantages of a 'gap-filler' approach

4.47 The IOGTR stated that the Bill creates a 'one-stop shop' for biosafety assessment of all GMOs and GM products by establishing a centralised national regulator who undertakes risk assessment of all GMOs and GM products.[45]

4.48 The IOGTR stated that the advantages of this approach are that it:

- recognises the roles of each of the existing regulators, and the desirability of assessing GM products along with their non-GM counterparts under the relevant regulatory framework. For example, GM therapeutic goods are most appropriately assessed for safety, quality and efficacy under the therapeutic goods scheme, with advice on the safety aspects of the medicine associated with the genetic manipulation being provided by the Gene Technology Regulator;
- ensures that like products are treated in a similar way (reducing market distortions) while also ensuring that any risks posed by gene technology are considered in all cases;
- ensures that the GTR acts as a centralised area of expertise on genetic safety associated with gene technology who will make advice available to other regulators of GM products. This reduces costs to government by eliminating the need for each regulatory agency to establish a centre of expertise on gene technology;
- ensures that all aspects of production, manufacture, sale etc of GMOs and GM products are regulated and that there are no 'gaps' in regulatory coverage. The system also ensures that the GTR either directly regulates, or provides advice to other regulators, on all GMOs and GM products;
- minimises duplication by implementing strategies to improve the interface between regulators. For example, the legislation requires exchange of information between regulators; the GTR to hold a centralised database of all

43 Parliamentary Library, p.5.

44 Parliamentary Library, p.5.

45 Submission No.77, p.71 (IOGTR).

approvals for GMOs and for GM products approved in Australia (the Record of GMOs and GM product approvals); and the GTR to work with other agencies to harmonise data requirements, assessment and standards in relation to risks posed by gene technology; and

- is able to be implemented by 3 January 2001. A more complex single agency to regulate all GMOs and GM products would take significantly longer to establish and community and industry demand for a fully operational GTR by 2001 could not be met.[46]

Conclusion

4.49 The Committee believes that it is important that a comprehensive regulatory scheme be established to control the various dealings with GMOs and to provide a high level of reassurance to the community that any risks posed by the use of gene technology are minimised.

4.50 The Committee acknowledges that the proposed structure in the Bill establishes a regulatory regime that will interface with existing regulators. This option ensures that all aspects of the production, manufacture and sale of GMOs and GM products are regulated and that there are no 'gaps' in regulatory coverage. The system also ensures that the Regulator either directly regulates, or provides advice to other regulators, on all GMOs and GM products.

4.51 The Committee believes, however, that there may be significant benefits in introducing a 'one-stop shop' arrangement for business and the community generally. The Committee believes that this approach would ensure a more comprehensive regulation of all activities and dealings involving GMOs or GM products and a more streamlined assessment process. The Committee is, however, mindful that complete reform of existing systems and the establishment of a 'super-regulator' would also take considerable time and therefore believes that the option of introducing a 'one-stop shop' should be considered after an assessment has been made of the overall effectiveness of the proposed scheme and as part of the review of the scheme that the Committee has previously recommended should occur (see Chapter 3).

Recommendation

The Committee RECOMMENDS that as part of the review of the scheme as recommended by the Committee, the review consider the feasibility of introducing a 'one-stop shop' model having regard to the operational effectiveness of the proposed 'gap filler' arrangements.

46 Submission No.77, p.72 (IOGTR). See also IOGTR, Additional Information dated 18 September 2000.

Risk assessment processes

4.52 The Gene Technology Bill provides that, before issuing a licence, the Regulator must prepare a comprehensive risk assessment and risk management plan (sub-clause 50(1)). The risk assessment would:

- identify any hazards to public health and safety or the environment with the dealing, based on objective information;
- estimate the probabilities of hazards occurring; and
- estimate the risk that is a function of the above factors.[47]

4.53 'Risk assessment' is the process of determining and evaluating the potential risks posed by the dealings with a GMO, the magnitude of the risks and the probability of the risks occurring. For the purposes of the regulatory system for gene technology, the objective of risk assessment is to identify and evaluate the potential adverse effects of GMOs to the environment, or to human health. Risk assessment is followed by 'risk management', which is the identification of options and strategies to manage the risk.[48] The risk management plan may provide that the risks cannot be managed and, as such, a licence should not be granted. Alternatively, the plan could set out conditions that would be necessary for the risks to be effectively managed.

4.54 Whether or not there is significant risk in relation to the dealings proposed to be authorised by the licence, the Regulator must prepare a comprehensive risk assessment and risk management plan to manage any risks so as to protect the health and safety of people and the environment (sub-clause 50(2)).[49]

4.55 The Bill details a range of matters which must be considered by the Regulator in preparing the risk assessment. Those matters include the risks posed by the proposed dealings, submissions made to the Regulator, and any advice provided by the Gene Technology Technical Advisory Committee, and Commonwealth, State and local government agencies (sub-clause 51(1)).

4.56 In preparing the risk management plan, the Regulator must consider a range of matters including the means of managing any risks to the health and safety of people and the environment posed by the proposed dealing, submissions made to the Regulator, and any advice provided by the Gene Technology Technical Advisory Committee, the Commonwealth Environment Minister and Commonwealth, State and local government agencies (sub-clause 51(2)).

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47 Explanatory Memorandum, Gene Technology Bill 2000, p.63.

48 Submission No.77, pp.57-8 (IOGTR).

49 Explanatory Memorandum, p.63; Parliamentary Library, Bills Digest No 11 2000-01, Gene Technology Bill 2000, p.14.

4.57 After preparing the risk assessment and risk management plan, the Regulator must invite written submissions from the public on those documents. The Regulator must also seek advice on the risk assessment and risk management plan from the States, Gene Technology Technical Advisory Committee, the Commonwealth Environment Minister and Commonwealth authorities or agencies prescribed in the Regulations (clause 52). This issue is discussed further in Chapter 5.

4.58 The Regulator also has a discretion to take other action, such as hold public hearings (clause 53). Although the Regulator is required to take into account the advice given by these persons and bodies, he or she is not required to follow the advice given by any of them – the ultimate decision to issue a licence remains with the Regulator.[50]

Assessment processes in other Australian legislative schemes

4.59 The IOGTR stated that the proposed gene technology scheme will adopt a scientific risk assessment model not unlike those already in place for food, therapeutic goods and agricultural and veterinary chemicals.

4.60 The IOGTR noted that while other regulatory schemes have elements of a consultative process, the gene technology regulatory regime is the only scheme that provides two rounds of consultation on all high risk applications; enables public access to the full application provided by the applicant; sets out legislated criteria requiring consultation with the Environment Minister, Commonwealth agencies and States; establishes a statutory expert advisory committee to advise on all applications; sets out legislated criteria requiring the Regulator to take into account all advice received in relation to the application; and provides public access to details of the final decision on a consolidated database.[51] A table which compares the risk assessment processes of the existing regulatory systems is at Appendix 5.

Assessment processes in overseas countries

4.61 The IOGTR provided information on the assessment process provided for under the Bill compared to processes employed by overseas bodies in the United States of America, New Zealand, Canada, the European Community, the United Kingdom, Germany, Japan, South Korea, and South Africa.

4.62 The IOGTR stated that the following general comments may be made about the Bill in comparison to other countries:

- many other countries have utilised existing environment protection or plant legislation to regulate GMOs. For example, in both the UK and Canada, existing environment protection legislation is utilised, but with regulations made under the legislation specifically to deal with the release of GMOs into the

50 Parliamentary Library, p.15.

51 Submission No.77, pp.66-7 (IOGTR).

environment. Other countries such as Germany, Austria and South Africa have enacted specific legislation dealing with GMOs;

- of the countries examined, all distinguish between contained work and deliberate releases into the environment, with a more streamlined system of regulation applying in relation to contained work and a more detailed risk assessment being necessary in relation to deliberate releases into the environment. Many countries deal with contained work in separate legislation from that dealing with intentional release of a GMO into the environment;
- all the countries examined define GMOs slightly differently, consistent with the parameters of the legislation under which the GMO is regulated. For example, in Canada and New Zealand, GMOs are assessed as new substances, and in the United States GMOs are assessed according to whether they are, or have the potential to be, a plant pest. The advantage of the Australian system is that specific legislation has been developed to deal with GMOs and, as such, the scope of the legislation has been able to be defined broadly and all relevant matters allowed to be taken into account;
- in relation to the intentional release of a GMO into the environment – of the countries examined, all require the proponent to submit a detailed data package against information requirements set out by the competent authority. For example, the EC Directive in relation to deliberate releases of GMOs includes an annex describing the data which must be provided by the applicant. Similarly, the regulations developed under the Gene Technology Bill will set out data requirements. During consultations, a number of people emphasised the importance of harmonising Australian data requirements with those of other countries. As such, the regulations have been developed having regard to the data requirements of other countries;
- most countries have the capacity to draw on expert advice or seek public comment on applications. For example, in the UK, the relevant Minister seeks advice from the Advisory Committee on Releases into the Environment and in Germany the Federal Ministry for Health seeks advice from the Advisory Committee for Biological Safety. Similarly, some countries have the capacity to seek public comment on applications but this is not required in all cases. For example, the EC directive provides that member states may consult the public on any aspect of the application. To date, no other system has been identified that requires (in legislation) consultation with both an expert scientific committee and two rounds of public consultation on applications involving release of a GMO that may pose significant risks to the environment, as the Gene Technology Bill requires;
- in some countries, the approval to release a GMO into the environment may be subject to conditions, and in others, such as New Zealand and the United States, no conditions may be applied once an approval has been granted. During consultations on the Gene Technology Bill, stakeholders emphasised the importance of the GTR being able to impose conditions, where necessary, to

manage any risks posed by the GMO. A number of commentators on existing systems overseas have also emphasised the importance of being able to impose conditions, the Gene Technology Bill therefore provides for the imposition of any conditions that are necessary to manage risk;

- most countries have the capacity to appoint inspectors to enforce the legislation. For example, under general environment protection legislation in Canada, inspectors may be appointed to monitor compliance with the legislation, remedial action may be required and penalties may be imposed for breach of the legislation. Compared to other countries, the Australian Bill provides for significant monitoring, inspection and enforcement powers.[52]

Flaws in risk assessment processes

4.63 Several submissions and other evidence from environmental groups argued that the risk assessment framework provided for in the Bill is weak and needs to be significantly improved.[53]

Failure to incorporate the precautionary principle

4.64 Evidence from environmental and other groups argued that the Regulator should apply the precautionary principle in decision-making relating to GMOs, given the potential uncertainties and risks surrounding gene technology.[54] ACEL argued that:

> The precautionary principle should be the central foundation on which the entire regulatory superstructure of gene technology is built. The precautionary principle finds its basis in the principles of economically sustainable development which should also be taken into account by the Regulator in deciding whether to issue a licence. Adopting the precautionary principle, the Bill should require that the lack of full scientific certainty about risks entailed by activities or dealings involving gene technology cannot be used as a pretext for not taking measures or making decisions to prevent risks to health and safety, the environment or biological diversity.[55]

4.65 ACF GeneEthics Network argued that 'the principle is now enshrined in many international treaties and Australian laws, to ensure protection for the environment and

52 Submission No.77, pp. 69-70 (IOGTR).

53 *Committee Hansard*, 24.8.00, p.308 (ACF); Submission No.51, p.5 (Friends of the Earth (Fitzroy)); Submission No.40, p.4 (ACF).

54 *Committee Hansard*, 24.8.00, pp.305-6 (ACF); *Committee Hansard*, 25.8.00, p.357 (ACEL); Submission No.34, p.5 (ACEL); Submission No.51, p.4 (Friends of the Earth (Fitzroy)); Submission No.40, pp.1-2 (ACF); Submission No.54, p.6 (OFA); Submission No.85, p.7 (ACF GeneEthics Network); Submission No.6, pp.7-8 (Consumers' Association of SA).

55 Submission No.34, p.5 (ACEL).

public health. With a new technology capable of affecting all living organisms, such precaution is very appropriate and it has huge public support'.[56]

4.66 Submissions argued that the application of the precautionary principle under the Bill should provide that the Regulator should not issue a licence unless there is sufficient evidence that the activities or dealings involving gene technology pose no significant risk to health and safety, the environment or biological diversity. The submissions emphasised that in making the determination about risk, the precautionary principle requires extensive risk assessment using rigorous methodology.[57]

4.67 Submissions and other evidence from industry groups were opposed to incorporating the precautionary principle into the risk assessment process. Avcare Ltd stated that 'sound science must be used for risk assessment purposes. We do not subscribe to the proposition that the precautionary principle should be used for risk assessments…a precautionary approach should be applied to risk management'.[58] Avcare also noted that the Bill provides for the Regulator to take a cautious approach in making licensing decisions and that there is sufficient sound science available on which to grant a licence – 'if there is not, then a licence will not be issued'.[59]

4.68 Avcare also stated that there 'are about 12 different definitions of the precautionary principle, and there has not been an agreement yet what a universal definition should be'.[60] Avcare also commented that 'very few' overseas countries have the precautionary principle spelt out in their legislation.[61]

4.69 The IOGTR stated that the Commonwealth and the States agreed that the risk assessment and management process outlined in the proposed legislation embodied a *precautionary approach*.[62] The IOGTR further stated that:

> …rather than explicitly referencing the Precautionary Principle and potentially creating uncertainty about its interpretation, all jurisdictions agreed it was better to provide clear directions to the Gene Technology Regulator about how to apply precaution in considering each application. Debate on the adequacy of the legislation should therefore focus on the adequacy of the risk assessment and management process in the legislation

56 Submission No.85, p.7 (ACF GeneEthics Network).

57 Submission No.34, p.5 (ACEL); Submission No.51, pp.4-5 (Friends of the Earth (Fitzroy)); Submission No.85, p.7 (ACF GeneEthics Network).

58 *Committee Hansard*, 25.8.00, p.381 (Avcare Ltd).

59 Submission No.32, p.4 (Avcare Ltd).

60 *Committee Hansard*, 25.8.00, p.381 (Avcare Ltd).

61 *Committee Hansard*, 25.8.00, p.381 (Avcare Ltd).

62 Submission No.77, p.74 (IOGTR).

rather than be misdirected into argument about the interpretation of the Precautionary Principle.[63]

Conclusion

4.70 The Committee believes that given the potential risks and uncertainties associated with gene technology the Bill needs to be amended to provide clear directions to the Regulator about how to apply precaution when considering licence applications. The issue of the precautionary principle is further discussed in Chapter 3.

Recommendation

The Committee RECOMMENDS that the Objects of the Bill contain the same words that appear in the *Environment Protection and Biodiversity Conservation Act 1999* in relation to the Precautionary Principle.

Referral to the Environment Minister

4.71 As noted above, the Bill only requires that the Regulator 'seek advice' from the Environment Minister in preparing risk assessment and risk management plans for intentional releases of GMOs into the environment (sub-clause 50(3)).

4.72 Submissions and other evidence from environmental and other groups argued that this is a significant dilution of any requirement to conduct an environmental impact assessment (EIA) under the proposed consequential amendments to the *Environment Protection and Biodiversity Conservation Act 1999* (EPBC Act).[64] In January 2000 the Environment Minister released a draft proposal for consultation whereby the EPBC Act would be amended to provide for the environmental assessment of GMOs. This provision was contained in the first Gene Technology (Consequential Amendments) Bill 2000 released in late January 2000.

4.73 These amendments would have introduced a new Part 4A to the EPBC Act – 'Special Rules for GMOs'. The proposed Part 4A would have required the referral of releases of GMOs to the Minister for the Environment and Heritage ('Environment Minister') for environmental assessment pursuant to the EPBC Act.

4.74 Under the proposed amendments to the EPBC Act, the Gene Technology Regulator would refer certain applications for a GMO licence under the Gene Technology Bill to the Minister for the Environment and Heritage. All applications involving a deliberate release of a GMO into the environment would be referred to the Environment Minister. Proposed GMO dealings which do not include a deliberate

63 Submission No.77, p.74 (IOGTR); IOGTR, Additional Information dated 18 September 2000. See also *Committee Hansard,* 25.8.00, p.381 (Avcare Ltd).

64 Submission No.86, p.1 (WWF & HSI); Submission No.69, p.3 (Friends of the Earth (Perth, WA Group)); Submission No.34, pp.5-6 (ACEL); Submission No.40, p.2 (ACF); Submission No.50, p.6 (Consumer Food Network); *Committee Hansard,* 24.8.00, pp.306-7, 328-9 (ACF); *Committee Hansard,* 25.8.00, pp.358, 367, 373-4 (ACEL).

release into the environment but which pose a significant risk of harm to the environment would also be referred.

4.75 Upon receiving a referral, the Environment Minister would determine whether the broader risk assessment process being carried out by the Gene Technology Regulator is adequate to ensure a full assessment of environmental risks and, if not, what further environmental assessment under the EPBC Act is to be carried out.

4.76 The proposed GMO dealing would be subject to the assessment provisions of the EPBC Act (Part 8 of the EPBC Act). Under Part 8 of the EPBC Act (as applied), there are various assessment options available to the Environment Minister. For example, if the risk assessment process being undertaken by the Gene Technology Regulator is adequate in relation to a particular proposal, then the Environment Minister can accredit that process. If further assessment is required, the Environment Minister can direct the preparation of, for example, an EIS.[65]

4.77 The draft amendments were intended to ensure that any environmental assessment process under the EPBC Act would, to the greatest extent possible, be effectively integrated with the broader risk assessment process carried out by the Regulator under the Gene Technology Bill. This would ensure a rigorous and efficient assessment process that avoids unnecessary duplication and delay.

4.78 After the environmental assessment is conducted, the Environment Minister would provide advice to the Gene Technology Regulator. The Gene Technology Regulator would take this advice into account before making a licence decision and would report to the Minister on how the environmental advice was dealt with.

4.79 The IOGTR stated that following consultation on the proposal to amend the EPBC Act, the States, Territories and the Commonwealth considered that the objectives of the proposed amendments 'could be better met by providing for comprehensive assessment of environmental risks, through the Gene Technology Bill rather than through amendments to the EPBC Act'.[66]

4.80 The World Wide Fund for Nature (WWF) and the Humane Society International (HSI) stated that the proposed amendments to the EPBC Act have a number of benefits, in that it ensures rigorous environmental assessment and input by the Environment Minister; and that there is only one process, administered by the Regulator, and one approval, from the Regulator.[67]

4.81 Submissions stated that risk assessment, as proposed under the Gene Technology Bill, is no substitute for a detailed EIA. ACEL argued that:

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65 *Environmental Assessment of Genetically Modified Organisms – Draft Amendments to the EPBC Act 1999.*

66 IOGTR, Additional Information dated 18 September 2000.

67 Submission No.86, Addendum (WWF & HSI).

> …while risk analysis and assessment can produce information on one aspect of a proposal, EIA is capable of bringing together information on a variety of aspects. The simple fact is that an EIA is much more comprehensive than risk assessment can be, and by jettisoning EIA requirements, the *GTB* 2000 jeopardises not only public health and safety, but also Australia's unique environment, its myriad ecosystems and mega-biological diversity. Indeed, risk assessment does not ordinarily entail consideration of the environment apart from its potential effects on human health and safety.[68]

4.82 ACEL also argued that by failing to include the EIA trigger under the EPBC Act 'the probability that harm to humans or damage to the environment will be caused by gene technology is greatly increased because it is much more likely that something will be overlooked'.[69] WWF & HSI also argued that without the provision of an EIA under the EPBC Act the Bill 'will not achieve its object of protecting the environment'.[70]

4.83 Some submissions argued that the Environment Minister should have an even stronger role in the regulation of GMO releases. The EPBC Act currently provides that actions which are likely to have a significant impact on one of the defined matters of 'national environmental significance' (for example, nationally threatened species) will require approval from the Minister for the Environment and Heritage. Submissions argued that the EPBC Act should be amended to include the release of GMOs into the environment as a 'matter of national environmental significance'. This would ensure that where there is the potential for a GMO release to have a significant impact on the environment, full environmental assessment would occur under the EPBC Act. It would also go further than the earlier proposal, by giving the Environment Minister power to veto any GMO releases if the risks were considered too great.[71]

Conclusion

4.84 The Committee believes that the success of the new regulatory system will in part depend on ensuring that there is a single process through which applications must pass. The Committee has discussed the advantages of this approach in relation to the proposed structure of the OGTR (see earlier discussion).

4.85 The Committee does, however, believe that the Environmental Impact Assessment as outlined in the EPBC Act has merit and provides for a comprehensive approach to safeguard the environment from the potential risks posed by gene technology. Rather than have two separate processes, the environmental provisions in the Gene Technology Act and regulations should closely parallel the procedures in the EPBC Act.

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68 Submission No.34, p.6 (ACEL).

69 Submission No.34, p.6 (ACEL).

70 Submission No.86, p.1 (WWF & HSI). See also Submission No.85, p.8 (ACF GeneEthics Network).

71 Submission No.86, p.2 (WWF & HSI); Submission No.85, p.8 (ACF GeneEthics Network).

4.86 If this is done, the Committee does not see a need for the Environment Minister to have a veto on the release of GMOs. It believes that the ultimate authority for approval of applications should rest with the Regulator.

Recommendation

The Committee RECOMMENDS that in preparing risk assessment and risk management plans for the intentional release of GMOs into the environment, the Regulator be required to follow a process that should be no weaker than the Environmental Impact Assessment process set out in the *Environment Protection and Biodiversity Conservation Act 1999.*

Other inadequacies in the risk assessment process

4.87 Submissions argued that there several other inadequacies relating to risk assessment processes in the Bill.

Risk assessment – matters to be taken into account

4.88 The Australian Conservation Foundation (ACF) argued that there is no requirement that the risk assessment include consideration of the potential impacts on the environment posed by the dealings (clause 51). ACF argued that the Regulator should be required to consider a range of factors when preparing the risk assessment of any dealings with GMOs, including all relevant scientific evidence; the general characteristics of both the GMO or product and the parent organisms; the native environments of the recipient organism and donor organism; the intended use(s) of the GMO or product; potential impact of the GMO or product on the environment; effects of the GMO or product on human, plant and animal health; socio-economic impacts; conformity with ethical norms; and details of risk assessments completed elsewhere.[72]

4.89 The IOGTR stated that the Bill is not prescriptive about the specific tasks that the Regulator must consider as part of the risk assessment process – this was intentionally excluded from the Bill because there are many different types of GMOs that the Regulator will be examining, and the Regulator will need flexibility to examine any risks posed by the proposed dealings with the particular GMO. However, some broad categories of risk have been prescribed in the Regulations to be taken into account by the Regulator. For example, the Regulator must take into account:

- any previous assessment, in Australia or overseas, in relation to allowing or approving dealings with the GMO; and
- the potential of the GMO to be harmful to other organisms; adversely affect any ecosystems; transfer genetic material to another organism; have selective

72 Submission No.40, pp.4, 9-13 (ACF).

advantage in the natural environment; spread or persist in the environment; and be toxic, allergenic or pathogenic to human beings.[73]

4.90 The IOGTR stated that it is currently working on other criteria that the Regulator must take into account in preparing a risk assessment and risk management plan and that will be subject to further public consultations.[74]

4.91 The Committee believes that several of the concerns of environmental groups have been addressed by the regulations in relation to matters to be taken into account in risk assessment plans. The Committee considers that other criteria, yet to be developed, that the Regulator must take into account in preparing risk assessment plans should also be prescribed in the regulations.

Recommendation

The Committee RECOMMENDS that a complete listing of broad categories of risk that the Regulator must consider as part of the risk assessment and risk management plans, be prescribed in the regulations to the Bill.

Level of risk

4.92 Environmental groups also noted that when preparing risk assessment and risk management plans for dealings not involving the intentional release of a GMO into the environment, the Regulator need consider fewer matters than would be required if the dealing involved the release of a GMO into the environment. Several groups argued that the Regulator should be required to consider the same matters when preparing risk assessment and risk management plans for dealings not involving the intentional release of a GMO into the environment as would be required if the dealing involved the intentional release of a GMO into the environment.[75]

4.93 The IOGTR noted, however, that the proposed regulatory regime is based on a system whereby the level of regulation applied to particular dealings with GMOs is commensurate with the level of risk posed by the particular dealings.[76] The Interim Office also noted that overseas countries distinguish between contained work and deliberate releases into the environment, with a more streamlined system of regulation applying in relation to contained work and a more detailed risk assessment being necessary in relation to deliberate releases into the environment.[77]

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73 Explanatory Guide to the Draft Commonwealth Gene Technology Regulations 2000, August 2000, pp.25-6.

74 Explanatory Guide to the Draft Regulations, p.26.

75 Submission No.40, pp.3-4 (ACF); Submission No.51, p.5 (Friends of the Earth (Fitzroy)).

76 Submission No.77, p.59 (IOGTR).

77 Submission No.77, p.69 (IOGTR).

4.94 The Committee believes that the approach proposed in the Bill whereby the level of regulation applied to particular dealings with GMOs is commensurate with the level of risk posed by the particular dealings is appropriate.

Insurance coverage

4.95 A further issue raised by environment groups was that there is no requirement for the Regulator to consider whether the applicant has access to insurance coverage for the proposed GMO dealing. These groups argued that the Regulator should determine whether insurance is available to cover the risks associated with the dealings for which the licence has been applied. Furthermore, the lack of insurance coverage should constitute prima facie evidence that the risks are too high or uncertain for the licence to be issued.[78] This issue is discussed further in Chapter 6.

4.96 The Committee believes that in setting licence conditions, the Regulator should satisfy him or herself that applicants have made provision for suitable insurance coverage to cover the risks associated with the dealings.

Recommendation

The Committee RECOMMENDS that the Bill be amended to require that in prescribing or imposing conditions of licences, the Regulator may satisfy him or herself that applicants have made provision for suitable insurance coverage to cover the risks associated with the dealings.

Confidential commercial information

4.97 The Bill provides that a person may apply to the Regulator for a declaration that certain information is confidential commercial information (clause 184). The Regulator is obliged to declare information to be confidential commercial information if it is:

- a trade secret;
- information with commercial or other value which would be destroyed or diminished by disclosure; or
- information about the commercial or financial affairs of an organisation or person if disclosure would unreasonably affect that person or organisation (clause 185).

4.98 However, the Regulator has a discretion to refuse to declare the information confidential commercial information if, in the Regulator's opinion, the public interest in disclosure would outweigh the prejudice (sub-clause 185(2)).

4.99 Environs Kimberley stated that:

78 Submission No.34, p.5 (ACEL); Submission No.40, p.4 (ACF); Submission No.51, p.5 (Friends of the Earth (Fitzroy)).

> The phrase "commercial in confidence" has an extremely wide meaning in the Act (clause 184) and at common law, and it is well known that it is used as a mechanism to prevent legitimate public inquiry into matters that may, or have, harmed the public or the environment.[79]

4.100 Environs Kimberley further stated that although sub-clause 185(2) provides scope for the Regulator to disregard this assessment of confidential commercial information when disclosing information concerning GMOs, 'this does not necessarily deal with the potential breadth of information hidden by this clause'.[80] The Parliamentary Library also noted that it seems likely that a broad range of information in applications for research and development in new gene technology would encompass 'trade secrets' and 'commercial information' under the Bill.[81]

4.101 The Parliamentary Library also commented that there are significant limitations on the use of confidential commercial information. Such information:

- cannot be disclosed in the information provided to the public during the community consultation on GMO licence applications (clause 54);
- cannot be used by the Regulator in considering other GMO licence applications, unless the information owner gives written consent (clause 45). The clause is intended to combat the 'free rider' effect, where it would be possible for a second applicant to minimise the resource implications of a licence application by referring to, or using, information already made available to the Regulator in support of another application; and
- is not recorded on the Record of GMO and GM Product Dealings (sub-clauses 138(3), (4), and (5)).[82]

4.102 The Committee believes that the Bill needs to strike a balance between the protection of confidential information and the need for a high level of transparency of the regulatory regime. This issue is discussed in Chapter 3.

Powers and investigative capability of the Regulator

4.103 The Bill provides a number of provisions to enforce compliance with the legislation. The relevant provisions relate to:

- imposition of conditions;
- monitoring of compliance with conditions;
- reporting obligations;

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79 Submission No.82, p.7 (Environs Kimberley). See also Submission No.35, p.9 (GE-Free Tasmania); Submission No.69, p.2 (Friends of the Earth (Perth, WA Group)).

80 Submission No.82, p.7 (Environs Kimberley).

81 Parliamentary Library, p.24.

82 Parliamentary Library, p.24. See also Explanatory Memorandum, p.61.

- powers to investigate alleged breaches;
- enforcement powers; and
- penalties.

Imposition of conditions

Licences issued by the GTR may be subject to four different types of conditions. These are conditions:

- set out in the Bill - there are currently three such conditions described in clauses 63, 64 and 65. These statutory conditions require all licence holders to:
    - inform anyone covered by a licence of the conditions that relate to them. This is a minimum requirement. Conditions applied on a case-by-case basis may set out exactly how such people are to be informed (for example, through labelling, training etc.);
    - allow the GTR, or a person authorised by the GTR, to enter premises for the purposes of auditing and monitoring; and
    - inform the GTR of any additional information that becomes available regarding risks to public health and safety and the environment or contraventions of the legislation.
- prescribed by the Regulations;
- imposed by the GTR at the time of issuing the licence. The GTR may impose any conditions that are necessary to manage risk, as assessed on a case-by-case basis. The GTR may limit where the GMO is used, who uses the GMO and how it is used. For example, the GTR may require specific containment measures, waste disposal methods and reporting requirements; and
- imposed by the GTR after the licence is issued.[83]

Burden of proof

4.104 ACEL argued that given the potential risks associated with the use, application or release of GMOs, it is imperative that the regulatory framework clearly establishes that the applicant for a licence bears the burden of proof in connection with an application for a licence.[84]

4.105 In particular, ACEL maintained that the applicant should be required to demonstrate beyond reasonable doubt that granting the application will not result in damage or harm to human health or to the environment.[85] ACEL commented that

83 Submission No.77, pp.83-4 (IOGTR).

84 Submission No.34, p.7 (ACEL); *Committee Hansard*, 25.8.00, pp.369-70 (ACEL).

85 Submission No.34, p.7 (ACEL); *Committee Hansard*, 25.8.00, pp.369-70 (ACEL).

'imposing that sort of burden is like making somebody prove a negative. It is not done very often. It is very difficult to prove. Maybe it is not entirely appropriate for every application, but it certainly is appropriate where there is likely to be a significant impact on the environment'.[86]

4.106 The Committee agrees that it is the primary responsibility of the applicant to provide adequate scientific support for its case to the Regulator. However, in order to maintain credibility, the Regulator is obliged to make his or her decision based on independent assessment and evaluation of data provided by the applicant and through the public and committee processes.

4.107 In addition, the Regulator needs to be able to commission additional independent research and undertake monitoring to satisfy any concerns. The Committee believes that for an applicant to bear the sole burden of proof would in fact compromise the perceived indpendence of the Regulator and limit his or her ability to make decisions on a wide range of information.

Exemptions to the licensing system

4.108 Certain dealings with GMOs are not subject to the licensing system. Exempt dealings, dealings listed on the GMO Register and notifiable low risk dealings will be able to be conducted without going through the licensing system.

4.109 Exempt dealings are exempt from the requirements of the legislation on the basis of the negligible risk posed by the dealing with the GMO. Exemptions are prescribed in the Regulations (Part 1 of Schedule 1).[87] The exemptions in the Regulations are based on the current exemptions in the GMAC Guidelines for Small Scale Genetic Manipulation Work. The GMAC exemptions have been developed over the last 25 years, based on the experience of assessing applications in Australia. The exemptions apply to a very limited number of dealings with GMOs that:

- have been assessed over time as presenting no significant biosafety risks to public health and safety, including occupational health and safety, or the environment; and
- are undertaken within contained facilities, that is, they do not involve intentional release of a GMO into the environment.[88]

4.110 The IOGTR stated that the dealings with GMOs that are included on the list of exemptions will be reviewed regularly. In addition, any member of the public may, at any time, make a submission to the GTR proposing that certain dealings with GMOs be removed from the list of exemptions, or be included on the list of exemptions.

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86 *Committee Hansard,* 25.8.00, p.370 (ACEL).

87 Explanatory Guide to the Draft Regulations, p.22. Exempt GMOs are those that are set out in Part 1 of Schedule 1 of the Regulations.

88 Explanatory Guide to the Draft Regulations, p.39.

Before making changes to the list of exemptions, the GTR will undertake a full analysis of any risks posed by the dealings to determine whether they are justified in being removed from, or added to, the list of exemptions.[89]

4.111 Dealings listed on the GMO Register will be exempt following a period of licensing, monitoring of any risks and a determination that the GMO no longer requires licensing based on the absence of risk. Notifiable low risk dealings will be exempt on the basis that the work is to occur within a contained facility and does not present any significant risks. Notifiable low risk dealings are prescribed in the Regulations and will rely on self-assessment by researchers with the assistance of Institutional Biosafety Committees.[90] The Regulator, will, however, provide independent oversight of assessments.[91]

4.112 Submissions and other evidence argued that in some cases the requirement to obtain a licence may be circumvented if the proposed dealing falls within the blanket exemptions provided to dealings that are declared exempt dealings, dealings listed on the GMO Register and notifiable low risk dealings. As noted previously, dealings included on the GMO Register will be exempt following a period of licensing, monitoring of any risks and a determination that the GMO no longer requires licensing based on the absence of risk. The submissions argued that the blanket exemptions should be removed from the Bill so that all uses of GMOs should require a licence.[92]

4.113 The IOGTR argued that the Bill recognises that different types of dealings with GMOs present varying levels of risk, and that different levels of assessment and regulatory oversight are appropriate in relation to each.[93] The Interim Office noted that to remove the exemptions or the notifiable low risk dealings from the Bill would lead to the 'ludicrous situation' whereby very low risk activity would be required to undergo the comprehensive licensing process.[94]

4.114 The Committee believes that that the proposed system of exemptions should be retained in the Bill. The Committee does not consider that all dealings with GMOs should be subject to the same level of regulation and considers that the proposed regulatory regime recognises that different types of dealings with GMOs present varying levels of risk and that low risk dealings can be exempt.

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89 Explanatory Guide to the Draft Regulations, p.39.

90 Explanatory Guide to the Draft Regulations, pp.27-8.

91 Submission No.77, p.75 (IOGTR).

92 Submission No.40, p.5 (ACF); Submission No.51, p.11 (Friends of the Earth (Fitzroy)); *Committee Hansard*, 24.8.00, p.308 (ACF).

93 Submission No.77, pp.75-6 (IOGTR).

94 Submission No.77, p.76 (IOGTR).

Review of licences

4.115 Some submissions argued that the Bill should include requirements for the review or renewal of licences. The Bill provides that a licence remains valid either until the end of a specified period, or until it is cancelled or surrendered (clause 60). ACEL argued that it is unacceptable that licences will be issued in perpetuity without an established system for review or renewal. The Centre stated that review and renewal procedures are common in licensing regimes across Australia.[95] ACEL argued that the review should take place after three years, whereas ACF argued that a licence should not exceed a five year duration without renewal.[96]

Recommendation

The Committee RECOMMENDS that the Bill be amended to include provisions for the mandatory review or renewal of all licences granted by the Regulator; and that this review or renewal take place at intervals of not more than three years.

Buffer zones

4.116 The Bill does not set specific buffer zones around GM crops to protect organic and GM-free crops growing nearby. The Organic Federation of Australia (OFA) argued that the Regulator should be required to impose conditions to ensure that protection of the right to farm GM free is maintained by limiting pollen flow through the application of buffer zones and strict handling controls. OFA argued that the Regulator should not issue a licence for the release of a GMO without conditions that ensure that contamination of GM-free produce or land cannot occur.[97]

4.117 The IOGTR stated that the Regulator may set conditions to limit the dissemination or persistence of the GMO or its genetic material in the environment (clause 62). For example, the Regulator may require licence holders to establish buffer zones and the like to prevent contamination of non-GM crops.[98] The Parliamentary Library also commented that the Regulator will have power to impose conditions to limit contamination. It will be up to the Regulator whether it does so, and the level of stringency required, although the Regulator must be satisfied that any risks to the environment or to human health and safety can be adequately managed (sub-clause 56(1)). The Regulator also has power to vary a licence, including imposing additional conditions or removing or varying existing conditions. The Regulator cannot vary a licence for contained dealings to authorise the intentional

95 Submission No.34, p.12 (ACEL).

96 Submission No.34, p.12 (ACEL); Submission No.40, p.4 (ACF). See also Submission No.51, p.5 (Friends of the Earth (Fitzroy)).

97 Submission No.54, p.9 (OFA); *Committee Hansard*, 23.8.00, p.150 (OFA).

98 IOGTR, Additional Information dated 25 August 2000.

release of a GMO, and must be satisfied that any variations to the licence enable risks to be managed adequately (clause 71).[99]

4.118 The IOGTR also noted that there other mechanisms within the legislation to protect GM-free status of crops from potential contamination from GM crops. The legislation provides that the Regulator must not act inconsistently with policy principles issued by the Ministerial Council. So, if the Ministerial Council decided to make a policy principle, for example, to 'protect the diversity of Australian farming systems' the Regulator would have to make sure that appropriate conditions were put in place to give effect to this. The legislative framework also works under the assumption that all applications for dealings involving the intentional release of a GMO into the environment should be made publicly available, subject to limited exemptions for legitimately confidential commercial information.[100]

4.119 The Committee believes that the regulatory regime needs to ensure that the strictest controls are in place to ensure that organic farms and other non-GM farming systems are not subject to contamination by genetically modified crops. The Committee considers that the Regulator should not issue a licence for the release of a GMO without stringent conditions to ensure, as much as possible, that contamination of GM-free produce or land cannot occur.

Recommendation

The Committee RECOMMENDS that the Bill be amended to require that the Regulator not issue a licence for the release of a GMO without conditions that ensure, as much as possible, that contamination of non-genetically modified produce or land cannot occur.

Monitoring of compliance with conditions

4.120 The legislation provides the capacity for the GTR to monitor compliance with the legislation in a range of ways. The GTR may:

- require regular auditing to be undertaken by a licence holder and the results of such auditing to be reported to the GTR;
- undertake routine audits of a licence holder. This may involve notifying the licence holder and undertaking site inspections or 'on-site' audits of paperwork demonstrating compliance with conditions of licence. As currently occurs under the interim arrangements, the GTR will prepare a monitoring plan which ensures that the GTR undertakes site inspections at times when the risks posed by the GMO may be greatest and compliance with conditions of licence is most critical (for example, when GM crops are flowering); and

99 Parliamentary Library, pp.16-17.

100 IOGTR, Additional Information dated 25 August 2000.

- undertake 'on-the-spot' inspections or audits of dealings with GMOs. As detailed above, it is a statutory condition of licence that a licence holder must allow the GTR, or a person authorised by the GTR to enter premises for the purposes of auditing or monitoring the dealing. This enables the GTR, or his/her delegate to undertake inspections without providing prior notice to the licence holder.[101]

Auditing processes

4.121 Submissions argued that that the monitoring and auditing processes (clause 64) are inadequate, as there is no stipulation as to how often such monitoring or auditing should take place or the extent to which this should take place.[102] ACF argued that it should be a condition of a licence that a licence holder must monitor and evaluate, on a continuing basis after the licence is issued, any risks associated with the activities or dealing involving GMOs that are subject to the licence. ACF also argued that it should be a condition of a licence that licence holders must submit annual reports to the Regulator in respect of this monitoring.[103] The IOGTR stated that at a minimum, it is anticipated that all licence holders will be required to report annually, however the GTR may on a case-by-case basis determine that more regular auditing and reporting is necessary based on the level of risk posed by the dealings with the GMO.[104]

4.122 The licence-holder has a statutory obligation to inform the Regulator of any additional information as to risks, any contravention of the licence or any unintended effects of the dealings, that he or she becomes aware of (clause 65). If a GMO licence contains a particular condition relating to monitoring or auditing, persons authorised by the licence have an obligation to allow the Regulator into premises, to undertake such auditing or monitoring (clause 64).[105]

4.123 The Parliamentary Library stated that GMO licences may also contain conditions requiring licence holders to conduct regular monitoring, conduct periodic reviews of risk monitoring plans, or undertake sampling and testing to check for unintended environmental effects, however, 'these conditions are not legislatively required under the Bill, but may be imposed on a licence holder at the discretion of the Regulator'.[106]

4.124 The Parliamentary Library noted that the Bill provides for monitoring through random inspections and an obligation on licence-holders to report any breaches of the licence or unintended effects (Part 11 and clause 65). However, comprehensive

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101 Submission No.77, p.84 (IOGTR).

102 Submission No.51, p.6 (Friends of the Earth (Fitzroy)); Submission No.40, pp.4-5 (ACF).

103 Submission No.40, pp.4-5 (ACF).

104 Submission No.77, p.84 (IOGTR).

105 Parliamentary Library, p.23.

106 Parliamentary Library, pp.23, 41.

independent auditing to ensure compliance with licence conditions is not required unless it is made a condition of the GMO licence.[107] The Parliamentary Library further stated that:

> There is no provision in the Bill for a comprehensive independent auditing process to check the quality assurance systems being used by the licence-holder, and ensure the licence conditions and risk management plans are being followed.[108]

4.125 The Committee believes that that the monitoring and auditing processes in the Bill need to be strengthened. The Committee considers that a licence holder should be required, as a condition of a licence, to monitor any risks associated with the activities or dealing involving GMOs. The Committee also considers that as a condition of a licence, an independent audit of a licence holder should be undertaken by the Regulator to ensure compliance by the licence holder with the conditions of his or her licence.

Recommendations

The Committee RECOMMENDS that as a condition of a licence, a licence holder be required to monitor, on a continuing basis, any risks associated with the activities or dealing involving GMOs that are subject to the licence and the results of such monitoring be reported annually to the Regulator.

The Committee RECOMMENDS that as a condition of a licence, a licence holder be required to submit to an independent audit of his/her activities by the Regulator to ensure compliance with licence conditions.

Investigation of alleged breaches

4.126 The legislation enables the Regulator to appoint inspectors for the purposes of investigating alleged breaches of the legislation (clause 150).

4.127 The IOGTR stated that the investigation of breaches is a serious matter that is dealt with quite separately in the legislation from the general monitoring powers of the GTR. This is because if a breach of the legislation has been alleged, care needs to be taken not only to ensure that any evidential material (that will assist with a prosecution) is not lost but also to ensure that inspectors do not trespass unduly on personal rights and liberties.[109]

4.128 In the event of non-compliance with the conditions imposed, the legislation describes a range of investigative powers that may be used by inspectors appointed under the legislation for determining whether a breach has in fact occurred. These

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107 Parliamentary Library, p.30.

108 Parliamentary Library, p.23.

109 Submission No.77, p.85 (IOGTR).

powers include search powers, seizure powers and emergency powers (clauses 153,154,155).

4.129 The IOGTR stated that the inspection powers described in the legislation are similar to those of the Australian Federal Police, Customs agents and inspectors appointed under the Therapeutic Goods Act. The powers of inspection are 'significant' and are consistent with Commonwealth criminal law policy.[110]

Inspectors

4.130 Several submissions argued that sufficient funding must be provided for the employment of suitably qualified inspectors to enforce the compliance provisions of the Bill.[111] AFGC stated that 'it will be the number, independence and calibre of inspectors that will prove the adequacy of the inspectorial powers and inspectorial system'.[112]

4.131 The Committee believes that the problems with the Mt Gambier contamination issue is testament to the importance of strict enforcement of compliance with licence conditions to ensure consumer confidence in the regulatory system.

Recommendations

The Committee RECOMMENDS that suitably qualified inspectors be employed by the Regulator to enforce the compliance provisions in the Bill.

The Committee RECOMMENDS that the Regulator fund the employment of adequate numbers of inspectors to provide for sufficient frequency of inspection to act as a deterrent to non-compliance.

Enforcement powers

4.132 The Bill describes a range of enforcement powers available to the GTR. The Regulator may:

- vary conditions of licence to require a licence holder to take any further actions that are necessary;
- suspend or cancel a licence (which may necessitate the recall of the GMO or the cessation of any dealings with the GMO);
- seek an injunction from the Federal Court to restrain a person from continuing to engage in certain activities that are in breach of the legislation; and

110 Submission No.77, pp.84-5 (IOGTR).

111 Submission No.17, p.3 (NGAA); Submission No.102, p.4 (CSIRO).

112 Submission No.71, p.13 (AFGC).

- issue directions to the licence holder, or person covered by the licence, requiring the person to take any necessary steps to comply with the Act.[113]

4.133 As noted above, the Regulator has power to suspend or cancel a licence for a number of reasons. These include, if the Regulator:

- believes on reasonable grounds that the licence-holder or the person covered by the licence has breached a condition of the licence, including by not providing additional information to the Regulator;
- believes on reasonable grounds that the licence-holder or the person covered by the licence has committed an offence against the Bill or the Regulations; or
- becomes aware of risks which the licence-holder is not in a position to deal with adequately (clause 68).

4.134 If a licence holder or a person covered by a licence does not act in accordance with the legislation, and their actions are likely to cause, or are causing, harm to the health and safety of people or to the environment, then the GTR may give written directions to the person directing them to comply with the legislation. If the person does not take the necessary action within a specified period of time, the GTR may take additional steps, or direct that necessary steps be taken, to ensure compliance with the legislation. This provision effectively enables a 'clean-up' or remediation to be undertaken, either by the GTR or by the licence holder under the direction of the GTR.

4.135 The legislation further provides that if costs are incurred by the GTR in taking steps to bring the activity back into compliance with the legislation, such costs may be recovered from the licence holder or the person covered by the licence (as applicable).

4.136 The legislation also enables an inspector to take immediate action where there is an imminent risk of danger to health and safety of people or to the environment. In such circumstances, the inspector can take such steps as are necessary without first giving written notice to the licence holder or applicant requiring them to take the necessary steps. Such action, by the inspector or others, is also cost recoverable from the offending party.[114]

Offences and penalties

4.137 A holder of a GMO licence is guilty of an offence if they do something, or fail to do something, that results in a breach of a condition of licence. A similar offence exists for persons covered by a GMO licence who do something, or fail to do something, which results in a breach of a condition of licence.

113 Submission No.77, p.85 (IOGTR).

114 Submission No.77, p.85 (IOGTR).

4.138 There are a range of offences associated with a breach of a condition of licence that may be pursued depending on the circumstances of the particular case:

- in the case of a less serious or technical breach – the prosecution would just need to establish that the licence holder took action (or failed to take action) and that contravened the licence. In such a case a penalty could be imposed without the need to establish any 'mental element' of knowledge or recklessness. In this case, a penalty of up to 50 penalty units may be imposed. This equates to $5 500 for an individual and $27 500 for a corporation;
- in the case of a serious offence - the prosecution would need to establish that the licence holder or the person covered by the licence, intentionally took an action (or failed to take an action) that they knew (or they were reckless as to knowing) contravened a condition of licence. A larger penalty (500 penalty units) could then be imposed. This equates to $55 000 for an individual and $275 000 for a body corporate; or
- in the case of a breach of condition that causes significant damage, or is likely to cause significant damage, to the health and safety of people or the environment, two alternative penalties may be pursued:
    - if the prosecution can establish knowledge or recklessness a penalty of up to 2000 penalty units may be imposed. ($220 000 for an individual and $1.1 million for a body corporate).
    - if the prosecution pursues a strict liability offence (in these instances knowledge or recklessness does not have to be shown) then the penalty is 200 penalty units which equates to $22 000 for an individual and $110 000 for a corporation.[115]

4.139 The IOGTR stated that the draft Bill that was circulated in late 1999, did not include provision for 'tiered' offences or for strict liability offences. The need for strict liability offences and flexibility to respond to different types of breaches, was pointed out during consultations. The Bill was therefore amended to reflect these concerns.[116]

4.140 The IOGTR stated that the offence provisions, and the accompanying penalties in the Bill are consistent with criminal law policy of the Commonwealth and each of the States and Territories; and are significant compared to the penalties applied under other regulatory schemes.[117]

115 Submission No.77, pp.86-7 (IOGTR).

116 Submission No.77, p.87 (IOGTR).

117 Submission No.77, p.87 (IOGTR).

4.141 The Australian Law Reform Commission, while not directly commenting on the Bill, argued that there is a need for a range of regulatory and penalty mechanisms within a regulatory regime. The Commission argued that:

> A range of penalty options provides the flexibility to fit the penalty to the act or omission, escalating the penalty in relation to persistent or serious non-compliance. A pyramid [approach]…provides a range of penalty options, with the most serious appearing at the apex…an effective pyramid approach leads to cost-effective regulation…Cost effective regulation allows resources to be devoted to the most effective forms of regulatory activity with the most severe sanctions reserved for the few serious or persistent offenders…a regulatory regime should include an escalating range of penalty responses. An example…includes, from the base of the pyramid, persuasion, warning letter, civil penalty, criminal penalty, licence suspension, licence revocation.[118]

Adequacy of penalties

4.142 Several submissions argued that the penalties under the proposed legislation are inadequate. Submissions emphasised that in order for penalties to be effective in ensuring compliance, they need to be sufficiently large.[119] Submissions, however, generally welcomed the Government's decision to introduce strict liability offences to the Bill since the release of the consultation draft.[120]

4.143 ACF stated that penalties for committing an offence under the Bill (clauses 32 to 38) are 'grossly inadequate', particularly for strict liability offences and should be increased to provide a minimum penalty standard that 'is commensurate with the potentially irreversible and unlimited scale of the damage'.[121] Friends of the Earth (Fitzroy) argued that the maximum penalties for infringing the provisions of the Bill should be increased ten fold.[122]

4.144 Another submission argued that the penalties for a corporation in the case of a breach that causes significant damage – of up to $1.1 million – 'would seem out of proportion to a potential catastrophe' and a fine of this size 'is minuscule to the vast sums multinational corporations hope to profit by with this technology. It would seem a very small deterrent'.[123]

4.145 The Parliamentary Library noted that environmental statutes commonly impose, in addition to a monetary penalty, a further penalty for each day a breach

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118 Submission No.23, p.2 (ALRC).

119 Submission No.40, p.8 (ACF); Submission No.51, p.13 (Friends of the Earth (Fitzroy)); Submission No.34, pp.13-14 (ACEL); *Committee Hansard*, 24.8.00, pp.308-9 (ACF).

120 Submission No. 40. p.8 (ACF); Submission No.51, p.13 (Friend of the Earth (Fitzroy)).

121 Submission No.40, p.8 (ACF).

122 Submission No.51, p.13 (Friends of the Earth (Fitzroy)).

123 Submission No.17, p.3 (National Genetic Awareness Alliance).

continues, thus creating a strong incentive to remedy breaches as quickly as possible. The Library noted that this approach has not been adopted in the Bill.[124] For example, under the *Protection of the Environment Operations Act 1997* (NSW) the penalties for individuals who cause water and air pollution are $120 000 and $60 000 for each day the offence continues.[125]

4.146 Further, environmental statutes often provide for terms of imprisonment in addition to substantial fines. For example, the *Environment Protection and Biodiversity Conservation Act 1999* (Cth) prescribes jail terms of up to 2 years for offences relating to endangered or threatened species. The maximum fine payable for these offences is 1000 penalty points. Under the *Protection of the Environment Operations Act 1997* (NSW) the maximum penalty for wilfully or negligently causing harm to the environment by disposal of waste, leaks or spillage is $250 000 or 7 years imprisonment.[126] Whereas other, less serious, offences contained in the Gene Technology Bill (clauses 175, 187 and 192) may result in a term of imprisonment, no terms of imprisonment are available as an alternative penalty for major offences (clauses 32 to 38), even though they may result in substantial environmental damage or health hazards.[127]

Conclusion

4.147 The Committee believes that monetary penalties for breaches of a condition of licence are insufficient and need to be increased to act as a sufficient deterrent. In particular, the Committee considers that the penalties for strict liability offences (up to $22 000 for an individual and $110 000 for a corporation) are totally inadequate. The Committee also believes that in addition to a monetary penalty, a further penalty for each day a breach of a licence continues should apply to create an incentive to remedy breaches as quickly as possible. The Committee further considers that terms of imprisonment should be available as an alternative to a monetary penalty for major offences under the Bill.

Recommendations

The Committee RECOMMENDS that the Bill be amended to require that monetary penalties for breaches of a condition of a licence, especially in the case of a breach of condition of licence that causes significant damage or is likely to cause significant damage, be substantially increased.

The Committee RECOMMENDS that the Bill be amended to provide, in addition to a monetary penalty, a further penalty for each day a breach of a licence continues.

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124 Parliamentary Library, p.30.

125 Parliamentary Library, p.44. See also Submission No.82, p.5 (Environs Kimberley).

126 Parliamentary Library, pp.30, 44. See also Submission No.82, p.5 (Environs Kimberley).

127 Parliamentary Library, p.30.

The Committee RECOMMENDS that the Bill be amended to provide for terms of imprisonment to be imposed for major offences relating to breaches of condition of a licence.

Cost recovery and funding measures

4.148 Under the proposed regulatory system, it is intended that the costs incurred by the Regulator as a result of fulfilling his or her functions under the legislation will be 100 per cent cost recovered from the users of the regulatory regime. The Gene Technology Bill provides that the Regulator may charge for services provided by, or on behalf of, the Regulator in the performance of the Regulator's functions. The Gene Technology (Licence Charges) Bill 2000 provides an additional capacity for the Regulator to make charges in respect of licences.[128]

Opposition to full cost recovery

4.149 Most submissions and other evidence to the inquiry from a broad range of consumer, industry and environmental groups, opposed full cost recovery.[129]

4.150 The research and development sector expressed concern that cost recovery would further stretch already limited research budgets and inhibit 'blue skies' or innovative research. CSIRO commented that the organisation is by far the largest user of the existing GMAC system and is concerned that:

> …there has been inadequate policy discussions of the impact that full cost recovery may have on Australia's international competitiveness and capacity to continue its world-class basic research in this field. We are deeply concerned that full cost recovery may inadvertently increase the emphasis on commercial applications where regulatory costs can be passed on to commercial partners and diminish research aimed at increasing our understanding of molecular genetics, environmental impact and public good application of gene technology.[130]

4.151 CSIRO further stated that assuming an overall stable research budget, higher compliance costs through full cost recovery of regulatory oversight of basic research 'are likely to impact on the overall research and post-graduate education budget of universities and organisations such as CSIRO. They are also likely to flow onto

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128 Submission No.77, p.94 (IOGTR).

129 See, for example, Submission No.6, p.4 (Consumers' Association of SA); Submission No.17, p.3 (National Genetic Awareness Alliance); Submission No.36, p.3 (Valley Seeds Pty Ltd); Submission No.44, p.3 (Seed Industry of Australia); Submission No.58, pp.1-2 (Australian Biotechnology Association); Submission No.71, p.8 (AFGC); Submission No.61, p.5 (Aventis CropScience Australia Pty Ltd). See also *Committee Hansard*, 24.8.00, pp.335, 344-5,349-50 (Florigene Ltd); *Committee Hansard*, 25.8.00, pp.375, 379-80 (Avcare); *Committee Hansard*, 25.8.00, p.400 (AFGC); *Committee Hansard*, 25.8.00, pp.414, 417 (CSIRO).

130 CSIRO, Additional Information dated 20 September 2000.

reduced outputs, international scientific competitiveness and education of future scientists'.[131]

4.152 Australian industry utilising gene technology expressed concerns that, because it is an emerging industry with long lead times to commercialisation where the smaller companies are often making net losses, the introduction of fees and charges would retard the growth of the companies. Small biotechnology companies indicated that cost recovery would disadvantage fledging companies compared to multi-nationals. Valley Seeds Pty Ltd stated that the proposed arrangements:

> …will create a registration system that is too costly for small Australian companies to participate in this technology. We are a small company…any fees that are imposed, in addition to the higher compliance costs will put us and other Australian companies at a distinct disadvantage compared to larger multinationals.[132]

4.153 State Governments also indicated concerns with full cost recovery impacting on emerging biotechnology industries. The Western Australian Government stated that any cost recovery model must demonstrate:

> …its ability to ensure the development of Australian industry is not restricted by the application of full cost recovery principles that place an undue impost on a new industry.[133]

4.154 Avcare Ltd also commented that cost recovery arrangements needed to take into account the 'particular situation of smaller players…Cost recovery will hit them harder than the larger organisations'.[134]

4.155 Consumer groups and others expressed concern that full cost recovery may make the Regulator 'captive' of industry. The Consumer Food Network of the Consumers' Federation of Australia stated that 'we oppose 100% cost recovery from industry for the running costs of the GTR. This could lead to perceptions of "industry capture" of the regulator'.[135] AFGC also stated that:

> A key element of community confidence in the operation of the OGTR is independence, particularly from commercial interests. Retaining this independence, and perhaps more importantly the public perception of independence, while relying for funding on revenue generated from those being regulated will be problematic. Both the Regulator and industry will be open to criticism of collusion, with the Regulator particularly exposed as

131 Submission No.102, p.4 (CSIRO).

132 Submission No.36, pp.3-4 (Valley Seeds Pty Ltd).

133 Submission No.91, p.2 (Western Australian Government). See also Submission No.89, p.6 (Tasmanian Government).

134 Submission No.32, p.9 (Avcare Ltd).

135 Submission No.50, p.5 (Consumer Food Network).

being unduly influenced by industry through reliance on funding from granting permission to develop GMOs.[136]

4.156 Several submissions and other evidence emphasised the strong 'public interest' argument in ensuring the safety of all GMOs, and that it would be appropriate for Australian governments to pay all or at least part of the costs of the regulatory system. The Consumer Food Network stated that 'the GTR should be funded totally from consolidated revenue, as it will be performing a community service in protecting the health of people and the environment'.[137]

4.157 CSIRO also suggested that in determining the funding base for the Regulator 'account should be taken of the significant public benefits that may flow from enhanced knowledge of environmental impacts of GMOs, the assurance to the public about the safety of GMOs and specific, public benefit products that may arise from the research activity'.[138]

Alternative approaches

4.158 Several non-industry groups argued that OGTR should be taxpayer funded, especially to avoid any perception of 'industry capture' of the Regulator. The Consumer Food Network argued that the Regulator should be totally funded from consolidated revenue.[139] Some groups, such as the Organic Federation of Australia and the ACF GeneEthics Network, argued that if a form of cost recovery is introduced, the revenue from any licence fees should go directly into consolidated revenue.[140]

4.159 Evidence indicates that few regulatory regimes overseas impose full cost recovery. The KPMG Report into cost recovery stated that in overseas countries 'the spectrum for cost recovery for regulatory activities ranges from "recovery of the costs of selected activities" (e.g. release into the environment) in some European countries to zero cost recovery in the USA. Australia is relatively rare in pursuing full-cost recovery as a principal approach to regulatory charges'.[141] No country in the European Union charges fees that aim to recover the full cost of their regulatory regimes.[142] In

136 Submission No.71, p.10 (AFGC). See also Submission No.32, p.9 (Avcare Ltd).

137 Submission No.50, p.5 (Consumer Food Network).

138 Submission No.102, p.4 (CSIRO). See also Submission No.71, p.14 (AFGC); Submission No.58, p.2 (ABA); *Committee Hansard*, 28.8.00, p.400 (AFGC).

139 Submission No.50, p.5 (Consumer Food Network). See also Submission No.85, p.12 (ACF GeneEthics Network); Submission No.54, p.20. (Organic Federation of Australia).

140 Submission No.54, p.20 (Organic Federation of Australia); Submission No.85, p.12 (ACF GeneEthics Network).

141 KPMG Consulting, *A model for cost-recovery in the Office of the Gene Technology Regulator*, September 2000, p.30.

142 KPMG Report p.41.

the case of Canada, the fee schedules only cover a small range of processes, such as for confined trials or intentional release trials, and do not fully recover costs.[143]

4.160 The IOGTR stated that of the five regulatory agencies that interface with the proposed regulatory system for GMOs in Australia, all have some capacity to recover costs associated with the regulatory systems from the users of those systems. The majority of these agencies phased in cost recovery over a number of years. The Therapeutic Goods Administration introduced a policy of 50 per cent cost recovery in 1991, which by 1998-99 had increased to 100 per cent. Under its cost recovery policy all costs, including policy advice and compliance activities, are recovered from the TGAs client base. The TGA is, however, different from the regulatory regime proposed under the Gene Technology Bill in that it does not issue licences.[144]

4.161 The other regulatory agencies – the National Registration Authority, the Australian Quarantine and Inspection Service and the National Industrial Chemicals Notification and Assessment Scheme – are 100 per cent cost recovered for operational activities, but do not recover costs for policy advice. The Australia New Zealand Food Authority has not implemented cost recovery, but has the capacity to charge for applications which are outside the scope of its work program.[145]

4.162 Industry and primary producer groups argued that the costs of the proposed regulatory system should be split between 'public good' functions, which would be paid for by the community generally, and the cost of processing applications to be paid for by industry. Avcare Ltd argued that the costs of operation of the Regulator should be apportioned between 'public benefit' functions and services for which a fee to users would be charged.[146] The National Farmers' Federation (NFF) also supported the inclusion of a charge for assessing applications only.[147] Avcare also argued that in determining 'fees for services', charges to industry and scientific agencies should be phased in over a 5 year period.[148] A phase-in period was also supported by the NSW Farmers' Association. The Association argued that 'for a handful of applications to bear the full costs of the system in the early years would be unrealistic'.[149]

4.163 Florigene Ltd and Nugrain Pty Ltd argued that if fees are to be applied, all applicants should be treated equally – applicants from industry should not subsidise university or government research projects. The fees should also be 'very low' – if

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143 KPMG Report, p.35. See also Submission No.42, p.8 (Florigene Ltd & Nugrain Pty Ltd). See also *Committee Hansard*, 24.8.00, p.335 (Florigene Ltd).

144 Submission No.77, p.92 (IOGTR).

145 Submission No.77, pp.92-3 (IOGTR).

146 Submission No.32, p.9 (Avcare Ltd). See also Submission No.71, p.14 (AFGC); Submission No.59, p.4 (MLA).

147 Submission No.88, p.3 (NFF). See also Submission No.76, p.5 (NSW farmers' Association) .

148 Submission No.32, p.9 (Avcare Ltd). See also Submission No.42, p.8 (Florigene Ltd & Nugrain Pty Ltd).

149 Submission No.76, p.5 (NSW Farmers' Association).

they are high, expenditure of research grant money will be skewed towards small scale and field trial evaluation, instead of research. Fees should also be set on the basis of the time actually spent by the Regulator on each application and not a flat fee. If this is not done, the smaller crops – crops where there are is no environmental impact or products already cleared by GMAC may be unable to be commercialised.[150]

4.164 State Governments emphasised a need for a partial and phased approach to cost recovery indicating that the question of cost recovery is still subject to negotiations with the Commonwealth. The Western Australian Government stated that:

> …further detail must be provided on the cost recovery model, and its ability to ensure the development of Australian industry is not restricted by the application of full cost recovery principles that place an undue impost on a new industry. The overall costs associated with the proposed national regulatory system, and the extent to which those costs should be recovered from GMO proponents, remains the subject of negotiations.[151]

4.165 The Tasmanian Government stated that:

> It is imperative to note that there is generally not a level playing field in respect of the financial abilities of large and small biotechnology firms. While cost recovery is appropriate where researchers are "tied" to large biotechnology firms, in cases where public policy considerations dictate it may be appropriate for Government to bear at least part of the costs. This could initially be on a partial or "phasing in" basis as has occurred in other regulatory agencies.[152]

4.166 Evidence to the Committee also argued that any costing model needs to make a distinction between the impact of full cost recovery on research as opposed to the impact on industry. The National Health and Medical Research Council (NHMRC) argued that for many commercial applications there is a clear product which has the potential to provide an income stream to the proponent and thus may warrant some form of cost recovery. The Council noted, however, that much health and medical research is conducted at the fundamental end of the research spectrum:

> There is often no immediate benefits flowing to the institution or the proponent from the conduct of such research, unlike the case with the conduct of a field trial, prior to commercial release, of a genetically engineered crop for example. The cost of such a regime, and any charges imposed by the GTR, will thus be internalised by those who conduct health and medical research. Moreover, in the vast majority of cases, the benefits

150 Submission No.42, p.8 (Florigene Ltd & Nugrain Pty Ltd).

151 Submission No.91, p.2 (Western Australian Government). See also *Committee Hansard*, 14.8.00, p.28 (Western Australian Government).

152 Submission No.89, p.6 (Tasmanian Government).

> flowing from health and medical research are a public good…but little opportunity for the proponent to directly recoup these internalised costs.[153]

KPMG report on cost-recovery options

4.167 In May 2000, the IOGTR engaged an independent consultant KPMG Consulting to fully cost the regulatory regime and provide options for recovering the costs of the activities and functions of the OGTR.[154]

4.168 The KPMG Report concluded that a full cost recovery regime 'is considered to be impracticable in (at least) the first three to five years of operation of the OGTR'.[155] The Report stated that:

> …there is a degree of fragility in attempting to fully recover all the costs of the OGTR – especially in the first few years of operation of the Office. That is not to say that such a regime could not be introduced at a later stage when the gene technology industry has evolved to achieve a sustainable market position in Australia. It merely emphasises the fact that, currently, there is limited industry income to fund any fees and charges with any degree of equity.[156]

4.169 The Report estimated that the total costs of operating the GTR/OGTR would be $7 787 786 in the first year.[157]

4.170 The Report stated that the Government's policy of requiring full cost recovery needs to recognise that most clients of the GTR – approximately 94 per cent of all applications for gene technology dealings – are publicly funded organisations undertaking research, with little or no budgetary capacity to address additional cost imposts without detracting from the funds available for gene technology research.[158] KPMG argued that:

> Consequently, an inappropriate cost recovery regime could lead to much proposed R&D work not being undertaken in Australia, or being moved off-shore. Under either scenario, Australia would be a major loser – both economically and in its attempt to remain in the global mainstream of gene technology development.[159]

4.171 In addition, the Report argued that most companies dealing in gene technology will have limited commercial production for, at least, the next few years –

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153 Submission No.103, pp.9-10 (NHMRC).

154 Submission No.77, pp.97-103 (IOGTR).

155 KPMG Report p.ii.

156 KPMG Report, p.iii.

157 KPMG Report, p.iii.

158 KPMG Report, p.i.

159 KPMG Report, pi.

'as a consequence, it is unlikely that many such companies will have a sustainable income stream to support any significant level of fees–which can be passed on to the end consumer of any products they market. This issue will be an important factor in the sustainability and development of the gene technology industry'.[160]

4.172 KPMG presented four cost recovery options. The latter three include a levy across the different sectors of the gene technology industry:[161]

- *Option 1* (full cost recovery) – direct fees for applications of $4.9 million (63 per cent) and $2.9 million (37 per cent) for monitoring;
- *Option 2* (75 per cent cost recovery) – direct fees for applications of $2.8 million (36 per cent) and $1.6 million (21 per cent) for monitoring; levy of $1.4 million (18 per cent); and Government Assistance $1.9 million (25 per cent). This and subsequent options cover the full cost of the OGTR by a combination of reduced application fees, an industry levy and a proportional level of Government Assistance.
- *Option 3* (50 per cent cost recovery) – direct fees for applications of $1.6 million (21 per cent) and $0.9 million (11 per cent) for monitoring; levy of $1.4 million (18 per cent); and Government Assistance $3.9 million (50 per cent);
- *Option 4* (25 per cent cost recovery) – direct fees for applications of $0.3 million (4 per cent) and $0.2 million (3 per cent) for monitoring; levy of $1.4 million (18 per cent); and Government Assistance $5.9 million (75 per cent).[162]

4.173 The Report stated that 'best practice' across a range of cost recovery regimes indicates that:

- those imposing costs on the regulator should pay the charges necessary to cover those costs;
- Government should provide funding where there are public interest, public good or equity reasons;
- costs charged to applicants should relate only to the costs of processing, assessing and deciding on applications;
- charges should be imposed for services that provide identifiable recipients with direct benefits beyond those received by the general public;
- where there are both public and private benefits from a service, fees should be less than the full cost of delivering the services;

160 KPMG Report, p.i.

161 The levy has three rates: research/universities – $4000; small companies – $20 000; large companies – $200 000.

162 KPMG Report, p.iii; Part 2, p.15.

- where direct beneficiaries of the regulatory process can be identified, they, rather than the taxpayers in general, should pay for the services creating the relevant benefits; and
- the Government should not seek to make a profit from regulatory charges.[163]

Conclusion

4.174 Evidence to the inquiry argued strongly against the introduction of full cost recovery for the proposed regulatory scheme. The Committee, while not supporting full cost recovery, supports a system of partial cost recovery. The Committee believes that the introduction of full cost recovery would compromise the integrity of the Office of the Regulator, noting that a body charged with protecting human health and environmental safety would be seriously compromised if it were funded entirely by the groups it is supposed to be regulating.

4.175 The Committee is also concerned about the effect full cost recovery would have on the future of research and development in the emerging biotechnology area. Evidence to the Committee, including the KPMG Report, emphasised that full cost recovery would lead to proposed research and development work not being undertaken in Australia or being moved off-shore. The Committee believes that it is essential that the development of Australian industry is not restricted by the application of full cost recovery principles that place an undue impost on a new industry.

4.176 While the Committee believes that a partial system of cost recovery should be introduced with industry and other users contributing in addition to part funding by Government, the Committee notes that the Productivity Commission is currently considering the specific issue of cost recovery as it applies to Government instrumentalities. The Committee therefore believes that further discussion about, and proposals (including the KPMG Report) relating to, cost recovery and the operation of the OGTR be deferred until after the Productivity Commission report and its recommendations are available and that, until such time, the Government fully fund the operation of the OGTR.

4.177 The Committee notes that evidence received during the inquiry indicated support for a cost recovery system that imposed differential fees and charges in respect of universities and research organisations; smaller-scale companies in the start-up research and development phase; and larger, more established companies so that innovative research and smaller biotechnology companies are not disadvantaged under the cost recovery regime. The Committee also notes that evidence received indicated that there were strong ‘public interest’ arguments relating to the public benefits that will flow from the development of gene technology that support a Government contribution towards the cost of the regulatory regime.

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163 KPMG Report, p.ii.

Recommendations

The Committee RECOMMENDS that further discussion about, and proposals (including the KPMG Report) relating to, cost recovery and the operation of the OGTR be deferred until after the Productivity Commission report and its recommendations are available. The Committee further RECOMMENDS that until such time, the Government fully fund the operation of the OGTR.

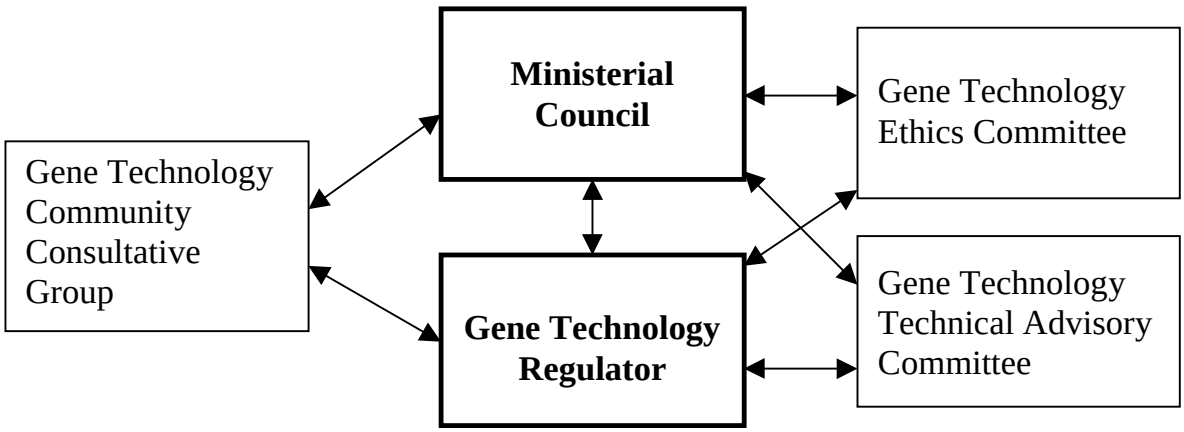
CHAPTER 5

THE EXPERT COMMITTEES AND MINISTERIAL COUNCIL

5.1 This chapter discusses the functions and powers of the Gene Technology Technical Advisory Committee, the Gene Technology Community Consultative Group and the Gene Technology Ethics Committee; and the role and membership of the proposed Ministerial Council. The chapter also discusses the procedures for review of decisions and, in particular, the rights of third-parties to seek review of decisions of the Regulator.

5.2 The Bill provides for the establishment of a Gene Technology Technical Advisory Committee, a Gene Technology Community Consultative Group and a Gene Technology Ethics Committee to provide expert advice to the Regulator and the Ministerial Council overseeing the national legislative scheme.

Figure 2: Proposed regulatory structure under the Gene Technology Bill



Source: Submission No.77, p.106 (IOGTR).

5.3 The following sections discuss the functions and powers of the three proposed advisory committees.

Gene Technology Technical Advisory Committee

5.4 The function of this committee is to provide scientific and technical advice, at the request of the Regulator, or of the Ministerial Council, on a range of matters including:

- gene technology, genetically modified organisms (GMOs) and genetically modified (GM) products;
- applications made under the Bill;

- the biosafety aspects of gene technology; and
- the need for policy principles, policy guidelines, codes of practice and technical and procedural guidelines in relation to GMOs and GM products and the content of such principles, guidelines and codes.[1]

5.5 The committee is to comprise up to 20 part-time members appointed by the Minister. The Minister appoints the chair of the committee, but must not appoint a member to chair the committee unless a majority of the States and Territories agree to the appointment.[2]

5.6 Prior to appointing any members the Minister must consult a range of stakeholders including the States; the Regulator; scientific, consumer, health, environmental and industry groups; and any Ministers considered appropriate. The areas of expertise to be reflected on the committee include molecular biology; ecology; plant, animal or human genetics; virology; entomology; agricultural systems; biosafety engineering; public health; and occupational health and safety; risk assessment; clinical medicine; biochemistry; pharmacology; plant or animal pathology; microbiology; and animal biology. The committee members are subject to conflict of interest and disclosure of interest requirements, which are outlined later in this chapter. The Minister must also appoint a layperson as a member of the committee. The Minister may also appoint one or more 'expert advisers' to the committee. These advisers may be appointed on an ad hoc or continuing basis and will be expected to supplement the expertise of the committee where this is necessary in relation to the consideration of particular applications.[3]

Role of the committee

5.7 Several submissions commented on the limited powers of the committee. Submissions noted that the committee is only able to act on the request of the Regulator or the Ministerial Council. It was argued that the committee should be required to provide advice on all aspects of dealings that may pose a significant risk to human health or the environment.[4] The Australian Conservation Foundation (ACF) argued that the Bill should be amended to ensure that this committee, and the other two advisory committees, are consulted by the Regulator in consideration of all licence applications.[5]

5.8 The Interim Office of the Gene Technology Regulator (IOGTR) noted, however, that the committee 'will consider individual applications and provide

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1 Explanatory Memorandum, Gene Technology Bill 2000, pp.78-9.

2 Explanatory Memorandum, p.78.

3 Explanatory Memorandum, pp.78-9.

4 Submission No.35, p.20 (GE-Free Tasmania); Submission No.25, p.10 (Mr A Macintosh); Submission No.70, p.2 (Professor A Gibbs); *Committee Hansard*, 25.8.00, p.430 (Professor A Gibbs).

5 Submission No.40, p.6 (ACF). See also Submission No.70, p.2 (Professor A Gibbs); Submission No.69, p.3 (Friends of the Earth (Perth, WA Group)).

scientific advice on the possible risks posed by the application to public health and safety and to the environment'.[6] The Regulator will take this advice into account, along with advice received from public submissions, other Commonwealth agencies and the Environment Minister, in preparing risk assessment and risk management plans.[7] The committee has, however, no power to initiate the provision of advice and/or information on a dealing, GMO or GM product. In addition, in most matters the Regulator is under no obligation to seek the advice of the committee on any matter.

5.9 The IOGTR stated that in most overseas regulatory regimes ultimate responsibility for the scientific assessment of risk, and the approval of any applications, lies with an independent decision-maker like the GTR, rather than a committee of experts. Many regulators do, however, seek advice from an expert committee. For example, in Germany, the Federal Ministry of Health seeks advice from the Advisory Committee for Biological Safety. In Canada, the Federal Minister for the Environment seeks advice from the National Advisory Council on the management of toxic substances.[8]

5.10 The Committee considers that the proposed functions of the Gene Technology Technical Advisory Committee as outlined in the Bill are adequate. The Committee believes that the scientific committee in providing scientific and technical advice, at the request of the Regulator, or the Ministerial Council, on a range of matters, including licence applications, will play an important role in the regulatory system.

Composition of the committee

5.11 Several submissions commented on the narrow proposed range of experts on the committee. Submissions argued that the membership of the committee will be dominated by gene technologists.[9] ACF GeneEthics Network argued that 'these people are not independent or impartial. Environmental and other relevant technical and scientific experts must be included. Without a broad range of expertise, this committee will be like GMAC, not a genuinely rounded expert body'.[10]

5.12 One submission argued that the membership of the committee should be reviewed to include experts in the fields of nutrition, agriculture, animal husbandry, veterinary science and environmental science.[11] Another submission argued for the

6 Submission No.77, p.113 (IOGTR).

7 Submission No.77, p.113 (IOGTR).

8 Submission No.77, p.113 (IOGTR).

9 Submission No.70, p.2 (Professor A Gibbs); Submission No.85, p.13 (ACF GeneEthics Network).

10 Submission No.85, p.13 (ACF GeneEthics Network).

11 Submission No.11, p.17 (Canberra Consumers Inc).

addition of economists, ethicists and trade experts to ensure that the impact of GMOs is considered in the 'broadest possible way'.[12]

5.13 It was argued that it was important that this committee not be the captive of 'vested interests' as it is the only committee to view, and advise on, applications for permits for GM work.[13]

5.14 One submission also questioned the effectiveness of having only one layperson in a committee of 20 experts and suggested that the person would be 'overwhelmed'.[14] The IOGTR stated the inclusion of a layperson on the committee was supported by many people during consultations and reflects the current GMAC practice.[15]

5.15 Several submissions also argued that there needs to be cross-membership of the committees with a representative of the community consultative group and the ethics committee on the scientific committee.[16] While the IOGTR stated 'there is actually a requirement in the legislation that there be cross-membership between all three committees'[17], the Committee notes that the proposed legislation only makes it a requirement that:

- the Minister must appoint a layperson as a member of the Gene Technology Technical Advisory Committee;
- the Minister must ensure that the Gene Technology Community Consultative Group includes the following members:
    - a person who is a member of Gene Technology Technical Advisory Committee; and
    - a person who is a member of the Gene Technology Ethics Committee; and
- the Minister must ensure that the Gene Technology Ethics Committee include a member of the Gene Technology Technical Advisory Committee.

Recommendation

The Committee RECOMMENDS that the Bill be amended to require that the Gene Technology Technical Advisory Committee include a member of the Gene Technology Community Consultative Group and a member of the Gene

12 Submission No.54, p.19 (OFA).

13 Submission No.85, p.13 (ACF GeneEthics Network). See also Submission No.70, p.2 (Professor A Gibbs).

14 Submission No.11, p.16 (Canberra Consumers Inc).

15 Submission No.77, p.113 (IOGTR).

16 Submission No.54, p.19 (OFA); Submission No.11, p.17 (Canberra Consumers Inc)..

17 *Committee Hansard,* 14.8.00, pp.45-6 (IOGTR).

Technology Ethics Committee, and preferably that that person should be the Chair of their respective committee.

5.16 The Committee believes that the Gene Technology Technical Advisory Committee should essentially be comprised of members who are able to provide scientific and technical advice to the Regulator and the Ministerial Council but should comprise members with a broad range of scientific and related expertise, including environmental and other relevant technical and scientific experts, and represent a diverse range of scientific views.

Recommendation

The Committee RECOMMENDS that the Bill be amended to require the Minister, in appointing members of the Gene Technology Technical Advisory Committee, appoint members representative of a range of scientific disciplines and a diverse and broad range of scientific views.

Disclosure of interests

5.17 Several groups and individuals argued that there was a need to ensure committee members are subject to strict disclosure of interest provisions. Submissions argued that all members of the committee should be under a statutory obligation to disclose all interests in the development and commercialisation of gene technology. Further, members should be obliged to perform their duties in an independent manner and must be required to excuse themselves from participating in matters where there is a potential for a conflict of interest.[18]

5.18 The draft Regulations, tabled on 25 August 2000, detail the conflict of interest and disclosure of interest requirements. The Committee regrets that the draft Regulations were available so late during the Committee's inquiry. This did not provide witnesses with the opportunity to comment on the adequacy or otherwise of the Regulations during the Committee's hearings into the Bill.

5.19 Under the draft Regulations, committee members, and any expert advisers, will be required to:

- make a declaration setting out all direct or indirect interests, financial or otherwise, that a person is aware that he or she has in any matter of a kind to be considered at a meeting of the committee, before being appointed; and
- a member who is aware that he or she has a direct or indirect interest, pecuniary or otherwise, in a matter being considered, or about to be considered, at a meeting of the committee must disclose the nature of the interest at, or before, the meeting of the committee. Disclosure must include interests of the member, of the member's spouse, of parents of the member and of the spouse, of the

18 Submission No.35, p.20 (GE-Free Tasmania); Submission No.17, p.4 (National Genetic Awareness Alliance); Submission No.25, p.10 (Mr A Macintosh).

children of the member and of any other children of the member's spouse, that provide, or could provide, a substantial source of income or a substantial asset; and could be perceived to represent a possible conflict of interest.

The disclosure must be recorded in the minutes of the meeting and the member must not be present during any deliberation of the committee about the matter; nor must he or she take part in any decision of the committee about that matter.[19]

5.20 The Committee believes that committee members should be subject to strict disclosure of interest provisions. The Committee believes that the proposed disclosure of interest provisions are adequate and appear to meet the concerns expressed in evidence regarding the need for stringent disclosure provisions.

Terms of appointment

5.21 Submissions also argued that there should be fixed and specified terms of tenure for committee members as the positions are potentially very influential given the commercial aspects of the work.[20]

5.22 The Regulations specify that members of the committee are to be appointed for a period of three years, or a lesser period specified in writing. The IOGTR stated that the period of three years was selected because it balances continuity of membership with the need to ensure that membership does not become static. It is anticipated that changes in membership will be staggered to ensure there is not a complete turnover of committee members, with resulting loss of accumulated knowledge, every three years.[21]

Gene Technology Community Consultative Group

5.23 The function of the Consultative Group is to provide advice, at the request of the Regulator or the Ministerial Council, on matters of general concern in relation to GMOs, and on the need for, and content of, policy principles, guidelines, codes of practice and technical and procedural guidelines in relation to GMOs and GM products.[22]

5.24 The IOGTR stated that it is expected that the committee will fulfil this role by ensuring that the Regulator and the Ministerial Council are kept in touch with community views. The Group may do this by:

- providing advice on how it thinks community consultations might most effectively be undertaken;

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19 Draft Regulations, Part 4, Division 1.

20 Submission No.70, p.2 (Professor A Gibbs); *Committee Hansard*, 25.8.00, p.430 (Professor A Gibbs); Submission No.35, p.20 (GE-Free Tasmania).

21 Explanatory Guide to the Draft Commonwealth Gene Technology Regulations 2000, August 2000, p.32.

22 Explanatory Memorandum, p.80.

- providing advice on draft codes of practice developed by the Regulator;
- suggesting that certain policy principles be developed; and
- raising issues of ethical concern that they wish to be examined by the Gene Technology Ethics Committee.[23]

5.25 The Minister is to appoint up to 12 members of the Consultative Group on a part-time basis. Prior to appointing the members the Minister must consult the Regulator; the States; such scientific, consumer, health, environmental and industry groups considered appropriate as well as other Ministers considered appropriate. Appointees to the committee must have skills or experience pertaining to gene technology in one or more of the following areas – environmental issues; consumer issues; the impact of gene technology on the community; issues relevant to the biotechnology industry; issues relevant to gene technology research; public health issues; issues relevant to primary production; and issues relevant to local government.

5.26 The Consultative Group must include a person who is a member of the Gene Technology Technical Advisory Committee (to provide scientific assistance to the Group); and a person who is a member of the Gene Technology Ethics Committee (to assist with advice on ethics issues).[24] The Minister appoints the chair of the committee but may not appoint a chair unless a majority of the States and Territories agree to the appointment.[25]

5.27 The IOGTR stated that it is not intended that the appointees to the Consultative Group be scientific experts in gene technology, rather it is expected that they will be able to speak to certain issues that are relevant to gene technology, such as environmental or consumer issues.[26]

Role of the Consultative Group

5.28 Several groups argued that the role of the Group is too limited and that it should be consulted in relation to all licence applications considered by the Regulator.[27] Submissions noted that the role is only confined to providing advice at the request of the Regulator or the Ministerial Council.[28] GE-Free Tasmania stated that the consultative group needed to have an expanded role so that it can 'take on a more pro-active role, and be able to initiate the advisory process where they feel it is appropriate'.[29] The Australian GeneEthics Network (AGN) concurred with an

23 Submission No.77, p.115 (IOGTR).

24 Explanatory Memorandum, p.80.

25 Explanatory Memorandum, p.81.

26 Submission No.77, p.117 (DHAC). See also Explanatory Memorandum, p.80.

27 Submission No.40, p.6 (ACF); Submission No.54, p.18 (OFA); Submission No.69, p.3 (Friends of the Earth (Perth, WA Group)).

28 Submission No.35, p.20 (GE-Free Tasmania); Submission No.9, pp.13-14 (HSCA).

29 Submission No.35, p.20 (GE-Free Tasmania).

expanded role, suggesting that the Group 'should actively hold roundtables and seek public support for the development of strong policy on broad categories of GE work'.[30]

5.29 As noted previously, only the Gene Technology Technical Advisory Committee will be directly involved in providing advice on GMO licences and other applications (clause 101). The Community Consultative Group (and the Ethics Committee) will be consulted only in relation to general principles or guidelines, not in relation to specific decisions.[31]

5.30 It was argued that the Consultative Group's brief should be broadened and its decisions should have the same weight and standing as GTAC decisions, so that it wins the confidence of the public. As the Organic Federation of Australia (OFA) stated: 'to limit this group to providing advice on policy only does not do justice to concerns in the community about the way regulation is made, and the desire for the community to move beyond the simplistic notion that decisions must be based on science and logic'.[32]

5.31 The IOGTR stated that individual applications for licences are not being referred to the Community Consultative Group:

> …on the basis that, as a result of other mechanisms incorporated into the proposed scheme, there is already extensive opportunity for community input on individual applications...Given this high level of community involvement in decision making (unrivalled in most existing regulatory schemes), the Commonwealth States and Territories did not consider that it was necessary to incur additional expense and resources by duplicating the consultation process and also tasking the GTCCG with examining individual applications.[33]

5.32 The Interim Office also noted that the establishment of a statutory community consultative group advising on matters of policy is itself fairly unique in both the Australian regulatory environment and internationally. The IOGTR stated that most of the existing Australian schemes for regulation of GM products do not have statutory established community committees. The Australian Quarantine and Inspection Service (AQIS), for example, does not have a community advisory committee to assist in its assessment of imports for quarantine risks, although it does involve the community through its consultation process. The Therapeutic Goods Administration (TGA) is,

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30 AGN, Additional Information dated 11 September 2000, p.4.

31 Department of the Parliamentary Library Bills Digest No 11 2000-01, Gene Technology Bill 2000, dated 16 August 2000, p.12.

32 Submission No.54, p.19 (OFA).

33 Submission No.77, p.116 (IOGTR). See also *Committee Hansard*, 14.8.00, p.45 (IOGTR); *Committee Hansard*, 25.8.00, p.454 (IOGTR).

however, proposing to establish, through administrative arrangements, a Consumer Health Forum.[34]

5.33 The Interim Office further stated that internationally most countries have not established a community consultative group under legislation and where community groups are utilised they provide advice on policy rather than on individual applications. In the case of the United Kingdom, the Agriculture and Environment Biotechnology Commission has been established to advise the Government on GM foods. While the Commission has strong community representation it will not comment on individual applications.[35]

5.34 Several submissions also argued that meetings of the Community Consultative Group and the technical committee should be held in public, exempting commercial in confidence items, and that they report all proceedings on the Internet. It was also argued that meetings should be convened around Australia to ensure a range of views are heard and evidence is received from a wide-range of interested citizens [36] OFA argued that this would 'ensure there is true transparency in monitoring the workings of these advisory committees'.[37] One submission argued that a local government representative should be a mandatory appointment to the committee.[38]

Terms of appointment/disclosure of interests

5.35 Several groups argued that there needs to be fixed and specified terms of tenure and strict provisions to ensure that members of the consultative group have no conflict of interest relating to their functions.[39]

5.36 The draft Regulations (Part 5) mirror the provisions that apply in relation to the conditions of appointment for the scientific committee. The Regulations provide that the members of the committee will be appointed for three year terms, and must abide by strict disclosure of interest provisions (as discussed in the previous section).

Conclusion

5.37 The Committee believes that Gene Technology Community Consultative Group should have a broader role than merely limited to matters of general concern in relation to GMOs, and on the need for policy principles, guidelines and codes of practice.

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34 Submission No.77, pp.116-17 (IOGTR).

35 Submission No.77, p.117 (IOGTR).

36 Submission No.54, p.20 (OFA); Submission No.9, p.14 (HSCA); AGN, Additional information dated 11 September 2000, p.4.

37 Submission No.54, p.20 (OFA).

38 Submission No.60, p.3 (District Council of Grant).

39 Submission No.70, p.2 (Professor A Gibbs); Submission No.40, p.6 (ACF); Submission No.35, p.20 (GE-Free Tasmania).

5.38 The Committee believes that there needs to be greater community input into the decision-making processes in relation to licence applications especially in light of the potential impact of gene technology on human health and on the environment and the need for effective community involvement in the regulatory processes. The Committee therefore considers that the Bill should provide that the Community Consultative Group provide advice on individual licence applications.

Recommendation

The Committee RECOMMENDS that the Bill be amended to require that the Gene Technology Community Consultative Group provide advice on individual licence applications made under the Bill.

Gene Technology Ethics Committee

5.39 The function of the committee is to provide advice, at the request of the Regulator or of the Ministerial Council, on ethical issues relating to gene technology; the development of codes of practice in relation to ethics in respect of conducting dealings with GMOs; and the development of policy principles in relation to dealings with GMOs that should not be conducted for ethical reasons.[40]

5.40 As in the case of the community consultative group, before appointing members to the committee, the Minister must consult the States, through the Ministerial Council, the Regulator, appropriate scientific, consumer, health, environmental and industry groups and appropriate Commonwealth Ministers. The Minister must ensure that the composition of the committee includes a member of the Technology Technical Advisory Committee, as well as a member of the Australian Health Ethics Committee with expertise in medical research.[41] The Minister appoints the chair of the committee, but may not appoint a chair without a majority of States and Territories agreeing to the appointment. The Minister may appoint one or more expert advisers to the committee. These advisers may be appointed on an ad hoc or continuing basis and will be expected to supplement the expertise of the committee where this is necessary in relation to the consideration of particular matters.[42]

5.41 There was general support for the establishment of the ethics committee. Heritage Seed Curators Australia (HSCA) stated 'we believe that the moral and ethical dimensions to gene technology are extremely important, However, this aspect goes largely ignored in the general debate on GE [genetic engineering]. We trust that the creation of this committee will bring this aspect of GE more to the fore in future'.[43] CSIRO also welcomed the proposed establishment of the committee but 'attaches urgency to its formation and productive output, particularly the provision of ethical

40 Explanatory Memorandum, p.82. See also DHAC, Additional Information dated 18 September 2000.

41 Submission No.77, pp.120-21 (IOGTR).

42 Explanatory Memorandum, p.82.

43 Submission No.9, pp.14-15 (HSCA). See also Submission No.40, p.6 (ACF); Submission No.50, p.5 (Consumer Food Network).

codes with a strong focus on the practical means by which their tenets are to be applied'.[44]

5.42 The IOGTR stated that the involvement of an independent ethics advisory committee in the regulation of gene technology places Australia ahead of similar regulatory schemes overseas. For example, no statutory ethics committee is involved in providing policy guidance in the United States, New Zealand, Japan or Canada. The IOGTR also noted that neither AQIS, TGA, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), the Australia New Zealand Food Authority (ANZFA), or the National Registration Authority (NRA) have established expert ethics committees.[45]

Role of the committee

5.43 Several groups argued that the role of the committee, as with the community consultative group, is too limited and that it should be consulted in relation to all licence applications considered by the Regulator.[46] Submissions noted that the role is only confined to providing advice at the request of the Regulator or the Ministerial Council.[47] HSCA also suggested that the committee's meetings should be public to enhance consumer confidence in the regulatory process.[48]

5.44 As noted previously, under the Bill as it stands, only the scientific committee will be directly involved in providing advice on GMO licences. The ethics committee and the community consultative group will be consulted only in relation to general principles or guidelines, not in relation to specific decisions. The ethics committee, along with the other two committees, may be consulted in relation to the need for, and content of, policy principles guiding the ethical decisions of the Regulator, and codes of practice applicable generally to dealings with GMOs.[49]

5.45 Evidence emphasised the need for an overlap in the membership of the committees. Dr Roush stated that 'if you really want ethics to infuse the whole debate, why not thoroughly integrate the so-called ethics committee, or the ethicists that are involved, in both the technical committee and the community committee. Why have a separate entity? If anything it reinforces the public view that ethics is over here and scientists are over here and the twain never meet.[50]

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44 Submission No.102, p.5 (CSIRO).

45 Submission No.77, p.120 (IOGTR). See also DHAC, Additional Information dated 18 September 2000.

46 Submission No.70, p.2 (Professor A Gibbs); Submission No.40, p.6 (ACF); Submission No.35, p.20 (GE-Free Tasmania).

47 Submission No.35, p.20 (GE-Free Tasmania); Submission No.40, p.6 (ACF).

48 Submission No.9, p.15 (HSCA).

49 Parliamentary Library, p.12.

50 *Committee Hansard*, 22.8.00, p.101 (Dr Roush).

Terms of appointment/disclosure of interests

5.46 Several groups argued that there needs to be fixed and specified terms of tenure and strict provisions to ensure that members of the committee have no conflict of interest relating to their functions.[51]

5.47 The draft Regulations (Part 6) mirror the provisions that apply in relation to the conditions of appointment for the scientific committee and the community consultative group. The Regulations provide that the members of the committee will be appointed for three year terms, and must abide by strict disclosure of interest provisions (as discussed in the previous sections).

Conclusion

5.48 The Committee believes that the Gene Technology Ethics Committee should have a broader role than that envisaged in the Bill and that the moral and ethical dimensions in relation to gene technology should be considered in relation to licence applications.

5.49 The Committee therefore considers that the Bill should provide that the Regulator may, if he or she deems it necessary, refer individual licence applications to the Gene Technology Ethics Committee for advice.

Recommendation

The Committee RECOMMENDS that the Bill be amended to provide that the Regulator may, if he or she deems it necessary, refer individual licence applications to the Gene Technology Ethics Committee for advice.

The Ministerial Council

5.50 The Bill provides that a Ministerial Council comprising Ministers from the Commonwealth and each State and Territory will be established, under an Intergovernmental Agreement on Gene Technology (IGA), to provide broad oversight of the regulatory framework and guidance on matters of policy that underpin the legislation. The Ministerial Council will be responsible for:

- undertaking general oversight of the implementation of the scheme and considering and agreeing any proposed changes to the national scheme;
- issuing 'policy principles,' 'policy guidelines' and 'codes of practice' to underpin the regulatory system (see below);
- seeking advice from each of the statutory committees;

51 Submission No.70, p.2 (Professor A Gibbs); Submission No.40, p.6 (ACF); Submission No.35, p.20 (GE-Free Tasmania).

- ensuring coordination with other Ministerial Councils on matters relating to gene technology; and
- advising on the appointment and termination of the Regulator and the Chairpersons of the three committees to be established (see above).[52]

5.51 'Policy principles' are disallowable instruments and therefore are subject to review by the Parliament. Policy principles deal with ethical issues relating to GMOs or other matters prescribed by regulations (clause 21), and are issued by the Ministerial Council after consultation with relevant Commonwealth, State, industry and community organisations, including the three advisory committees (clause 22). The Regulator must not issue a GMO licence that is inconsistent with a policy principle (clause 57).[53]

5.52 'Policy guidelines' are issued by the Ministerial Council, and may deal with matters relevant to the Regulator's functions. They will be guidance notes to the Regulator, and will not be prohibitive or akin to a direction, but will be advisory. The Regulator must have regard to policy guidelines in deciding whether or not to issue a GMO licence (clause 56), but is not bound to follow them. Unlike policy principles, policy guidelines are not required to be made in consultation with anyone, although the Ministerial Council may choose to consult. Policy guidelines are not disallowable instruments (clause 23), and therefore are not subject to Parliamentary scrutiny.[54]

5.53 'Codes of practice', with which GMO licence-holders may be required to comply, are developed by the Regulator and issued by the Ministerial Council after extensive consultation with each of the committees, relevant Commonwealth and State agencies and industry and consumer groups. They will be disallowable instruments (clause 24), and therefore subject to Parliamentary scrutiny. The Regulator may apply a requirement that a code of practice be complied with as a condition of licence.[55]

Policy guidelines

5.54 Submissions argued that the Bill should be amended to ensure that the three advisory committees are consulted by the Ministerial Council when issuing policy guidelines.[56] As discussed above, unlike policy principles and codes of practice, policy guidelines are not required to be made in consultation with anyone, although the Ministerial Council may choose to consult.

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52 Submission No.77, p.108 (IOGTR).

53 Submission No.77, p.109 (IOGTR).

54 Submission No.77, p.109 (IOGTR).

55 Parliamentary Library, pp.11-12; Submission No.77, p.110 (IOGTR).

56 Submission No.40, p.6 (ACF); Submission No.85, p.14 (ACF GeneEthics Network).

Recommendation

The Committee RECOMMENDS that the Gene Technology Technical Advisory Committee, the Gene Technology Community Consultative Group and the Gene Technology Ethics Committee be consulted by the Ministerial Council when issuing policy guidelines.

Veto on licence applications

5.55 Some groups proposed that the Ministerial Council should have the power of veto on licences approved by the Regulator or be able to strengthen or include new conditions on a licence granted.[57]

5.56 The IOGTR stated that Commonwealth and State Governments considered that Ministerial direction or a power of veto on individual decisions by the Regulator would undermine the independence of the Regulator and cast aspersions on the Regulator's integrity and freedom from political processes.[58] The Australian Food and Grocery Council (AFGC) also stated that it was important that the Council not be involved in the day-to-day operation and decision making of the Regulator.[59]

5.57 The IOGTR noted that this approach is consistent with other regulatory systems in Australia. For example, in the case of therapeutic goods, the Minister sets policy and standards while the delegate of the Secretary of the Department of Health and Aged Care (DHAC) decides on individual applications for drug approval. Under the system of food regulation, the Australia New Zealand Food Standards Council has the power of veto over food standards, but does not rule on the application of these standards to individual cases – which is the responsibility of ANZFA.[60]

5.58 The Committee does not consider that the Ministerial Council should have the power of veto on licences approved by the Regulator. The Committee believes that Ministerial direction, or a power of veto on individual decisions would undermine the independence of the Regulator.

Membership of the Council

5.59 It is proposed that the Ministerial Council be comprised of one Minister representing each participating jurisdiction. The IOGTR stated that the Minister representing each jurisdiction will be determined by the governments of each jurisdiction. The Commonwealth will be represented by the Minister for Health and Aged Care.[61]

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57 Submission No.17, p.4 (National Genetic Awareness Alliance); Submission No.54, p.6 (OFA).

58 Submission No.77, p.111 (IOGTR).

59 Submission No.71, p.14 (AFGC).

60 Submission No.77, p.111 (IOGTR).

61 Submission No.77, p.111 (IOGTR).

5.60 Consumer and other groups argued that the Ministerial Council should comprise either Health and/or Environment Ministers.[62] OFA, arguing for the inclusion of Health and Environment Ministers on the Council, stated that this was necessary 'to give public confidence in the protection of health and safety and the environment'.[63] The National Farmers' Federation (NFF) argued that the Council should include representation from the Agriculture Minister.[64] NSW Farmers' Association argued for representation from Agriculture and Foreign Affairs and Trade Ministers, noting that it was important that there is representation of affected parties such as the agricultural industry on the Ministerial Council.[65]

5.61 AFGC argued that the Council should include Ministers from a range of portfolios so that the expertise resident in the different areas relevant to gene technology can be brought into the deliberations of the Council. AFGC argued that gene technology impacts on a wide range of portfolios including Health, Environment, Agriculture/Primary Industry, Science and Technology and Trade and Commerce.[66]

5.62 The Committee sought clarification from the IOGTR as to whether Ministers on the Council will comprise the same members or whether a State may elect to send different Ministers to each subsequent meeting of the Council.

5.63 The IOGTR advised the Committee that:

> The expectation that will underpin the intergovernmental agreement is that a consistent minister attends. If it is the agriculture, health, environment or whatever minister, it is envisaged that they consistently attend. There will certainly be flexibility to change the minister, particularly when the legislation may move portfolios within individual jurisdictions.[67]

5.64 DHAC advised the Committee that the Intergovernmental Agreement (IGA) that established ANZFA does not specify that the Health Minister will be the representative on the Council –'the practice of state governments has been to send the health minister, but it is not enshrined as the health minister [in the IGA]'.[68]

5.65 The Committee considers that the Ministerial Council should comprise one Minister representing each participating jurisdiction. The Committee considers that given that gene technology impacts on a wide range of portfolios it is important that the Council should be comprised of Ministers, who, while representing a specific

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62 Submission No.54, p.6 (OFA); Submission No.6, p.4 (Consumers' Association of SA).

63 Submission No.54, p.6 (OFA).

64 Submission No.88, p.3 (NFF).

65 Submission No.76, p.6 (NSW Farmers' Association).

66 Submission No.71, p.15 (AFGC).

67 *Committee Hansard,* 14.8.00, p.44 (IOGTR).

68 *Committee Hansard,* 14.8.00, p.45 (DHAC).

portfolio, have an understanding of broader issues relevant to gene technology and be able to bring a multi-faceted approach to the Council's deliberations.

Rights of third-parties to seek review of decisions

5.66 Several groups argued that third parties should have the right to seek review of a decision by the Regulator.[69]

Review of decisions

5.67 The Bill provides the following procedures for the review of decisions.

- *Internal review*

Division 2 of Part 12 of the Bill provides that certain persons may seek internal review of decisions made under the legislation. Essentially, those people include:

– licence applicants and licence holders;

– applicants for certification and holders of certification (for example, universities or companies who have sought certification to a certain containment level of the facilities owned or operated by them);[70] and

– applicants for accreditation and holders of accreditation (for example, universities and institutions who have sought accreditation, recognising that they have established and maintained an Institutional Biosafety Committee within their institution).

5.68 If the relevant decision has been made by a delegate of the GTR (for example, one of the senior staff members of the GTR) the person seeking a review of the decision would have to apply to the GTR for an initial review of the decision. The GTR would look closely at the delegate's decision and would substitute his/her decision where appropriate.[71]

- *Review by the Administrative Appeals Tribunal*

5.69 If the GTR made the decision personally, or if a person has sought review by the GTR and seeks further review of the decision, those people with standing (detailed above in relation to internal review) may make an application for further review to the Administrative Appeals Tribunal (AAT).[72]

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69 Submission No.6, p.4 (Consumers Association of SA); Submission No.85, p.14 (ACF GeneEthics Network Submission); Submission No.35, p.21 (GE-Free Tasmania); *Committee Hansard,* 25.8.00, pp.360-61 (ACEL).

70 Certification of a facility to a certain containment level is required under the Bill of any organisation who wishes to undertake notifiable low risk dealings, or who holds a licence for dealings with GMOs where the licence includes a condition that the work with the GMO be conducted in a facility certified to a particular containment level. See Explanatory Memorandum, p.74.

71 Submission No.77, p.129 (IOGTR).

72 Submission No.77, p.129 (IOGTR).

- *Review by the Federal Court under the Administrative Decisions (Judical Review) Act 1977*

5.70 The Bill, however, does not include any explicit provisions about who may apply to the Federal Court under the *Administrative Decisions (Judicial Review) Act 1977* – AD(JR) Act. The IOGTR explained that this is because a person may automatically seek review of a decision by the Federal Court provided the person can meet the Court's criteria for determining whether the person is 'aggrieved' by a decision made under the gene technology legislation. Therefore, there is no need, or requirement, for the capacity for review under the AD (JR) Act to be referenced in the Bill.[73]

5.71 Any person wishing to have a decision reviewed by the Federal Court under the AD (JR) Act must establish 'standing' or a 'special interest' as required by the Federal Court. While this is judged on a case-by-case basis, the general position is that an applicant must be able to show an interest above and beyond that of ordinary members of the public.

5.72 For example, an organisation that has as part of its constitution or terms of reference, a reference to gene technology (such as the GeneEthics Network), would be likely to be able to establish standing to seek review under the AD (JR) Act. Similarly, an organic farmer whose property adjoined the property of a farmer growing GM crops would be likely to be able to establish a 'special interest' in the relevant decision of the GTR.[74]

5.73 The IOGTR stated that The *Environment Protection Biodiversity Conservation Act 1999* specifically provides that certain individuals are taken to be aggrieved by a decision for the purposes of seeking review by the Federal Court. For example, an individual who has, in the two years immediately before the decision is made, been engaged in a series of activities in Australia for protection, conservation or research into the environment. This position essentially reflects current 'standing' arrangements under the Federal Court. As such, it was not considered necessary to specifically replicate this in the Bill.[75]

Views on rights of third parties to seek review

5.74 As noted above, several organisations argued that third parties should have the right to seek review of a decision by the Regulator.[76] The Australian Centre for Environmental Law (ACEL) argued that the Bill:

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73 Submission No.77, pp.129-30 (IOGTR).

74 Submission No.77, p.130 (IOGTR).

75 Submission No.77, p.130 (IOGTR).

76 Submission No.6, p.4 (Consumers Association of SA); Submission No.85, p.14 (ACF GeneEthics Network); Submission No.35, p.21 (GE-Free Tasmania).

> …unfairly discriminates against third parties wishing to appeal the grant of licences and incorporates limited standing provisions reminiscent of the 19th century. It certainly does not represent regulatory "best practice" in the nascent 21st century. The right to appeal is limited and exercisable only by applicants for licences. For members of the public that comprise third parties, this limitation is clearly discriminatory, against principles of natural justice, and against the public interest.[77]

5.75 ACEL agued that the Centre's review of environmental standing provisions around the world 'establishes that the "best practice" trend is towards open standing. Indeed, even the Commonwealth's most recent piece of environmental legislation, the EPBC Act, creates limited open standing for any individual or organisation (whether incorporated or not) that has been involved in conservation or environmental issues over the previous two years'.[78]

5.76 GE-Free Tasmania acknowledged that the provision of third party appeal provisions has the potential to place strain on the resources of the Regulator and the AAT. Accordingly, the group argued that it is appropriate that a limit be placed on the persons who should have the right to appeal and that this be limited to third parties who have an ongoing involvement in the GE debate and who seek to represent a significant social interest or concern.[79]

5.77 Industry and primary producer organisations did not support the need to make provision for third parties to appeal the decisions of the Regulator.[80] Industry groups stated that the Bill has extensive provisions which require the Regulator to seek comment and have regard to that comment from the public on risk assessment, risk management and licensing decisions (Division 2 of the Bill).[81] Avcare Ltd commented that:

> Licensing decisions and other actions of the Regulator are open to interlocutory injunctions if a person or community group believes that an inappropriate decision has been made. It is important that the Bill does not facilitate vexatious appeals, with all the delays these involve.[82]

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77 Submission No.34, p.14 (ACEL).

78 Submission No.34, p.15 (ACEL).

79 Submission No.35, p.21 (GE-Free Tasmania). See also Submission No.17, p.5 (NGAA).

80 Submission No.32, p.12 (Avcare Ltd); Submission No.88, p.4 (NFF); *Committee Hansard*, 24.8.00, pp.347-8. (Florigene Ltd).

81 Submission No.32, p.12 (Avcare Ltd); Submission No.59, p.5 (MLA).

82 Submission No.32, p.12 (Avcare Ltd). An interlocutory injunction is an injunction ordered by a court before the court makes a final order in the proceedings. An applicant for an interlocutory injunction must establish that there is a serious question to be tried; that he or she will suffer irreparable injury for which damages will not be an adequate compensation unless an injunction is granted; and that the balance of convenience favours the grant of relief. Interlocutory injunctions are granted to ensure that the purpose of an action is not frustrated by the dissipation of property the subject of the dispute.

5.78 Meat and Livestock Australia (MLA) stated that the proposed processes for review of decisions (Part 12, Division 2) recognise the rights of both applicants and other stakeholders. Applicants and holders of certification and/or accreditation have the opportunity of review and appeal through the AAT – 'which is an appropriate impartial mechanism'.[83] MLA also noted that the Regulator has the discretionary capacity to, at any time, vary, suspend or cancel a licence, and to review decisions relating to exemptions from the need for a licence and notifiable low risk dealings – 'there are adequate opportunities for third parties to raise objections relating to decisions, with the Regulator having extensive discretionary power to act on those objections if there are sufficient grounds'.[84]

5.79 The IOGTR stated that taking into account the open assessment processes described under the Bill, States, Territories and the Commonwealth considered that it would be appropriate to limit the right of review to the AAT to people immediately affected by a decision (such as licence applicants and licence holders). The States and Territories reached this conclusion because:

- the decisions of the Regulator are the product of extensive consultation processes that would be time consuming and costly to repeat on review;
- the details of all decisions are made publicly available on a database of decisions;
- the Bill is drafted to carefully define the people who are able to seek review of decisions. Under a number of other legislative schemes, the class of people who are able to seek review of decisions is not quite so clearly defined. This gives rise to a great deal of uncertainty, not only for the regulator (who must make a decision on whether a complainant has a right of review) but also for the general public, who have to seek interpretation from the AAT as to whether they can seek review of a particular decision;
- the review mechanisms are consistent with similar legislation, including the *Australia New Zealand Food Authority Act 1991* (Cth). Section 63 of this Act restricts applications for AAT review of a decision to reject an application to the applicant. There is no right of review over the decision to accept an application, which would in turn lead to a change in the relevant Standard;
- limiting AAT review to people immediately affected by a decision reduces the capacity for vexatious review of decisions. Without this capacity, certainty of decision-making would be reduced as licence holders, as well as holders of certifications and accreditations, could not truly rely on the decision of the Regulator until all possible avenues of review had been exhausted; and

83 Submission No.59, p.4 (MLA).

84 Submission No.59, p.5 (MLA).

- limiting rights of review to the AAT is consistent with Commonwealth policy. The approach adopted by the States, Territories and the Commonwealth, as reflected in the Bill, has been considered in detail by the Attorney-General's Department, which advised that the approach adopted is appropriate given the extensive consultation processes described in the Bill.[85]

Conclusion

5.80 The Committee considers that third parties should have the right to seek review of a decision by the Regulator. The Committee believes that the Bill as it stands unfairly discriminates against third parties wishing to appeal the grant of licences and as such is discriminatory, against principles of natural justice, and against the public interest and will undermine public confidence in the system.

Recommendation

The Committee RECOMMENDS that the Bill be amended to provide for the right of third parties to apply for review of a decision of the Regulator.

85 Submission No.77, pp.131-32 (IOGTR). See also IOGTR, Additional Information dated 18 September 2000.

CHAPTER 6

OTHER ISSUES – LIABILITY, STATE OPT OUT AND MOUNT GAMBIER

6.1 Terms of Reference (i), (j) and (k) deal with other issues not specifically included in the Gene Technology Bill 2000, though the issues are especially relevant to the national regulatory system proposed in the Bill. These issues are discussed in this chapter.

Term of Reference (i): Liability and insurance issues relating to deliberate and accidental contamination of non-genetically modified crops by genetically-modified crops and how those issues are being addressed in international regulatory systems

Contamination

6.2 Contamination is the unintended and/or unwanted presence of a substance, organism or part of an organism in a particular environment, including within organisms. In the context of genetically modified organisms (GMOs), contamination is the unintended/unwanted presence of a GMO, or the genetic material of a GMO or product of a GMO in an organism, environment or product. Contamination is particularly an issue in relation to agricultural crops, for example a GM seed in a non-GM seed sample.

6.3 Contamination can occur in a variety of ways but most commonly through pollen dispersal or cross-pollination, seed dispersal, and inadequate segregation of GM and non-GM crops or products during their processing, transport or distribution. Contamination can thus occur prior to the actual growing of the genetically modified (GM) crop.

6.4 One of the major concerns expressed by opponents of GM products and the reason that excessive caution is required with their use is that neither of the main sources of contamination (pollen or seed) can be entirely eliminated. At best they can be identified and managed. As the Interim Office of the Gene Technology Regulator (IOGTR) conceded:

> Like all crops, once GM crops are released they cannot be completely contained. The same principle is true for spray or fertiliser drift from one farming system to another. There is always the possibility of hybridisation and seed mixing between GM crops and organic or conventional crops, and contamination with chemical residues…
>
> Just as there are measures in place for pure seed and organic produce to minimise pollution caused by spray drift, fertilisers and other pollutants,

mechanisms may be put in place to minimise contamination resulting from outcrossing of GMOs.[1]

6.5 The IOGTR noted that during the consultations on the development of the Bill, a range of views were expressed on how the legislation should address the issue of contamination. All considered that it was imperative that the legislation addresses the situation where GMOs have the potential to impact negatively on the natural environment, for example, through outcrossing with native relatives. In respect of the impact on agricultural systems and whether the proposed national system should regulate to minimise contamination, views varied from the advocates of no release of GM crops into the environment, to farmers having the right to choose, to those who believed that a cooperative approach was necessary to comprehensively address the issue of contamination.

6.6 In addressing the risk of contamination, the Bill provides that the Regulator will undertake a comprehensive risk assessment of all applications involving intentional release of a GMO into the environment and must be satisfied that any risks to public health and safety and the environment can be managed before issuing a licence. The Regulator may also impose conditions to limit the dissemination of the GMO or its genetic material in the environment where there may be a risk that the release of the GMO could impact on other farming systems.

6.7 In addition to the capacity to impose conditions limiting the dissemination of a GMO, the Regulator will have the power to enforce these conditions. There are also significant monetary penalties should a licence holder breach the conditions of a licence or if a person deals with a GMO in breach of a condition specified on the GMO Register. The Bill provides for two levels of offences, one that requires the establishment of knowledge or recklessness and one that does not – a strict liability offence. If the breach of a licence condition causes or is likely to cause harm to the environment, the Regulator can direct that remedial action or a clean-up take place either by or at the expense of the person who breached the licence condition, although this does not extend to compensation for third parties who may be affected by the contamination.[2] The role and powers of the Regulator were discussed in detail in Chapter 4.

Liability and insurance

6.8 In relation to liability and insurance, the IOGTR outlined a range of views received during the consultations on the development of the Bill.[3] These views were also reflected in the evidence received by the Committee.

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1 Submission No.77, p.139 (IOGTR).

2 The Bill Part 4 – Regulation of dealings with GMOs and Part 10 – Enforcement. See Explanatory Memorandum pp. 55-8, 90-1 and Explanatory Guide pp.33-6, 61-3.

3 Submission No.77, pp.140-1 (IOGTR).

6.9 While strong support was expressed for the inclusion of the strict liability offences into the Bill, which had not been in the consultation draft, there was concern that the general penalties associated with the strict liability offences and the reckless offences were 'totally inadequate'. It was suggested that they should be increased significantly to reflect the risks associated with GMOs and to ensure that people complied with the provisions of the Bill.[4] The adequacy of penalties was discussed in Chapter 4.

6.10 There was widespread acceptance that any damage to the environment arising from a breach of condition of licence must be 'cleaned-up' and that the Regulator must have the capacity to recover any costs of such a 'clean-up' from the producer of the GMO. However, of concern was that the Bill does not create civil liability provisions for environmental damage, with the potential for persons responsible for environmental damage avoiding liability for the costs of remedying the damage.[5]

6.11 On the issue of liability for contamination of non-GM crops (as opposed to environmental damage) where the resulting damage was economic in nature, it was argued that if a GMO causes any damage to non-GM crops then the producer of the GMO, as opposed to the farmer who used the GMO, should be liable to pay for the damage caused. This should apply even if such damage was only economic in nature, for example, because an organic farmer could not market his/her crop as GM-free.

6.12 A number of suggestions were made about ways to ensure that monies are available to pay such compensation, including the establishment of a compensation fund; requiring that a bond be paid by the producer of the GMO; and requiring the producer of the GMO to hold insurance. The alternative argument was also put that existing legislation (such as State environment protection legislation) and the common law provided adequate recourse for anyone suffering loss as the result of contamination. These issues are discussed below.

Compensation fund

6.13 It has been suggested that the producers of GMOs or the persons dealing with GMOs and GM products should be levied and a compensation fund established. The compensation fund would be accessible to farmers who have suffered as a result of contamination and should also pay for unforseen environmental or public health calamities.[6] However, there were concerns that the establishment of a specialised insurance fund could spread costs unfairly amongst all users of gene technology and diminish the incentive for persons dealing with GMOs to ensure that they are able to remedy any damage associated with their GE dealings.[7]

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4 *Committee Hansard*, 24.8.00, p.309 (ACF).

5 Submission No.25, pp.11, 18 (Mr Andrew Mcintosh).

6 Submission No.85, p.16 (ACF GeneEthics Network).

7 Submission No.25, p.19 (Mr Andrew Mcintosh).

Bond

6.14 An alternative form of compensation funding that has been suggested is for the Regulator to require that a bond be paid by the producer of the GMO at the time that the GMO is approved for release and that the bond should be used to pay compensation to any farmer affected by contamination. Schemes requiring upfront applicant contributions were not supported by industry which considered them as unreasonable in deterring innovation and commercial development.[8]

Insurance

6.15 Many witnesses argued that the Regulator should have the power to require that the producer of the GMO holds insurance before a licence is issued and that in the event of contamination a claim could be made by a third party against the producer's insurance policy.[9]

6.16 Doubts were raised about the availability of specific insurance cover offered by insurance companies. The ACF GeneEthics Network referred to a 1998 report by the Swiss Reinsurance Company which said that the risks to the insurance industry were very unclear at that time and potentially so large that the insurance industry could suffer a serious economic setback if the worst case scenario eventuated.[10]

6.17 The differing views held about insurance were reflected in the submission by the Insurance Council of Australia (ICA). The ICA indicated that it is aware that views amongst its members vary on this topic, and believes that far more research is needed by insurers/reinsurers to gain an appreciation of the risk profile of this relatively new (for Australia) technology.

6.18 In relation to insurability the ICA advised that general insurers in Australia providing product liability and environmental insurance are prepared to accept risks where there is a clear perception of the nature and size of exposures producing losses (which can be quantified drawing on past empirical experience). There is little if any meaningful loss experience available to insurers on genetically engineered risks or products in Australia. The ICA referred to a perception amongst insurers and the community that genetic engineering is dangerous, characterised by an extremely diversified risk profile of a new technology. General insurers are reluctant to accept incalculable risks where it is difficult to predict what loss scenarios will arise.

6.19 Generally most insurers respond to risks involving new technology with great caution even following careful underwriting with the cooperation of scientists and safety engineers. In such circumstances the level of insurance protection offered by insurers may not always meet the full risk exposure presented by genetically

8 Submission No.59, p.5 (Meat and Livestock Australia).

9 For example *Committee Hansard*, 22.8.00, p.61 (Heritage Seed Curators Australia)

10 *Committee Hansard*, 24.8.00, pp.318, 332 (ACF GeneEthics Network).

engineered products. The ICA informed the Committee that the key points of concern to the insurance industry are:

- There is a lack of reliable loss experience history and means for calculation of likely loss patterns. This absence of data inevitably promotes a fundamental doubt over the insurability of such risks.
- For the insurance industry, genetic engineering is potentially one of the most exposed technologies of the future and insurers' experience with pharmaceutical risks could be seen as analogous.
- The less acceptance the public shows towards new risks, the less trust is placed in the means to deal with them. As a consequence there is the likelihood that the possible negative consequences of each new technology will become a financial burden for the insurance industry.
- The risk profile of genetic engineering is extremely diversified and very difficult to quantify. There is no clear perception of the risks involved, making genetic engineering exposures hard to measure and thus insure.
- The insurance industry is happy to open dialogue with all interested parties on the subject of genetic engineering. Risk-related information must however be exchanged openly and honestly and differing values taken seriously.[11]

6.20 Avcare sought to allay concerns expressed during the hearings that farming and related activities involving the use of GMOs may have been inadequately insured. Avcare referred to the suggestion in the ICA submission that appropriately tailored products were not generally available on the market to deal with the risks associated with the escape of GMOs into the environment and informed the Committee that:

> Avcare understands from all of its member companies currently undertaking activities involving GMOs that each and every one of them has taken out appropriate and effective insurance cover in relation to the risks that have been identified in the course of the Senate Committee's hearings.[12]

Application of existing legislation and common law

6.21 The Bill does not contain a provision for a statutory right of action or a compensation fund to compensate those affected by a breach of the legislation, nor is there provision for liability or immunity of GM-free farmers who inadvertently use GM products. The point was made that, in cases involving non-GM contamination where the activities of one farmer affect a neighbour, recourse is to existing statute and common law and that GMOs should not be treated any differently. It was therefore argued by some that persons affected by GMO contamination should

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11 Submission No.1, pp.1-2 (Insurance Council of Australia).

12 Submission No.32 (Avcare), Additional Information dated 8 September 2000. Serve-Ag also noted that in the opinion of the Company and the Company's insurance broker it is adequately insured for any potential liability - Submission No.8 (Serve-Ag), Additional Information dated 21 September 2000.

continue to have recourse to the common law of trespass, public or private nuisance, and negligence. The House of Representatives Committee viewed this 'as an appropriate arrangement'.[13]

6.22 Others have argued that although persons affected by GMO contamination will continue to have recourse to common law actions, these are not optimal remedies and are inadequate for a Bill which has the object of protecting public health and safety. A particular difficulty raised was the capacity to prove, on the balance of probabilities, where the contamination had emanated from. The Australian Conservation Foundation (ACF) commented that reliance on the common law test requiring an applicant to prove harm to personal property is 'totally unacceptable in modern best practice legislation'.[14] The Parliamentary Library has argued:

> Given that the open release of GMOs, particularly GM crops and animals, into the environment is a relatively recent trend, it seems questionable that the issue of potential liability for damage is left solely to the vagaries of the common law. Legal liability for negligently inflicted economic loss is still in a state of uncertainty. In this climate of uncertainty, it is at least arguable that the potential cost of damage from instances of GMO contamination should be incorporated into the regulatory system, perhaps by establishing a statutory compensation scheme or by creating a statutory cause of action specifying in what circumstances and against whom a suit could be brought.[15]

Comparisons with international regulatory systems

6.23 The IOGTR examined the regulatory schemes adopted by the United States of America; New Zealand; Canada; the European Community; the United Kingdom; Germany; and Japan.[16] The comparison of these international regulatory systems is at Appendix 3. In summary, the IOGTR examination found that there are three main ways in which these countries' regulations differ in their coverage of intentional releases of GMOs into the environment, and in particular how liability in relation to such releases is established. The three main ways are outlined below.

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13 *Work in Progress: Proceed with Caution*, Report by the House of Representatives Standing Committee on Primary Industries and Regional Services, June 2000, p.159.

14 *Committee Hansard*, 24.8.00, p.308 (ACF).

15 Department of the Parliamentary Library Bills Digest No. 11 2000-01, Gene Technology Bill 2000, dated 16 August 2000, p.31. The Digest notes at Endnote 112 that statutory liability currently exists in areas such as criminal injuries compensation and civil aviation carriers' liability, both in relation to personal injury or death and property damage. The rationale behind such schemes is that it is desirable that persons who suffer loss or damage be compensated for their loss, however, it is also desirable that the level of liability be capped.

16 This section is drawn from Submission No.77, pp.146-151 (IOGTR). A brief summary of the approaches adopted by each of the countries examined by the IOGTR is included in these pages.

Laws of horizontal application vs laws of vertical application

6.24 The terms horizontal and vertical regulation refer to the way in which laws affect different sectors. Horizontal regulation means that general laws will apply to different industries in an equitable way. For example, GMOs released into the environment would be regulated in the same way as any other product proposed to be released into the environment. Vertical regulation entails the creation of specific laws to deal with individual industries.

6.25 While there is some debate regarding whether a horizontal or vertical approach to liability for GMOs, including recovery by third parties for contamination, is preferable, the majority of countries support a horizontal approach (that is the use of existing legislation). Arguments about the advantages of a horizontal approach include efficiency and that it ensures that different types of contamination are dealt with equally and in accordance with the consistent application of general principles, thereby ensuring that damage suffered as the result of different types of contamination can be compared and compensation awarded consistently.

6.26 The IOGTR noted that in the development of the national regulatory framework the Commonwealth-State Consultative Group on Gene Technology (CSCG) recognised that specific legislation was necessary to regulate gene technology and that the legislation should include penalties and enforcement actions in the case of a breach of the legislation. However, in relation to recovery by third parties for any damage or economic loss arising from contamination, it was recognised that there are remedies available under common law and under general environment protection legislation that may be used.

Whether statute law or common law deals with any issues of liability arising from the use of GMOs

6.27 Some international legal systems deal with liability for contamination through legislative enactment, eg Germany. Others allow the common law to deal with liability under general tort or criminal law, eg the USA, the UK, Canada and Japan.

Strict vs fault-based liability

6.28 Some international legal regimes are based around ‘strict liability’ principles, which involve the imposition on the producer of the GMO of liability for contamination by the GMO, regardless of fault. Under such a system, the plaintiff need not demonstrate any wrongdoing in order to affix liability to the defendant, eg Germany. Under a fault-based liability system, compensation is dependent on the ability of the plaintiff to show negligence or some wrongdoing on the part of the producer of the GMO, eg the United States, Canada, the UK, New Zealand and Japan.

6.29 The IOGTR noted that each of the regulatory systems examined varies not only in their approach to the regulation of gene technology but also in how they deal with issues of liability arising from the use of gene technology.

Concluding comments

6.30 The Committee acknowledges that recourse to action under common law through negligence, trespass or nuisance may often be appropriate, though dependent on the facts in particular cases. However, the Committee does accept that the vagaries of common law and burden of proof on a plaintiff may not provide sufficient remedy in all cases.

6.31 The Bill does provide power to the Regulator to order a clean-up and to recover costs if a licence is breached, although this also may not be sufficient remedy in all cases.

6.32 The Committee is not persuaded to recommend the establishment of a compensation fund based on levies, but has preferred to strengthen the link with insurance by amending the Bill to require that in prescribing or imposing conditions of licences, the Regulator may satisfy him or herself that applicants have made provision for suitable insurance coverage to cover the risks associated with the dealings. Recommendations on this area are in Chapter 4. The Committee does note the uncertainty expressed over insurance coverage in this area and believes that the adequacy of insurance policies held by applicants will need to be an issue to be closely monitored by the Regulator.

Term of Reference (j): The validity and practicability of any proposed clause allowing individual States the right to opt out of the scheme and the implications of such an option in the context of Australia's international trade and related obligations

Background

6.33 As noted in the introductory chapter, impetus for the development of the Gene Technology Bill was given in 1997 by the formation of a Commonwealth-State Consultative Group on Gene Technology (CSCG). The CSCG agreed to a set of policy principles to guide the development of the regulatory system. Policy principle 7(d) stated:

> If a participating jurisdiction considers that the release of a GMO or a GMO product will pose an unacceptable risk within its territory, then it may decline to allow release within its own territory or impose additional conditions on release within its own territory.

6.34 The IOGTR advised that in 1997, the thinking behind this policy principle was that a State, Territory or the Commonwealth, regardless of the decision of the central national regulator, might have a health, environment or trade/economic reason for either prohibiting the release of a GMO in a jurisdiction altogether, or for applying more stringent conditions on the GMO's release.[17]

17 Submission No.77, p.155 (IOGTR).

6.35 By August 1999, the CSCG had developed detailed proposals for the new regulatory system and considered that some of the guiding policy principles had become dated. CSCG had now agreed that the regulatory system must focus on protecting the environment and the community – and that trade considerations, or economic or other advantages must not override this fundamental object. However, original policy principle 7(d) envisaged jurisdictions 'opting-out' of applying the regulator's decisions on any ground (health, environment, trade or economic advantage).

6.36 The IOGTR indicated that the CSCG now considered that the new regulator should be established as the authoritative regulator of all risks to the environment and to human health. In making decisions, the regulator must have thoroughly and rigorously assessed all risks. Decisions could not be made until the regulator had sought detailed advice from all States and Territories. The regulator would also be accountable to the States and Territories for how advice received had been taken into account in reaching decisions. The CSCG considered that there would, therefore, be no basis for a State or Territory to veto or opt-out of applying the regulator's decision on environmental or human health grounds. A flawed decision by the regulator would indicate the need to review the regulatory system as a whole, to be addressed on a national basis rather than by fragmenting the national system through the establishment of State-specific regulatory systems.[18]

6.37 This evolving position on the issue of an opt-out on the grounds of protection of human health or safety or the environment was included in the discussion paper 'Proposed national regulatory system for genetically modified organisms – How should it work?' released in October 1999. However, the discussion paper added that a State or Territory could choose to refuse the release on other grounds 'such as local trade considerations'. Even so, the discussion paper noted that there may be difficulties associated with the inclusion of an explicit opt-out provision based on trade and economic considerations, including 'constitutional issues, international trade issues, regulatory uncertainty and the potential for GMOs to move between jurisdictions despite the desires of a particular State or Territory'.

6.38 National consultations using the discussion paper were held during late 1999. The IOGTR advised that four (described as 'sometimes contradictory') messages came through consistently during the consultations. These were:

- that the new regulator must be, and must be seen to be, credible, powerful, expert and accountable;
- that the national regulatory system must be a national system and should not be fragmented by different decisions applying in different jurisdictions;

18 Submission No.77, pp.153, 156-7 (IOGTR).

- that trade and economic considerations must not be included as matters to be considered by the regulator in taking a decision – environment and health concerns must be paramount and exclusive; and
- that there should be a capacity for jurisdictions to opt-out of applying the regulator's decisions.[19]

6.39 Throughout the consultation period, the CSCG continued to explore the options for including an explicit provision allowing individual jurisdictions to opt-out of applying the regulator's decision on trade or economic or other (non-environmental or human health) grounds. In relation to constitutional risks and Australia's international trade obligations, advice was sought from the Australian Government Solicitor, Attorney-General's International Law Division and the Department of Foreign Affairs and Trade. Based on their advice, all jurisdictions (except Tasmania) concluded that there was a 'significant risk that any broad-based opt-out provision in the Commonwealth Bill would, if challenged, be ruled invalid by the High Court' and that there was 'some risk to Australia's international obligations associated with the inclusion of an explicit opt-out provision'. The constitutional and trade arguments are discussed below.

6.40 As a consequence of this perceived combination of risks, the jurisdictions (except Tasmania) agreed that an explicit opt-out should not be included in the Commonwealth Bill.

The Gene Technology Bill 2000

Operation as a national scheme[20]

6.41 The Bill is intended to operate as a national scheme, requiring complementary legislation at Commonwealth, State and Territory levels after all jurisdictions sign the Gene Technology Intergovernmental Agreement. The advantage of a national cooperative scheme is its ability to regulate comprehensively all dealings with GMOs. Any dealings that the Commonwealth is unable to regulate would be covered by identical State legislation.

6.42 Proposed sections 12 and 16 of the Bill deal with 'corresponding State law' and the concurrent operation of State laws. The Explanatory Memorandum notes that the intention of these provisions is to ensure that existing and future State legislation, eg general environmental, fisheries and land management legislation, continues to operate concurrently with the Bill, provided it is capable of doing so. However, where State legislation is enacted that is inconsistent with the national scheme of regulation for GMOs, or effectively establishes a dual licensing regime, there is capacity for such laws to be prescribed as not operating concurrently with the Bill.[21] Tasmania indicated

19 Submission No.77, p.158 (IOGTR).

20 Much of the comment in this section is from the Department of the Parliamentary Library Bills Digest No. 11 2000-01, Gene Technology Bill 2000, dated 16 August 2000, pp.9, 26-27.

21 Explanatory Memorandum, p.51.

it would be 'of grave concern' if these provisions were used to overturn State measures taken with constitutional authority to protect their agricultural industries.[22]

6.43 Despite these powers to revoke a declaration in relation to a 'corresponding State law' and to make regulations excluding the operation of non-conforming State laws, the Commonwealth has no ability to ensure that the national scheme is uniformly amended. The continued operation of the national scheme relies on further inter-governmental agreements to approve amendments, and the passage of legislation incorporating those amendments in every jurisdiction. If one or more of the States and Territories choose not to enact complementary legislation, or not to amend the legislation in line with other jurisdictions, the scheme could quickly cease to be uniform and national in its scope.

6.44 The Gene Technology Intergovernmental Agreement on which the scheme is to be based has not yet been signed. The Tasmanian Government has indicated that in the absence of an opt-out clause it will not sign the Agreement.[23] The future of a consistent national scheme appears to rest on uncertain foundations if agreement cannot even be concluded prior to the commencement of the scheme.

6.45 In spite of the difficulties experienced to date in achieving inter-governmental agreement, the Bill does not purport to operate to the full extent of Commonwealth constitutional power. In particular, the Commonwealth has chosen not to rely on its plenary constitutional power to legislate for the territories (section 122 of the Constitution), but is instead relying on complementary legislation being passed by the ACT and Northern Territory. This reflects, so it is argued, the Commonwealth's preference for a cooperative nationally consistent regulatory scheme, rather than Commonwealth legislation relying on every possible head of constitutional power.

Opt-out options under the Bill

6.46 While a specific opt-out provision has not been incorporated into the Gene Technology Bill 2000, the proposed legislation does, nevertheless, provide particular mechanisms that allow the Regulator to take the unique situations of local areas into account. For example, the Bill provides every opportunity for GMOs to be prohibited in any area of Australia where the health or environmental risk warrants such a prohibition. Therefore, if there are unique risks to the environment in Tasmania posed by a particular GMO release application, or a risk to any other particular geographic area, the application could be approved on condition that it not be released in those vulnerable areas.

6.47 The Bill also provides the Ministerial Council with the power to issue policy principles as disallowable instruments on particular matters relating to GMOs, in relation to which the regulator must not act inconsistently. The Council may decide to

22 Submission No.89, p.2 (Tasmanian Government).

23 Submission No.89, p.9 (Tasmanian Government).

issue a principle requiring the regulator to, for example, observe certain GMO free zones established on the basis of the need to protect the sustainability and commercial viability of all agricultural farming systems (including organic and conventional systems). In this case, the regulator must observe such a policy principle in relation to any decisions made under the legislation. The precise nature and content of these principles will be a matter for the Ministerial Council to determine and cannot be pre-empted. The Ministerial Council may also issue policy guidelines and codes of practice.[24]

6.48 The Tasmanian Government referred to correspondence from the Parliamentary Secretary to the Minister for Health and Aged Care which suggested that Ministerial Council policy principles or guidelines could be 'an appropriate vehicle for achieving an opt-out'. The Tasmanian Government expressed concern that the constitution of the Ministerial Council 'would make it uncertain as to whether such a policy guideline would be issued, or would not be changed at a future date'.[25]

6.49 The Organic Federation of Australia (OFA) also expressed reservations about this process, commenting that:

> The way that the legislation is drafted…we are left with the only way we can get buffer zones, protection of organic farming systems or any other genetically engineered free farming system is through the ministerial council making policy principles…Our worry is that to get a principle up through that council we have to go through an enormous process of getting the majority of that council to agree to that.[26]

6.50 The IOGTR noted that all jurisdictions had consistently agreed that, despite the limitations in relation to Commonwealth legislation, if a State or Territory wished to prohibit GM crops on grounds other than health or environmental safety and believed they could do so in a manner that did not breach Australia's international obligations, States should be able to pursue this option under their own legislation. Legal advice prepared by the Departments of Foreign Affairs and Trade, and Attorney-General's, was provided to CSCG participants on the feasibility of such an option as an alternative to achieving an opt-out using the Commonwealth legislation.

6.51 This advice concluded that a range of WTO provisions relevant to Genetic Engineering Free Zones (GEFZ):

> do not, in principle, appear to prevent the creation of GEFZs. However, they do impose a number of disciplines that would apply to the measures used to

24 Submission No.77, p.161 (IOGTR).

25 Submission No.89, p.7 and *Committee Hansard,* 23.8.00, p.230 (Tasmanian Government).

26 *Committee Hansard,* 23.8.00, p.150 (Organic Federation of Australia).

> create any GEFZs. Accordingly, the GEFZ proposals would need to be implemented in a manner consistent with these provisions…[27]

6.52 After considering the advice, CSCG participants from all State and Territory jurisdictions except Tasmania 'determined not to pursue this option and to rely on the strength of the national regulatory scheme and of the Intergovernmental Agreement to appropriately reflect and address any concerns they may have'.[28] However, Premier Bracks from Victoria has advised the Committee that:

> The Victorian Government has an election commitment to investigate the establishment of Gene Modification Free Zones throughout the State. This ongoing work is investigating legislative and other mechanisms which might be available to communities and industry should the need for such a zone be established…I believe this approach is preferable to formal 'opt out' as it maintains the national coverage of the proposed regulatory scheme and allows communities and industry to actively participate in the development of their local areas and economies.[29]

Constitutional issues

6.53 As noted above, the constitutionality of introducing a broad-based opt-put provision was considered by all the jurisdictions and, with the exception of Tasmania, jurisdictions concluded that there was a 'significant risk' that such a provision would, if challenged, be ruled invalid by the High Court. Two sections of the Constitution were especially considered: section 92 – Trade within the Commonwealth to be free and section 99 – Commonwealth not to give preference to any State. However, there was some diversity of opinion at the highest legal levels.

Section 92 - Trade within the Commonwealth to be free

6.54 The first paragraph of section 92 provides:

> On the imposition of uniform duties of customs, trade, commerce, and intercourse among the States, whether by means of internal carriage or ocean navigation, shall be absolutely free.

6.55 The interpretation of this section in relation to the inclusion of an opt-out provision in Commonwealth legislation did not attract much disagreement. The IOGTR submitted that the Australian Government Solicitor (AGS) advised:

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27 Submission No.77, p.207 (IOGTR). The advice 'The establishment of genetic engineering free zones: WTO aspects' is provided in full at Attachment F to the submission.

28 Submission No.77, pp.161-2 (IOGTR). The Tasmanian Government advised the Committee that the advice 'only deals with the WTO implications of GM-free zones on market image grounds, not environment and health and safety as stated in the IOGTR submission. No determination was ever signalled by Tasmania that we would not be pursuing this option'. *Committee Hansard,* 23.8.00, p.221.

29 Submission No.115, p.2 (Victorian Government, Mr Steve Bracks, Premier).

> that a decision by a State or Territory to opt-out would not necessarily impose a discriminatory burden of a protectionist kind, as the decision would apply equally to trade within the State as to interstate trade. As such, a mechanism in the Commonwealth Bill allowing for such a decision should not infringe section 92 of the Constitution.[30]

6.56 The Tasmanian Government indicated that advice from the Tasmanian Solicitor General indicated that an opt-out as had been proposed in policy principle 7(d) 'probably would not offend against Section 92'. This advice argued that:

> In order for a law to discriminate against interstate trade it must be protectionist in the relevant sense, by placing a discriminatory burden on trade in order to protect trade within the State (Cole v Whitfield (1988) 165 CLR 360 is authority for this proposition).
>
> Accordingly, where a State has declined to allow release within its own territory of a GMO, that would apply to trade within the State and trade with other States, therefore the law would not be protectionist in the relevant sense.
>
> In any event, legal authority exists for the principle that laws for the protection from a real danger or threat, or some other legitimate object of a State, will not offend section 92, if the law is appropriate for the achievement of that objective.[31]

6.57 The Committee received comments in a number of submissions favouring similar interpretations as referred to above.[32] The Parliamentary Library made an interesting observation in the Bills Digest relating to the Bill suggesting that while it is difficult to see how an opt-out provision of itself could infringe section 92, a State law attempting to give effect to the provision might infringe this freedom of trade between the States, depending on the nature of the law.[33]

Section 99 - Commonwealth not to give preference to any State

6.58 Section 99 provides that:

> The Commonwealth shall not, by any law or regulation of trade, commerce, or revenue, give preference to one State or any part thereof over another State or any part thereof.

6.59 In relation to this section the AGS argued that:

> Until recently, the scope of the provision appeared restricted to laws which could only be enacted under paragraph 51(i) of the Constitution (law of

30 Submission No.77, pp.158-9 (IOGTR).

31 Submission No.89, pp.12-13 (Tasmanian Government).

32 Submission No.25, pp.23-4 (Mr Andrew Mcintosh).

33 Department of the Parliamentary Library Bills Digest No. 11 2000-01, Gene Technology Bill 2000, dated 16 August 2000, p.31.

> trade or commerce). However, there is now ambiguity surrounding the interpretation of this section following recent decisions of the High Court, and it is unclear whether the role of section 99 is to be regarded as still being confined to the sphere of interstate trade, or whether it has taken on a broader role.
>
> Given the tendency of the High Court in recent years to reject formalism in favour of a purposive approach in interpreting provisions of the Constitution, there is a significant risk that the scope of section 99 would be extended to laws affecting trade or commerce made under other heads of power. AGS considered that, were the High Court to go down this route, there was a significant possibility that Commonwealth legislation to regulate GMOs would be regarded as a law of trade and commerce for the purposes of section 99 and the opt-out provision in that legislation would infringe that constitutional limitation.[34]

6.60 The Parliamentary Library similarly noted there have been no cases on section 99 of the Constitution since the 1960s and commented that:

> Accordingly, it is unclear if the narrow interpretation would continue to be applied today, particularly in light of the substantive and purposive interpretation now given to section 92. There have been suggestions that section 99, like section 92, is one of a series of constitutional provisions giving effect to the creation and maintenance of a free trade area throughout the Commonwealth… It may then be seen as a source of an individual right not to be treated differently in matters of trade and commerce merely on the basis of a person's State of residence. If this interpretation were to be adopted, it raises some doubts as to the constitutional validity of a Commonwealth "opt out" clause.[35]

6.61 The Tasmanian Government viewed the situation differently, submitting that:

> In order to offend section 99 of the Constitution, two elements must be made out. Firstly a law or regulation must be one of trade, commerce or revenue. Legal opinion obtained by Tasmania suggests that, as the laws in the Gene Technology Bill 2000 are to regulate the safe release of GMOs within Australia, it is not a law that can be classed as 'trade or commerce' for the purposes of section 99.
>
> Even if the High Court were to uphold the notion that the Gene Technology Bill 2000 is a law for trade and commerce, Tasmania is advised that the opt-out clause could not be interpreted as a law designed to give some commercial advantage or material benefit of a commercial or trading character. The law would apply equally to all jurisdictions, as any State,

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34 Submission No.77, p.159 (IOGTR).

35 Department of the Parliamentary Library Bills Digest No. 11 2000-01, Gene Technology Bill 2000, dated 16 August 2000, p.44 Endnote 100.

> Territory, or even the Commonwealth could exercise the right to decline to release the GMO within their territory.
>
> The situation would be different if the opt-out were expressed to apply to only one or more States, rather than all jurisdictions. The opt-out as agreed by policy principle 7(d) does not give preference to one State (or part of a State) over another, and cannot therefore be said to be discriminatory by giving preference. The proposed opt-out provision would be uniform in its application.[36]

6.62 The Committee notes that conflicting legal argument exists over the interpretation of section 99. The jurisdictions other than Tasmania have proposed a constitutionally cautious approach by agreeing not to include an opt-out provision. Ultimately such a provision could only have its constitutionality upheld by determination of the High Court.

International trade obligations

6.63 In addition to the constitutional issues, concerns were raised in relation to Australia's international rights and obligations under the World Trade Organization (WTO) agreements. The IOGTR noted that as a member of the WTO, Australia has agreed to adhere to a number of obligations. Breaching these obligations could lead to the possible imposition of sanctions on Australia.

6.64 The WTO agreements seen as relevant to the establishment of a national regulatory regime under the Gene Technology Bill 2000 are the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), the Agreement on Technical Barriers to Trade (TBT Agreement) and the General Agreement on Tariffs and Trade 1994 (GATT 1994). These agreements recognise the right of WTO members to adopt measures to protect the health and safety of people, and to protect the environment, as provided for in the Gene Technology Bill 2000.

6.65 Advice to the CSCG from the Departments of Foreign Affairs and Trade, and Attorney-General's on the WTO obligations relevant to gene technology regulation and the Commonwealth's responsibility for State and Territory measures under international law argued that there was some risk to Australia's international obligations associated with the inclusion of an explicit opt-out provision. The IOGTR summarised the advice as follows:

> any measure taken to constrain the release of GMOs in Australia, on the basis that such GMOs might contaminate or damage organic counterparts in a particular State, will only be consistent with Australia's international trade obligations if such damage occurs to the life or health of organic counterparts and that damage is capable of being assessed on the basis of scientific principles. Measures taken purely to respond to consumer

36 Submission No.89, p.14 (Tasmanian Government).

> concerns about the product which do not have a scientific basis will be found to be in breach of Australia's international trade obligation.
>
> …The Commonwealth government may well have an obligation to formulate and implement positive measures and mechanisms to support the observance of the WTO Agreement by local governments making up the Member State…By introducing a clause into the Bill providing for States and Territories to opt-out of the regulatory scheme on other than scientific grounds, there is a risk of contradicting this responsibility.[37]

6.66 Tasmania was again in disagreement with these views, noting that as yet no jurisprudence exists on GMOs in the context of WTO agreements. The Tasmanian Government indicated that it had received advice in relation to the SPS, TBT and GATT Agreements. This advice included:

> …if it were held that the [SPS Agreement] did apply to GMOs, it may be possible for an opt-out where Australia could establish that a particular State or Territory had SPS characteristics different from the rest of Australia. In this case, a proper risk assessment would have to have been completed. Tasmania considers that regional variations in SPS characteristics should be taken into account in the regulation of GMOs.
>
> …should it be found that GMOs are governed by the GATT agreement, then it may be that a particular State or Territory, wishing to opt-out, could do so without offending the agreement on the basis that the refusal to allow the release of a particular GMO was necessary for the protection of human, animal or plant life.
>
> …Assuming that the opt-out is a "technical regulation" and thereby falls within the ambit of the [TBT] Agreement, it is likely that the legitimate objectives of "protection of human health or safety, animal or plant health, or the environment" mentioned in the Agreement are objectives to which the opt-out would apply.

The Tasmanian Government was further advised that, 'even if regional approaches are not possible under the SPS agreement, a GM-free policy or zone based on ensuring the purity and quality of product from the zones to respond to consumer demand or cultivate a certain marketing image, would not offend WTO agreements'.[38]

6.67 Tasmania argued that as the relevant WTO agreements do not apply so as to prohibit restrictions:

> a State wishing to be GM-free or have GM-free zones would then have the following options available under the national regulatory regime:

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37 Submission No.77, p.160 (IOGTR). The advices are provided in full at Attachments D and E to the submission.

38 Submission No.89, p.15 (Tasmanian Government) and Submission No.39 (Department of Primary Industries, Water and Environment).

1. To permit licensed dealings with certain GMOs throughout the entire State, for example if a GMO posed an unacceptable risk to the environment, plant or animal health, purity and quality of produce or market image, the State could decline to have the GMO licence operate within their territory; or
2. To permit licensed dealings with all GMOs in certain parts of the State, for example only in established GM zones; or
3. To permit licensed dealings with certain GMOs in certain parts of the State, for example only those GMOs that the State did not consider imposed an unacceptable risk to the environment, plant or animal health, purity and quality of produce or market image and only within established GM zones; or
4. To permit all licensed dealings with GMOs throughout the entire State; or
5. To refuse to permit any dealings with GMOs throughout the entire State.[39]

6.68 Tasmania concluded that the opt-out arrangements should not, therefore, be considered as an all or nothing approach and should be provided as a measure for giving effect to sovereign States rights to control agricultural industries, including on a commodity by commodity basis. Minister Llewellyn advised the Committee that:

> The points that have been made here have moved from being able to refuse to permit any dealings with GMOs throughout the entire state through to permitting licensed dealings with certain GMOs throughout the entire state, or a regional part within the state. That would be up to states themselves to make those decisions based on their own circumstances. That is the nature of the opt-out provision that I am talking about.[40]

6.69 As noted above, the Victorian Government is now also looking at the possibility of GM-free zones within their State.

6.70 The idea that international obligations under the WTO could be used to bind States to activities that may impact negatively on their economies or environment was criticised in evidence. The OFA commented that:

> There is an international consumer and grassroots reaction to the activities of the WTO in forcing borders open in this way. It is likely that in the future there will be a resurgence of protection of the rights for countries and territories to govern their own affairs.[41]

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39 Submission No.89, p.16 (Tasmanian Government).

40 *Committee Hansard*, 23.8.00, p.232 (Minister David Llewellyn).

41 Submission No.54, p.18 (OFA).

The Tasmanian situation

6.71 While Tasmania dissented from the CSCG decision that an opt-out would not be accommodated in the Commonwealth legislation, based largely on contradictory legal advice on the Constitutional and WTO issues, other arguments were also advanced to support Tasmania's case.

6.72 Tasmania considers, that as a sovereign state, it has a right to decide on the appropriate level of protection for its environment and primary industries, including the right to decide whether GMOs are released in the State and if so on what basis.[42]

6.73 Many submissions were received from Tasmania which, along with their Government, argued that the State has a unique environment and a unique identity. As an island, Tasmania has a range of flora and fauna indigenous and exclusive to the State. The natural barrier of its geographic location and isolation has assisted it to remain relatively pest and disease free, providing a comparative advantage for its primary industry products. The 'clean, green, quality' image this conveys is used extensively to market food and other products. Niche markets are targeted for domestic and international export, which, by using the 'clean, green, quality' image can attract a premium for Tasmanian products.

6.74 Evidence was given that Tasmanian primary producers who may be unable to compete effectively in mass product markets, have a comparative advantage in servicing these premium-priced niche markets. The Committee was advised of international markets where consumer rejection of GE products was rapidly increasing, with a consequent growing demand for organic and certified non-GE products. The ability to compete in these expanding markets relies heavily on marketing and marketing perceptions. It was therefore argued that the release of GMOs into Tasmania would threaten the capacity of Tasmanian food producers to utilise GE free status to compete in both Australian and overseas markets, thereby jeopardising the Tasmanian producers' 'clean, green' market image and undermining consumer confidence in the GE status of their produce.[43]

6.75 The Committee received evidence from and about companies operating in Tasmania which differed dramatically as to the impact the release of GM products and consequent loss of GM free status could have on the viability of their companies in relation to export potential.

6.76 Members from GE-Free Tasmania advised the Committee that they had seen 'major employers and significant companies in Tasmania like Lactos declare that they stand to lose $12 million a year in annual earnings if they forfeit their GE-free status'. In addition, they had seen 'declarations from the pome fruit industry, three of the

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42 *Committee Hansard,* 23.8.00, p.220 (Tasmanian Government).

43 Submission No.25, Appendix A: Reasons for an Opt-Out Clause and a GE-Free Tasmania, p.33 (Mr Andrew Mcintosh). See also Submission No.35, pp.25-6 (GE-Free Tasmania) and Submission No.107, pp.23-6 (Food Industry Council of Tasmania).

largest dairy producers, the salmon industry, the viticulture industry and the apiarists'.[44]

6.77 Serve-Ag, a company covering the whole spectrum of agricultural production, questioned whether Tasmania had to be totally GM free to enhance the 'clean, green' image and suggested that it did not. Serve-Ag argued that the products and markets where GM or GM free would be an advantage needed to be considered on a case-by-case basis.[45] In relation to the Tasmanian agricultural industry, trials have been mainly with canola involving herbicide and disease tolerant strains and poppies involving a strain to produce a greater alkaloid yield.

6.78 The poppy industry is unique in that Tasmania is the only State licensing commercial poppy cultivation for sale to the pharmaceutical industry. Sales are growing rapidly from $23 million in 1996 to an expected $100 million in 2000, of which 95 per cent is export, accounting for about 25 percent of the global market share. While cultivation of GE poppies on a commercial scale is not envisaged for at least five years, the industry would like to explore the technology through limited field trials to ensure overseas competitors do not gain an advantage over the Tasmanian industry. Tasmanian Alkaloids argued that if Tasmania were to opt-out of the Commonwealth regulatory system, an arrangement should be worked out to allow the limited poppy field trials to be conducted on a fully controlled basis.[46]

6.79 The Tasmanian Government has acknowledged that there may be circumstances in which Tasmania's niche markets demand certain products to be either GM or non-GM. In such a rapidly changing climate requiring further research and investigation with few easy answers, a parliamentary inquiry was established in Tasmania to examine issues relating to GMOs, including economic costs and benefits for Tasmania, market opportunities for both GM and non-GM primary products, environmental risks and food safety.

6.80 The establishment of the Tasmanian inquiry followed a declaration made on 26 July 2000 that any genetically modified plant or plant product would be a 'pest' under the Plant Quarantine Act. In conjunction with this declaration a 12-month moratorium was imposed on such products in Tasmania. The declaration and inquiry were made in accord with the current position of the Tasmanian Government 'that the issues surrounding adoption of GMOs is unclear and with such a degree of uncertainty that the Tasmanian Government is unwilling to have GMOs present in our agricultural systems until the issues are resolved'.[47]

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44 *Committee Hansard*, 23.8.00, pp.160-1 (GE-Free Tasmania).

45 *Committee Hansard*, 23.8.00, p.195 and Submission No.8, attached Position Paper – GM in Tasmania (Serve-Ag).

46 Submission No.10, pp.1-3 and *Committee Hansard*, 23.8.00, pp.208-9 (Tasmanian Alkaloids).

47 Submission No.89, p.1 (Tasmanian Government).

6.81 The Food Industry Council of Tasmania has adopted a similar line of argument in making a number of recommendations. The Council believes that there are a number of issues requiring clarification before determining whether Tasmania should refrain from or adopt GM technology. These issues revolve around the impact on Tasmania's export markets and their future acceptance of GM or GM-free produce, and the effects of GMOs in food production. The Council recommends a moratorium while further research is undertaken into these issues, noting that research for GMOs should be contained with no releases into the open environment.[48]

6.82 Minister Llewellyn clarified that the moratorium imposed by the Government is 'currently on the open research and trialing of GM crops in the Tasmanian environment. It is not a moratorium that will stop research in laboratories, in plant houses or in covered cages in the environment'.[49]

6.83 Some companies were critical of the decision in relation to the impact it would have on industry. Indeed, Aventis commented that 'one might almost characterise it as capricious'. Aventis, which has been conducting canola trials in Tasmania since 1998-99, claimed that it now had to reassess conducting 13 trials this spring for which GMAC approvals had already been received and that the growers involved have had their coming season thrown into uncertainty. Aventis provided the Committee with a copy of legal advice by Deacons indicating the legal prospect of having the Declaration ruled invalid was high.[50]

6.84 Concern was expressed at the possibility of a legal challenge by Aventis and the impression this would have on the community.

> They claim to be a corporate citizen and yet the community down here, as reflected and represented by the government, have said that they do not want these field trials at this stage. If they had any integrity they would respect that…They would gain acceptance of this technology by slowing down.[51]

Conclusion

6.85 The Committee has noted the variations in interpretation as to the constitutional and international trade implications of an opt-out clause being inserted into the Commonwealth legislation. Ultimately these variations may only be determined through legal rather than parliamentary decisions.

6.86 The Committee's considerations have led it to conclude that with so much uncertainty over the impact of rapidly developing gene technology, it is imperative that the integrity of a strong national regulatory system remains paramount. The

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48 Submission No.107 (Food Industry Council of Tasmania).

49 *Committee Hansard,* 23.8.00, p.225 (Tasmanian Government, Minister Llewellyn).

50 Submission No.61, p.5 and *Committee Hansard,* 22.8.00, p.123 (Aventis).

51 *Committee Hansard,* 23.8.00, p.151 (OFA).

Committee cannot support States or Territories being permitted to withdraw entirely from a national regulatory system and establishing their own systems, with the inherent problems of duplication and the development of inconsistent systems.

6.87 Nevertheless, the Committee has sympathy with the argument put by many Tasmanians, and others in evidence, and supports the strengthening of State rights and powers within the proposed national regulatory system. With the Regulator having to accept State or Territory viewpoints to prevent the release of GMOs within their jurisdictions and the capacity to establish GM-free zones, the national regulatory system established in the Bill should effectively provide an opt-out. The Committee considers that the relevant provisions of the Bill should be strengthened to ensure that this scenario is entrenched in the Bill so as to achieve an outcome acceptable for the States without undermining the integrity of the national system.

6.88 The Committee also considers that the strengthening of the Commonwealth legislation should also be replicated in the complementary State legislation through the inclusion of a clause reflecting the Commonwealth provisions.

Recommendation

The Committee RECOMMENDS that provisions in the Bill requiring the Regulator to accept State or Territory viewpoints to prevent the release of GMOs within their jurisdictions be strengthened.

Term of Reference (k): The alleged genetically-modified canola contamination in Mount Gambier and the processes followed by the Interim Office of Gene Technology in investigating and reporting on the allegations

Background

6.89 In 1996, the Genetic Manipulation Advisory Committee (GMAC) approved an application to conduct field trials of canola (*Brassica napus*) modified for resistance to the herbicide glufosinate ammonium (PR-62).[52] The gene expressed in the genetically modified canola came from the bacterium *Streptomyces viridochromogenes* and coded for an enzyme phosphinothricin acetyl transferase (*pat*). This enzyme chemically modifies the herbicide glufosinate ammonium and renders it inactive. A plant expressing this enzyme is tolerant to this herbicide.

6.90 In the same year, GMAC approved the field trial of a genetically modified canola with a new hybridization system to ensure cross pollination rather than self pollination to produce higher-yielding hybrid varieties (PR-63).[53]

6.91 To achieve the hybrid, the canola was modified in two ways:

52 PR-62 *Development of glufosinate ammonium tolerant canola cultivars*, GMAC advice notified 25 June 1996.

53 PR-63 *Field evaluation of a genetically modified canola (Brassica napus) with a new hybridization system*, GMAC advice notified 25 June 1996.

- a male sterile line was created by inserting into the canola a gene (barnase) from the bacterium *Bacillus amyloliquefaciens*. The gene codes for an enzyme that inhibits the development of anthers, the pollen producing male parts of the plant. This renders the plant male sterile.
- a second fertility restorer line is created by inserting another gene (barstar) from the same bacterium which produces an enzyme which inhibits the enzyme produced in the male sterile line.

By crossing the male sterile line and the fertility restorer line a fertile hybrid is produced.

6.92 The phosphinothricin acetyl transferase gene from the bacterium *Streptomyces hygroscopicus* was also present in the male sterile and fertility restorer lines to confer tolerance to glufosinate ammonium. Some lines also contained the neomycin phospho transferase gene, from the bacterium *Escherichia coli,* which confers resistance to the antibiotic kanamycin. Both of these genes were used as marker genes to allow identification and selection of transgenic plants.

6.93 In 1997, GMAC also approved a field trial involving a different species of canola (*Brassica rap*a) which contained the new genetic system for making hybrid varieties, and genes for tolerance to the herbicide glufosinate ammonium (PR-85).[54]

6.94 GMAC notified advice and recommendations for a number of extensions to these field trials between April 1997 and September 1998. The extensions for PR-62 and PR-63 evolved from the initial development of glufosinate ammonium tolerant canola cultivars (PR-62), to field evaluations with the new hybridization system (PR-63), to small and large scale seed production (PR-63X(2)) and finally to the release of glufosinate-ammonium tolerant hybrid and open-pollinated canola cultivars (PR-63X(4)). Extensions to PR-85 were aimed at increasing seed stocks of genetically modified canola (*Brassica rapa*).

6.95 Aventis submitted to GMAC proposals for further extensions to these trials on 8 December 1998 (PR-63X(4)) and on 2 March 1999 (PR-85X(2)), with summaries of the two proposals included on the GMAC website and advertised in the *Commonwealth of Australia: Government Notices Gazette* on 24 December 1998 and 25 March 1999 respectively. Public comment in relation to the two proposals was called for and interested persons, including relevant local, state and territory governments, were notified. Thirty days were allowed for comment on the proposals, with only one response received.

6.96 Following consideration of the proposals and on the basis of its risk assessment, GMAC provided advice to Aventis in relation to the trials PR-63X(4) and PR-85X(2) on 25 March 1999 and 17 June 1999 respectively.

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54 PR-85 *Small and large scale seed increase of a genetically modified canola (Brassica rapa) with a new hybridisation system*, GMAC advice notified September 1997.

6.97 GMAC provided the following advice in the form of recommendations to Aventis in relation to the proposals:

- each trial site was surrounded with a 15 metre buffer crop of non-transgenic canola to minimise the escape of pollen;
- the trial sites were separated from other *Brassica* crops by at least 400 metres;
- a 400 metre zone around each site was monitored for the presence of canola (Brassica napus);
- a 50 metre zone around each site was monitored for species that were sexually compatible with the trial species;
- the person responsible for each site should also be responsible for monitoring and clean-up of the site [PR-63X(4) only];
- data was collected on gene transfer [PR-63X(4) only];
- all trial sites would be monitored for 3 years post trial to detect and remove volunteer canola plants;
- harvested seed not required for other field trials was destroyed;
- there was compliance with GMAC guidelines concerning seed transport;
- GMAC was notified of trial site locations prior to planting;
- GMAC was provided with a copy of a press release; and
- GMAC was notified of the procedure for appropriate disposal of field trial trash before these products were utilised.

6.98 PR-63X(4) and PR-85X(2) involved up to 83 trial sites in canola-growing regions of Western Australia, South Australia, Victoria, Tasmania and New South Wales, including Mt Gambier, SA and Wagga Wagga, NSW.

6.99 On 14 March 2000 the IOGTR received information in a letter from a private individual, Ms Leila Huebner, concerning the lack of local canola buffer zones surrounding a GM canola crop at Moorak near Mount Gambier. The IOGTR responded by advising Ms Huebner that the Office intended to investigate the matter but that it required further information, and by writing to the Minister noting that an apparent breach of GMAC conditions had been reported that would be investigated and a report prepared.

6.100 Ms Huebner did not receive the IOGTR letter faxed on 16 March, and, concerned that no response had been made to her earlier letter contacted the IOGTR by phone on 31 March. Ms Huebner finally received a copy of the IOGTR response and provided the requested information on 3 April.

6.101 During this period, on 24 March, a reporter from *The Age* sought background information from the IOGTR relating to a story that was subsequently published on

25 March. The article made allegations relating to GM canola crops at Moorak and the disposal of GM canola plants. The IOGTR identified that the field trials being referred to were PR-63X(4) and PR-85X(2) – the same trials described in the earlier allegations by Ms Huebner.

6.102 When the information provided by Ms Huebner and *The Age* reporter were considered against the GMAC recommendations for these trials, IOGTR considered that some of the recommendations (as highlighted above) may have been breached.

Existing system of administrative controls over genetically modified organisms

6.103 Before outlining the investigation of these possible breaches, it is important to understand the administrative system in place at the time of the possible breaches.

6.104 As has been noted earlier in this report, Australia does not have a system of legislative controls to regulate dealings with genetically modified organisms. It relies on a system of voluntary compliance whereby organisations dealing with GMOs choose to submit information about a GMO to GMAC. GMAC assesses the biosafety risks associated with the GMO and provides recommendations to the organisation about any biosafety risks and how they can be managed. The organisation voluntarily implements and complies with those recommendations.

6.105 Until May 1999, this voluntary system was overseen by GMAC with the support of a small secretariat. Non-compliance with GMAC recommendations were identified primarily through self-reporting by entities dealing with GMOs as required under the GMAC guidelines and notification of possible breaches by third parties. All breaches notified to GMAC were reported in the GMAC Annual Reports between 1985-1999.

6.106 Clearly, such a self-reporting system is inappropriate and unsatisfactory. Even so, up until May 1999 13 breaches of GMAC guidelines and seven incidents involving GMOs had been notified to GMAC.[55] Given that this has been a self-reporting system, one can only speculate as to the extent of other breaches that may have gone unreported.

6.107 The IOGTR was established in May 1999. While the Office's primary function is to develop and implement the new national regulatory system for gene technology, it has also implemented improvements to GMAC's monitoring and investigation systems. These improvements included the development of a new monitoring strategy involving spot checks of field trials by IOGTR officials accompanied by independent experts, the preparation of a protocol for reporting

55 A summary of these breaches/incidents as described in GMAC Annual Reports between 1985-1999 is in Submission No.77, Table K1, p.166 (IOGTR). The ACF GeneEthics Network noted that the Mount Gambier incident was 'only the latest in a long line of releases outside GMAC guidelines and advices over the past decade', Submission No.85, p.17.

breaches, and the implementation of new arrangements for investigating possible breaches of GMAC recommendations and for reporting on these.

6.108 Nevertheless, the IOGTR has conceded that there are continued shortcomings with the current system:

> While considerable administrative improvements have been implemented to underpin the current system of voluntary controls, the IOGTR has no legislative underpinning to conduct investigations into an entity's voluntary compliance with recommendations made by GMAC to manage risks associated with GMOs.
>
> Pending establishment of the new regulatory system, the IOGTR has, therefore, limited capacity to access documents or premises or to investigate matters unless the entity concerned chooses to cooperate. Similarly, the IOGTR has no legislative capacity to enforce compliance with GMAC recommendations or to enforce compliance with risk management plans.[56]

It is within this system with all its shortcomings that the investigation into the alleged breaches at Mount Gambier was undertaken.

The investigation

6.109 The IOGTR provided an overview of the steps taken to investigate Aventis' compliance with GMAC conditions in relation to PR-63X(4) and PR-85X(2). In addition to the particular Moorak site, the IOGTR widened the investigation to include all sites associated with these field trials to establish whether any breaches reflected a problem with overall trial management or whether the problems were confined to the particular site.

6.110 An overview chronology of events during the investigation follows[57]:

13 March 2000: Ms Leila Huebner, a private individual, confirms concerns relating to GE canola trials in the Mount Gambier district with Mr Scott Kinnear from the Organic Federation of Australia, who advises Ms Huebner to raise her concerns with the IOGTR.

14 March 2000: Ms Huebner faxes letter expressing concerns to the IOGTR.

16 March 2000: IOGTR wrote to Ms Huebner requesting further details of the alleged breach. This letter was apparently faxed, though Ms Huebner did not receive it.

IOGTR forwarded advice to the Minister concerning the matters raised in Ms Huebner's letter, the IOGTR's request for additional information from

56 Submission No.77, p.169 (IOGTR).

57 This overview is based on a chronology from Submission No.77, pp.171-5 (IOGTR) with further information added from other submissions and evidence. The Committee notes that there was some dispute in evidence as to the detailed timing of when certain events occurred (see especially Submission No.55, supplementary submission, dated 12 September 2000).

Ms Huebner and the need for the apparent breach of GMAC recommendations to be investigated.

17 March 2000: Prof Rick Roush, a member of GMAC and Head, CRC for Weed Management, provided with copy of Ms Huebner's letter. Shortly after, Prof Roush arranges to meet Ms Huebner on 3 April after meetings in Mount Gambier.

24 March 2000: Mr Geoff Strong, a reporter from *The Age*, contacted the IOGTR by telephone and identified possible breaches of GMAC recommendations, and the location of the offending trial site.

IOGTR provided notification to relevant Departmental officials and the Minister's Office of the further information provided by the reporter in relation to the matters raised by Ms Huebner.

25 March 2000: *The Age* prints article by Mr Strong 'GM crop dumped at tip'.

27 March 2000: IOGTR wrote to Aventis asking for documentation of compliance with GMAC's recommendations and for details of the information Aventis had provided to contracted growers.

IOGTR notified relevant Commonwealth agencies including the Department of Prime Minister and Cabinet, the Department of Agriculture, Fisheries and Forestry and the Department of Industry, Science and Resources of a possible breach and subsequent investigation.

IOGTR determined that the scope of the investigation should be broader than the Yells Road, Moorak site identified thus far. Taking into account the fact that as many as 83 sites were involved in the two trials, it seemed appropriate to determine whether the matters raised in respect of Yells Road, Moorak were isolated incidents, or systemic problems.

IOGTR began identifying an expert to undertake site inspections and put arrangements in train for this inspection.

28 March 2000: IOGTR forwarded advice to the Minister on matters raised in relation to possible breaches in *The Age* article and through discussions with Mr Strong from *The Age*.

IOGTR wrote to the Department of Premier and Cabinet in South Australia.

First response received from Aventis, including a range of documents.

29 March 2000: IOGTR wrote a second letter to Aventis requesting that information provided in Aventis' letter of 28 March 2000 be provided in the form of a statutory declaration. In the absence of a legislative framework for the conduct of the investigation, IOGTR considered that evidence provided in this form would introduce as much rigour as was possible under a voluntary system.

Aventis responded to IOGTR's second letter, providing the requested Statutory Declaration.

Aventis attended a meeting with IOGTR to discuss the alleged breaches.

30 March 2000: IOGTR sought legal advice from the Australian Government Solicitor about relevant matters.

31 March 2000: An expert from the CRC for Weed Management and an IOGTR official carried out unaccompanied (ie. not in the company of Aventis) site inspections in South Australia, visiting several properties growing transgenic canola as part of the field trials under investigation.

Ms Huebner follows-up by phone lack of response by IOGTR to her 14 March letter. A copy of the IOGTR response is finally received.

3 April 2000: Prof Roush investigated sites in the Mt Gambier region in the company of Aventis and attended a public meeting in Mt Gambier.

After meetings, Prof Roush meets Ms Huebner to discuss her observations and concerns and is given copies of her videotapes and photos. IOGTR is provided with further details of alleged breach in response to request to Ms Huebner.

4 April 2000: IOGTR sent a third letter to Aventis, seeking further details and documentation on matters referred to in Aventis' letter of 28 March.

Report of site inspection conducted on 31 March 2000 received by IOGTR. Necessary follow-up actions were identified.

5 April 2000: The alleged breaches was one of the matters raised when the IOGTR appeared before the House of Representatives Standing Committee on Primary Industries and Regional Services. An offer was made by the IOGTR to provide the Committee with a progress report in a fortnight of the hearing. IOGTR stressed that it could not put a timeframe on the completion of the investigation.

6 April 2000: Response received from Aventis to IOGTR's third letter.

11 April 2000: Literature search completed and documents forwarded to relevant GMAC members for review.

13 April 2000: Advice from GMAC re sexually compatible weeds completed.

17 April 2000: File search of relevant GMAC files and document review completed.

19 April 2000: Draft determination completed and forwarded to Aventis in accordance with advice from Australian Government Solicitor. Aventis invited to correct any factual inaccuracies (with supporting documentation) and provide any additional information. Aventis' response was requested by 4 May.

Progress report provided to the House of Representatives Standing Committee on Primary Industries and Regional Services in accordance with the undertaking given on 5 April.

Copies of these documents were provided in electronic form to relevant departmental officials and to the Minister's office.

27 April 2000: Formal advice provided to the Minister asking that the progress report and the draft determination be noted, and informing him that Aventis had been invited to comment on the draft determination by 4 May 2000.

2 May 2000: Aventis advised, by fax, that due to the volume of work involved, and the long Easter break, Aventis would not be in a position to meet the

	IOGTR's deadline of a 4 May response to the draft determination. Aventis advised that it would provide a response on 18 May 2000.
8 May 2000:	Breach and draft determination discussed at GMAC Release Subcommittee meeting.
18 May 2000:	Report received from Professor Roush in respect of the site inspections conducted on 3 April 2000. Oral reports had been previously given to GMAC and IOGTR on 3 and 4 April and 8 May.
19 May 2000:	Aventis' response to the draft determination provided to IOGTR and discussed at a meeting between Aventis representatives and the Office. Aventis subsequently indicated that they wished to provide additional information.
24 May 2000:	The further advice foreshadowed at the meeting of 19 May 2000 was received from Aventis.
30 May 2000:	Further information requested from Aventis concerning fate of seed from field trials and method for dealing with monitoring zones which encroach on neighbouring properties.
2 June 2000:	Aventis advised a delay in replying to the above request.
8 June 2000:	Reply from Aventis to question on fate of seeds received. Aventis were requested to supply information in answer to the second issue (encroachment of monitoring zones).
15 June 2000:	Response received from Aventis on issue of monitoring zone encroachment on neighbouring properties.
	IOGTR staff spoke with a reporter in Mt Gambier from *The Border Watch,* and to a waste contractor in the Mt Gambier area.
16 June:2000:	*The Age* prints article by Geoff Strong 'Seeds of discontent' relating to the investigation's progress.
20 June 2000:	Final determination and summary document for IOGTR Quarterly Report sent to the Chair of GMAC for clearance.
21 June 2000:	Final determination sent to Aventis.
22 June 2000:	Comment on final determination received from Aventis.
29 June 2000:	Report provided to the Minister.
12 July 2000:	Minister approved report.

6.111 The detail of the investigation undertaken is important for the lengthy timeframe involved – from 14 March to 12 July. In particular, this emphasises the lack of power to enforce compliance and delays in the investigative process. These deficiencies were recognised by the IOGTR which commented that in relation to the content and the timing of the completion of the report, it should be noted that:

- while the IOGTR can propose timeframes for matters dealt with in this report, it cannot force third parties to comply with those timeframes;
- the investigation dealt with a large amount of data and required further scientific interpretation from the scientific committee; and

- while recognising there is considerable media interest in this matter, the breaches did not constitute a risk to human health and safety or any significant risk to the environment.[58]

6.112 Even Aventis considered that:

> the IOGTR has faced significant difficulties of process in "investigating" so-called "breaches" of what are in fact "recommendations". There were no statutory provisions to govern their procedures and they faced the common law duty to observe due process (sometimes called natural justice). There was no power to compel witnesses to do anything they wished not to do.[59]

Conclusions and outcomes from the IOGTR's investigation

6.113 The IOGTR investigation identified that Aventis had failed to demonstrate compliance with 5 GMAC recommendations, as follows:

> Breach 1: Aventis failed to demonstrate that a 15metre buffer of non-transgenic canola had been established around summer plantings of field trials under PR-63x(4) and PR-85x(2);
>
> Breach 2: Aventis failed to demonstrate adequate monitoring for the presence of the weed *H. Incana* as a species which is sexually compatible with canola;
>
> Breach 3: Aventis failed to implement appropriate measures, in at least one instance, to give effect to the monitoring for volunteers;
>
> Breach 4: Aventis failed to demonstrate compliance with GMAC's Guidelines for the Deliberate Release of Genetically Manipulated Organisms (April 1998) for transport of transgenic seed to and from trial sites; and
>
> Breach 5: Aventis failed to notify GMAC as required, and did not institute practices that would demonstrate compliance with the requirement to bury trial trash under 1 metre of soil.[60]

6.114 Aventis disagreed with the findings in relation to Breach 1 and Breach 2. Aventis maintained that the 'so-called breaches' were of a technical, administrative or very minor kind. In several cases the 'so-called breach' arose from a lack of certainty as to what GMAC 'recommendations' mean, and how in practice they should be interpreted. Aventis contends that 'there was not enough clarity and certainty in some of the GMAC "recommendations" (and they are that, not rules or orders), for anyone

58 Submission No.77, p.175 (IOGTR).

59 Submission No.61, p.9 (Aventis).

60 Submission No.77, p.176 (IOGTR). The findings in relation to each breach are described in detail on pp.177-8 of the submission.

to characterise the divergences between GMAC's expectations and Aventis' performance as "breaches"'.[61]

6.115 The IOGTR assessed the risks to human health and safety, and the environment, arising from the breaches of the GMAC recommendations as found in their investigation. In summary, the IOGTR reported:

> Risks to human health and safety: GMAC advises that none of the breaches referenced above represent an increased risk to human health and safety because there was negligible risk of transfer of the gene to commercial canola crops (which were not grown in the area during the trial period). Even if such transfer did occur, oil derived from this variety of transgenic canola is approved by ANZFA for human consumption.
>
> Risks to the environment: GMAC advises that the breaches may have resulted in an increased risk to the environment because non-compliance with GMAC recommendations has increased the potential for out-crossing of GM canola, including through uncontrolled seed dispersal.[62]

6.116 After identifying the breaches of GMAC recommendations and assessing the risks arising from them, the IOGTR developed a risk management plan to address environmental problems and technical problems arising from the breaches. The risk management plan forms the basis for a strategy to control further problems that may arise from the current trials and minimise risks in future trials. The main components of the plan are:

- monitoring of sites where a 15 metre buffer zone was not observed;
- monitoring for the presence of sexually compatible species;
- 400 metre zone around trial sites;
- monitoring for volunteers;
- monitoring of transport routes and burial sites; and
- written evidence from farmers and companies that they understood and are adhering to GMAC recommendations.[63]

6.117 The implementation of this plan addresses specific problems associated with the particular breaches of this case. It is imperative that such an approach is adopted for the wider picture.

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61 Submission No.61, pp.9-10 (Aventis).

62 Submission No.77, p.177 (IOGTR).

63 Submission No.77, pp.178-181 (IOGTR).

Monsanto and the release of GM cottonseeds

6.118 While not specifically relating to the Mount Gambier term of reference, the Committee received evidence of a breach by Monsanto that raised issues similar to those addressed in the preceding section. The breach in question related to GM cottonseed from a Roundup ready cotton trial not being segregated, and so becoming mixed with non-GM cottonseed. The GM cottonseed thereby entered normal commerce after being crushed as oil for export or for stock food.[64]

6.119 Under the self-reporting procedure, Monsanto notified GMAC after their monitoring processes discovered the breach and an audit process was instituted. The IOGTR advised that while Monsanto had not fully complied with a GMAC recommendation about how the GM crop should be dealt with, due to the thorough risk assessment of Roundup ready cotton conducted in response to the application, there was no increased risk to human health or safety or to the environment resulting from the breach.[65]

6.120 This incident exemplified, as did Aventis at Mount Gambier, a breakdown in compliance with GMAC recommendations, which continued the line of breached GMAC recommendations referred to earlier in the chapter. The IOGTR commented that the current voluntary system would be improved by the legislation providing a full regulatory system where compliance processes are readily available to the regulator. Monsanto also acknowledged that it did not think the breach would have occurred under the procedures of the new regulatory system.[66]

Issues arising from this case for the future

Approval of trials

6.121 Aventis submitted that difficulty arises out of the informal nature of the present 'approval' processes. The process was described as normally involving:

> a detailed exchange of correspondence, more in the nature of a negotiated arrangement than the issue of an order of determination by duly constituted authority. This exchange of information and advice is a two-way process. The proponent explains their intended action and the GMAC comes to a series of "recommendations" (and that is the word used) about what they believe should be done.[67]

6.122 The Committee considers that, in the light of the breaches and Aventis' response, this process clearly needs strengthening with greater legislative authority required. Licensing of trials and greater certainty in the conditions under which they

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64 *Committee Hansard,* 25.8.00, p.389 (Dr Blowes, Monsanto).

65 *Committee Hansard,* 25.8.00, p.451 (IOGTR).

66 *Committee Hansard,* 25.8.00, pp. 449-51 (IOGTR) and p.390 (Dr Blowes).

67 Submission No.61, pp.7-8 (Aventis).

must take place requires the backing of legal authority. The responsibility of the licensed party in adhering to conditions must be clearly understood with the backing of severe sanctions for any breach of conditions.

Secrecy issues

6.123 It was argued in evidence that while some correspondence was sent to the district council about these trials in their district, the council and local community were not informed of the location of these trials. There was also claimed to be a lack of information among some farmers growing GE canola, who believed they had been deliberately deceived over the status of the canola they were growing. In other situations land had apparently been leased to grow GE canola without the owners' knowledge or consent.[68] Professor Roush disputed these claims, saying that discussions he had with farmers with whom Aventis had worked indicated that they 'knew what was going on'.[69]

6.124 Aventis suggested that in relation to this issue, 'it depends on your definition of secrecy'. They noted that they 'have to convey a lot of information to the farmers' and have contractual obligations that provide minimal requirements. Aventis did concede that in initial contracts there was no reference to genetic modification, though 'we have certainly updated and improved our information flows between our farmers and ourselves and included in the contracts definitions which include that of a GMO'.[70]

6.125 The Committee believes that if the development of GM crops is to receive consumer support and confidence, the apparent levels of secrecy surrounding their trialing, as evidenced at Mount Gambier, must be overcome. The oft-repeated aim of transparency underpinning the current legislation can only be achieved if such trials are conducted in an open fashion. This issue is also discussed in Chapter 3. The Committee considers that the public will only embrace the developing technology if they have understanding and confidence, which can only be accomplished through honesty and information.

Power to enforce recommendations in trials

6.126 The inability of GMAC to enforce adherence to their recommendations is demonstrated by both the Aventis Mount Gambier and Monsanto cottonseed incidents. Aventis proffered the argument that if a transparent and unambiguous regulatory process, with clear rules or codes of practice to follow backed by the force of law had been in place, the Mount Gambier incident 'would not have happened the

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68 Submission No.9, p.17 (Heritage Seed Curators Australia); *Committee Hansard*, 22.8.00, p.76 (Ms Huebner), p.82 (Mr Rankin) and 23.8.00, p.161 (GE-Free Tasmania).

69 *Committee Hansard*, 22.8.00, pp.96, 102 (Professor Roush).

70 *Committee Hansard*, 22.8.00, pp.125, 130 (Aventis). Aventis tabled at the hearing the standard form of licence agreement from September 1999 and June 2000 to show the evolution.

way it did'.[71] The Committee believes that the existence of a regulatory regime in and of itself should not be required to ensure that companies undertake the trialing of GM products in a totally safe and responsible manner.

6.127 The Committee considers that it is perfectly natural for the public to be deeply worried by the apparent willingness of companies to only be concerned at meeting whatever minimal process and procedures may be in place, irrespective of the possible detrimental outcomes to public health and safety, and the environment.

6.128 It is argued that the establishment of the regulatory system proposed in this Bill will impose the absolute necessity of adhering to procedures by companies and provide the Regulator with the powers and sanctions to enforce adherence.

Monitoring of trials

6.129 Deficiencies with the existing system in monitoring trials to ensure recommendations are being adhered to were also demonstrated by the Mount Gambier incident. The Committee was informed that suspicion about the trial crops in question only emerged following 'local gossip' at a TAFE.[72]

6.130 The development of spot checks is an important step in monitoring trials. Such procedures must be further developed and be fully resourced. The legislation should establish a rigorous and funded framework for routine inspections of sites to improve public confidence. Yet again the question of public confidence is paramount. Breaching trial recommendations can be seen as the cardinal sin. To mix metaphors 'the horse has bolted and the genie cannot be put back in the bottle', both in respect of environmental contamination after it has occurred and the resultant community distrust of a system that allows such an incident to occur.

Investigative procedures

6.131 As noted earlier, a period of nearly four months elapsed from the date the IOGTR received allegations of possible breaches to the Minister's final approval of the report. Claims and counter claims have been made in evidence of delays in responding to information, providing assessment reports and commenting on evidence. The Committee notes the advice of the Australian Government Solicitor who stated:

> we have not been able to identify any act or omission by IOGTR or GMAC which would amount to defective administration as defined for the purposes of the scheme… we do not think that the investigation of the alleged breaches can be said to have been carried out in a tardy manner.[73]

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71 Submission No.61, p.10 (Aventis).

72 *Committee Hansard,* 22.8.00, p.8*2* (Ms Huebner).

73 AGS to IOGTR, dated 1 August 2000 (in Submission No.77 additional information provided 25.8.00).

6.132 Nevertheless, the Committee considers the timeframe as unnecessarily long. Whilst the risk assessments concluded that none of the breaches represented an increased risk to human health and safety but may have resulted in an increased risk to the environment, this was only determined after the investigation was concluded. A number of procedures have been identified above that will give the Regulator significantly enhanced powers in conducting such investigations in the future.

Global considerations

6.133 In addition to the issues involving the specifics of a regulatory system, breaches such as occurred at Mount Gambier can also have international ramifications. The AWB Ltd commented (more in the general than the particular):

> These days, it is a global world out there. If our customers overseas see that there are serious breaches here in Australia, for whatever issue, whether it is a GM issue or a food safety issue, they know about it, and they start to raise questions with marketers such as ourselves, such as, "What controls do you have in place there to make sure that you are fully in control of what you are doing there?" So any breaches such as that, whether deliberate or not, are of concern to us.[74]

6.134 While the Committee notes that the IOGTR has commenced an audit of all Aventis trials following the Mount Gambier incident, it believes that in order to reassure the Australian public that no further incidents such as this have or are currently occurring, that all current field trials being conducted in Australia should be audited.

Recommendation

The Committee RECOMMENDS that all field trials currently being conducted in Australia be audited by the IOGTR as soon as possible and the results of the audit be made publicly available.

Concluding comment

6.135 In conclusion, the issues arising from the Mount Gambier trials are exceptionally important and provide pertinent instruction for the future regulatory system. Summary comments from the House of Representatives Primary Industries and Regional Services Committee and the Premier of South Australia are especially apposite:

> The committee is of the view that the alleged breaches would have been much less likely to have occurred if stringent, transparent regulatory processes…had been in place. The committee is unanimous in believing that rigorous, independent regulatory processes must be instituted as quickly as possible. A more prompt, open, transparent approach must be taken to breaches of guidelines. It is essential that the IOGTR act much more

74 *Committee Hansard*, 24.8.00, p.300 (AWB Ltd).

efficiently and effectively than the IOGTR has been able to if it is to reassure the Australian people that their interests are being strenuously protected. If this does not happen, public confidence in GMOs and their regulation will be badly prejudiced.[75]

The incident in question highlights the need for the adoption of a robust legislative regulatory system in order to improve the capacity for enforcement, auditing and monitoring of compliance, and introduce substantial penalties for breaches. The treatment of this incident to date confirms for South Australia the importance of a transparent process and the necessity for the Regulator to be independent and to also be seen to be independent, in its assessment of such cases. Timeliness of reporting and a robust mechanism to ensure full reporting to States and Territories on such cases is important to strengthen community confidence in the treatment of alleged breaches.[76]

Senator the Hon Rosemary Crowley
Chair

75 *Work in Progress: Proceed with Caution*, Report by the House of Representatives Standing Committee on Primary Industries and Regional Services, June 2000, p.129.

76 Submission No.110, p.2 (South Australian Government – Mr John Olsen, Premier).

MINORITY REPORT

GENE TECHNOLOGY BILL 2000

BY GOVERNMENT SENATORS

The Government believes that the *Gene Technology Bill 2000* adequately meets its objectives in designing a key piece of legislation that aims to protect both the public health and safety of Australians and the environment from the risks associated with gene technology. The Bill also has strong support from the States and Territories.

Vast consultation across the board, from organisations, to individuals to government has occurred in structuring the Bill as it stands. This high degree of consultation is unprecedented and any alteration now has the very real potential to jeopardise its implementation.

Government Senators would make the following observations about some of the recommendations that have the potential for such uncertainty.

Chapter 3

Risk assessment provisions currently in the Bill give sufficient weight to the consideration of the impact of the release of GMOs into the environment especially given Australia's unique flora and fauna and mindful of maintaining Australia's biodiversity. Measures to achieve this outcome include the establishment of a statutory officer (the Gene Technology Regulator), the prohibition of people from dealing with GMOs except in certain circumstances, the establishment of a scheme to assess human health and environmental risks in various dealings with GMOs, provision for monitoring and enforcement of the legislation, and the establishment of three key advisory committees each dealing with different aspects of gene technology.

Commercial in confidence provisions in the Bill are designed in order not to compromise the objectives of the Bill or dilute the transparency of the regulatory regime. If a licence applicant desires that certain information be protected, the GTR must assess each case individually and make a decision. If the GTR decides the release of information may be detrimental to an applicant, he or she may decide that the public good outweighs the interests of the applicant.

Independent review of the Act in three years is not practical for, as with any new scheme time is required to implement it fully. The Government is not amenable to any review before five years. After this time it is expected that review can more competently be performed after the legislation has been given sufficient time to be bedded down.

Chapter 4

The Committee recommendation concerning financial interest provisions overlooks provisions that already exist in the Bill. Strong conflict of interest provisions ensure that the Regulator is required to disclose to the Minister all interests, pecuniary or otherwise, that may conflict with the performance of his or her functions.

Precluding an individual who has worked for a regulated entity from holding the office of the Gene Technology Regulator for a two-year period is problematical. By virtue of the fact that this field is limited, this recommendation is totally impractical. As long as an individual declares his or her interests, an application must be assessed on a merit only basis.

The Government Senators are not opposed to the Bill being amended to require quarterly reporting, however provisions for reporting relevant breaches of licence conditions are already present requirements in the Bill.

The Government Senators however, are *entirely opposed* to the notion of the establishment of the Regulator as a Statutory Authority consisting of three people who will take the ultimate responsibility for decision making. This proposition is economically unviable, given the size of the GTR (50 people). Establishing the office as a Statutory Authority would cost at least an additional $500,000 a year. It would also be impossible to quantify the gain in establishing a Statutory Authority, given the high level of independence already achieved within the Bill.

Consideration of the feasibility of introducing a 'one-stop shop' model having regard to the operational effectiveness of the proposed 'gap-filler' arrangements is already something the Government is attempting to do. It is desirable that the arrangements as they stand encourage the 'one stop shop' concept however, continuing to be mindful that different authorities look after different areas of responsibility.

The Bill does creates a 'one-stop shop' for biosafety assessment of all GMOs and GM products by establishing a centralised national regulator who carries out risk assessment of all GMOs and GM products. This allows for the GTR to act as a centralised area of expertise that will make advice on GM products to other regulators. It also minimises duplication by employing strategies to improve the interface between regulators.

Significantly, this method will be able to be implemented in a shorter timeframe than a complex single agency to regulate all GMOs and GM products, which would take a great deal longer to establish and would fail to meet community and industry demand for a fully operational GTR by 2001.

In May 2000, the Federal Government established the Regulatory Reform Taskforce within the Department of Health and Aged Care in response to calls from consumers and industry for better coordination of public health regulators. The Taskforce is examining the current administrative arrangements for this regulation at Commonwealth level and will identify ways to improve it.

The Committee acknowledges that the proposed structure provides the option that ensures all aspects of the production, manufacture and sale of GMOs and GM products are regulated and that there are no 'gaps' in regulatory coverage. The system in the Bill guarantees the Regulator either directly regulates or provides advice to specific regulators on all GMOs and GM products.

The Government Senators believe that the assessment of environmental risks can be better met through the Gene Technology Bill rather than the *Environment Protection and Biodiversity Conservation Act 1999.* The objectives of the Bill are to meet environmental safety concerns in conjunction with human health and safety provisions. The GTR has been placed under the Health portfolio in this context. The issue of GTR flexibility is also a major point and risk assessments should be performed on a case by case basis whereby the Regulator must be afforded the flexibility to assess each case individually.

Listing of broad categories of risk once again addresses the notion of flexibility for each application on a case by case basis. The absence of prescriptive categories of risk was intentional because of the fact that there are so many varying types of GMOs that the Regulator will be required to assess. There are however, some broad categories of risk prescribed in the regulations, which the Regulator may take into account.

The Committee believes that the Regulator, when setting licence conditions may satisfy him or herself that applicants have made provisions with insurers for suitable coverage to protect them against the risks associated with the dealings.

Mandatory review or renewal of licences granted by the Regulator is provided for in the Bill and there is capacity for review at any juncture or time.

The Committee agrees that the ultimate responsibility lies with the applicant to provide adequate scientific support for its case to the Regulator. The Regulator is then obliged to make a decision based on independent assessment and evaluation of data provided by the applicant and then further through the public and committee processes. The Regulator will ensure, as much as is possible, that contamination of non-genetically modified produce or land cannot occur.

The Bill provides a number of requirements afforded to the Regulator to monitor compliance with the legislation. Provisions include the imposition of conditions, monitoring of compliance with these provisions, obligations to report, investigative powers addressing alleged breaches, enforcement powers and penalties.

Recommendations concerning licence holders to guarantee compliance is not necessary given companies will also monitor progress with dealings. The Regulator will also have the power to impose conditions to limit contamination and vary a licence, including imposing additional conditions or confiscating or altering existing conditions.

Furthermore, the Regulator is provided by the legislation with the following ways in which to monitor compliance with conditions. The GTR may require regular auditing

to be undertaken by a licence holder and reporting to be made to the Regulator. Routine audits may also be undertaken, as might 'on-the-spot' inspections or audits of dealings with GMOs.

The legislation allows for the Regulator to appoint inspectors for the purposes of investigating alleged breaches. In the event of non-compliance, the legislation describes a range of investigative powers that may be used by inspectors for determining whether a breach has indeed occurred.

Inspection powers are similar to those granted to the Australian Federal Police, Customs agents and inspectors appointed under the Therapeutic Goods Act and are substantial, and consistent with Commonwealth criminal law policy.

The 1999 Draft Bill has been amended to respond to requirement for monetary penalties in the instance of breaches of licence conditions, to reflect concerns that arose in previous consultation.

Provisions for penalties are clear and the Government believes suitably fitting. Offence provisions and penalties are consistent with criminal law policy and are significant in comparison to other regulatory schemes. It is clear that the Government has adequately introduced strict liability offences to the Bill. In the case of a breach of condition that causes significant damage to the health and safety of people or the environment, there are two alternative monetary penalties that may be pursued.

While the Government Senators recognise that there is a degree of anxiety about the issue of cost recovery, the policy is one hundred percent cost recovery. A KPMG Inquiry has determined that the annual cost for the first couple of years will be approximately $7.8 million. The Productivity Commission is in the process of looking at this issue and a draft report is due in March 2001.

Chapter 5

There is a requirement in the legislation that cross membership of the three advisory committees exist however, the Government Senators are not in favour of increasing the role of either the Community Consultative Group or the Ethics Committee.

The Committee believes that the Gene Technology Technical Advisory Committee should essentially be comprised of members who are capable of providing to the Ministerial Council and the Regulator scientific information and advice.

The function of the Gene Technology Community Consultative Group is to provide advice on matters of 'general concern' and will be consulted only in relation to general principles or guidelines, not in relation to specific decisions.

An increased role for either or both of these Committees would be entirely detrimental to the science-based decision making process. It would also be contrary to every other country's risk assessment policy and furthermore creates absolute uncertainty in the

process. Other foreseeable problems include unacceptable delays, increased costs for the OGTR and the possibility of leakage of in-confidence information.

Consultation by the Ministerial Council of the three Committees when issuing policy guidelines is both impractical and unworkable. The Ministerial Council is essentially political. This measure would also contribute to implementing another laborious procedure. The Bill as it is, is exceptionally consultative and need not be more so.

As a result of other mechanisms in the Bill, there is adequate opportunity for community input on individual applications. This high level of community involvement in decision making is unprecedented in most existing regimes.

It is not necessary to incur additional costs and resources to duplicate the process by allowing the Gene Technology Community Consultative Group to examine individual applications.

While the Bill does not directly provide for third party appeal, mechanisms exist for appeal. There are adequate opportunities for third parties to express discontent throughout the open process of assessment. It was also considered appropriate by the Government in conjunction with the States and Territories, that the right to review by the AAT to those directly affected by a decision would be limited. This was because of a number of issues including the concerns of the time and cost resources that would have to be donated to review after an already lengthy consultation process.

In addition, by limiting review to those immediately affected, the prospect of vexatious appeals is significantly reduced or eliminated and is consistent with Commonwealth policy. This is also consistent with similar legislation and hence the Government Senators believe is more than appropriate given the lengthy consultative process.

Also, by allowing the States appeal to the AAT, individuals are able to appeal to the State to make a representation on their behalf to contest the merits of a decision made by the Regulator.

Chapter 6

Provisions in the Bill requiring the Regulator to accept State or Territory viewpoints to prevent the release of GMOs within their jurisdictions has already been taken into account, in part through the States and Territories role in the Ministerial Council. It is imperative that the integrity of a strong national regulatory system be maintained – it cannot afford to be fragmented.

Government Senators believe it is acceptable to allow the results of breaches to be made publicly available. However, issues such as the cost and manpower required to audit and publicly report *all* dealings are impractical. Not only would this be expensive and time consuming, it would not allow for the flexibility to spend more time on high-risk GMO dealings.

Conclusion

This legislation is being introduced to coordinate a national regulatory system that is transparent, open and heeds stringent regulatory processes. The emergence of growing debate about gene technology and its consequences has highlighted the urgent need for a piece of legislation such as the *Gene Technology Bill 2000* and its implementation is well timed.

The community at large has been extensively consulted, as have the States and Territories.

The Government Senators strongly believe that measures in the Bill ensure that all aspects have been fully addressed in the objectives set out. We also believe that an independent and rigorous system needs to be implemented in as timely a fashion as possible. Any alteration to the Bill at this point is likely to severely jeopardise this occurring.

We recommend that the Bill proceed as soon as possible in unamended form.

Senator Sue Knowles, Deputy Chairman
(LP, Western Australia)

Senator Tsebin Tchen
(LP, Victoria)

AUSTRALIAN DEMOCRATS'

ADDITIONAL COMMENTS

While supporting many of the observations and recommendations contained within the Chair's Report, the Australian Democrats do not sign off on the document. The Democrats provide these additional comments as detail of our concerns with the proposed regulatory system and to provide an overview of the sustainable and responsible manner in which genetic technology should be undertaken and applied.

The Democrats' concerns regarding the Gene Technology Bill 2000 are not limited to the comments listed below. We submit them as a contribution to the increasing public debate surrounding the Bill as it is considered by the Senate. The Democrats will continue to monitor further developments and seek to amend the Bill as seen appropriate when it is considered by the Senate.

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1. ***The Australian Democrats believe that an effective gene technology regulatory system must contain - not to the exclusion of others - two elements:***

(i) community confidence;

(ii) independent public information and education.

2. ***Current Regulation of Gene Technologies***

2.1 *Domestic*

Six differing bodies, or schemes, regulate differing aspects of gene technology[1] at a Commonwealth level:

(i) Australia New Zealand Food Authority (ANZFA), regulating genetically modified foods;

(ii) Therapeutic Goods Administration (TGA), regulating genetically modified therapeutic goods and human gene therapy under the Gene and Related Therapies Research Advisory Panel (GTRAP);

(iii) National Registration Authority (NRA) regulating agricultural and veterinary (agvet) chemicals;

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[1] It is recognised that concern was expressed in the Committee to the terminology used to describe the science and techniques developed to manipulate an organisms genome. While quotes, excerpts from Committee submissions, and past Democrat releases and statements on the subject use varying terms, 'gene technology' will be used generally in the following paper as it is the title of the Bill referring to genetic modification, genetic manipulation, genetic engineering and transgenic processes rather than drawing distinctions between the terms.

(iv) National Industrial Chemicals Notification and Assessment Scheme (NICNAS) regulating use of industrial chemicals;
Australian Customs Service (ACS) and the Australian Quarantine and Inspection Service (AQIS) overseeing the importation and exportation of genetically modified organisms and related products.[2]

The Australian Democrats have wide-ranging concerns about aspects of current gene regulation in many of these bodies, the current disparate regulation and artificial delineations in gene technology processes and products created by the current regulatory system.

The Gene Technology Bill 2000 will not act to address this disparity, but will rather add another tier to the current regulatory system.

Another area of inadequate protection for the Australian community includes biosafety regulation currently overseen by the Genetic Manipulation Advisory Council (GMAC).

2.1.1 *Australian Democrat concerns with current regulatory system:*
While the following statement does not address the specific issues surrounding recent controversial threats to public health and biosafety, such as those surrounding the Mt Gambier field trials, it outlines general long-held concerns about biosafety procedures in Australia even when stipulated disposal and buffer requirements are adhered to:

> Australia's current voluntary system of biosafety regulation is not of an acceptable standard and the public can not be confident it is a reliable scheme or that it will deal with their concerns.
>
> At present voluntary regulation of small and large scale genetic manipulation work in containment facilities and the release of genetically modified organisms into the environment under GMAC are inadequate. GMAC regulates such activities by the issue of non-statutory guidelines which specify the procedures to be followed by institutions and researchers intending to undertake genetic manipulation work and detail requirement for containment facilities. Proposals for genetic manipulation work are assessed on a case-by-case basis giving varied conditions under which organisms are to be modified and released.
>
> The inadequacies of this system can be illustrated by the determination of buffer zone specifications under GMAC. Currently in Australia, 'refuge'[3] and 'buffer' zones[4] are not defined in GMAC's guidelines. Instead conditions are established on a case by case basis. The

[2] M Wooldridge, Gene Technology Bill 2000 *Explanatory Memorandum*, at page 7.

[3] Refuge zones are expanses of farm land of traditional crops designed to prevent the development of pesticide resistant organisms.

[4] Buffer zones are expanses of land designed to prevent cross pollination of genetically modified crops.

effectiveness of this practice is at the very least questionable as presently the production of transgenic Bt Cotton[5] requires a 'refuge' of 10% traditional crop to prevent the development of pesticide resistant organisms. This requirement means that such zones are of highly variable distances depending on the size of the field which the cotton is grown in. It does not take into account generally accepted international set distances or findings such as those in the UK which have established that bees can carry pollen four kilometres from test sites[6] by failing specifying a minimum distance for such zones.

The current regulatory arrangements not only fail to provide sufficient protection to consumer health and the environment but also fail to provide standard enforceable regulations which clearly specify to researchers, industry and primary producers the boundaries in which genetic technology applications may be used. The present practices do not insure industry or consumer confidence. Furthermore, case-by-case assessment of genetic manipulation applications will become more and more unsustainable as the 'biotechnology revolution' evolves in Australia and the frequency of such activities increases exponentially.

Institutional Biosafety Committees (IBCs) are internal committees which oversee the implementation of GMAC Guidelines in individual institutions and companies which use genetic manipulation techniques. These committees rely solely on the full and voluntary cooperation of research institutions and companies to report all manipulation activities for compliance with the guidelines which is clearly inadequate in light of the possible risks associated with this technology. Furthermore, IBCs under GMAC are granted commercial-in-confidence rights. This practice is inappropriate and inadequate to ensure accountability, consumer and environmental safety and additionally acts to undermine consumer confidence. I have called for a statutory, publicly accountable, transparent regulatory and independent testing system to be implemented which ensures the safety of the public interest.[7]

The Australian Democrats welcome the establishment of a public register under the Office of the Gene Technology Regulator.

However, the Democrats remain concerned about the extensive classification of information surrounding GMO trials and applications for release as commercial in-confidence.

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[5] Bt Cotton is a genetically modified cotton species produced by Monsanto which carries a gene (including Bt – Cry1Ac or Bt – Cry2A) derived from a baterium, *Bacillus thuringiensis*, that produces a Bt toxin killing pests of the crop.

[6] Nuttal N, 'Bees spread genes from GM crops', *The Times*, 15 April 1999.

[7] N Stott Despoja, Submission to the House of Representatives Standing Committee on Primary Producer and Regional Services' Inquiry into primary producer access to gene technology, June 1999, at page 5.

2.2 *International - The Cartagena Biosafety Protocol of International Biodiversity Convention.*

While it is recognised that the Cartagena Biosafety Protocol exempts many areas of transboundary movement of living modified organisms, such as those contained in pharmaceuticals, it does provide governments wider discretion to restrict imports than is permitted under the World Trade Organisation's (WTO) Agreement on Sanitary and Phytosanitary Measures.

The International Biosafety Protocol provides the best international legal framework to date for responsible international regulation and trade of genetically modified organisms. Australia's endorsement and signage of the Protocol will provide appropriate foundations for effective domestic regulation of gene technologies and the first step towards achieving public assurance that the benefits of biotechnology will be secured without damage to health and safety or the environment.

3. *Gene Technology - promises & risks*

Gene Technology is a nascent science, in which the potential and pitfalls are still being determined. Any science or technology is a tool that can be applied by a community for positive or negative outcomes.

The Chair's Report recognises "the significant number of and qualifications of scientists opposed to, or very concerned about, gene technology, its applications and possible consequences."[8]

The Australian Democrats recognise the nature and potential power of gene technology, and that its precision is hindered by the relative novelty of the science.

It was stated in Senator Stott Despoja's submission to the House of Representatives Standing Committee on Primary Producer and Regional Services inquiry into primary producer access to gene technology, June 1999 that:

> Genetic engineering is not at present a precise technology and the long-term consequences of the technology are poorly understood. Current manipulation techniques involve the insertion of genetic material randomly and do not provide a precise or chosen location for insertion. Further, the levels of expression depends to a large extent on the location of insertion and genes may move outside their intended spaces.
>
> It is reasonable to expect that pleiotropy (the affect of a single gene product on more than one trait) and epistasis (the capacity for one gene to modify the expression of another gene which is not an allele[9] of the first) will also

[8] Chair's Report, *Preface*, at page 1

[9] Alleles are different types of a gene for a particular trait which produce differing outcomes. To use the Mendelian example, one allele of a gene will produce a wrinkled seed whereas another allele of the same gene will produce round smooth seeds.

occur in trangenic crops, as they do in their traditional counterparts. These effects increase the complexity and difficulty of assessing the risks that transgenic crops may have on the environment, nutrition, consumer health, etc. This aspect of gene technology is presently poorly understood, poorly researched and does not appear to have been adequately assessed in proposed regulatory schemes. For example, the proposed substantial equivalence for gene food labelling would be unlikely to detect a predisposition in a food crop to accumulate heavy metals with its downstream health effects.

Two examples illustrate this concern:

(a) The production or conferral of weediness to agricultural and non-agricultural species is one aspect of agricultural gene technology which holds the potential to cause significant cost to primary producers in Australia. Scientists have suggested that some transgenes may confer or enhance the ability of a crop species to become a weed[10]. The risk of transgenic crop weediness is similar to that presented by the introduction of non-indigenous plant species into an environment, but the relatively few that can cause significant ecological disruption and a significant cost to agriculture, for example, through increased herbicide use and environmental degradation.

(b) Another concerning aspect of first generation agricultural gene technology is the insertion of virus genes into crop plants to protect them against disease. Experiments have shown migrating viruses can acquire the inserted genes and produce novel viruses with new properties. Work on inserting virus genes for resistance is advancing in many countries, including Australia, and is well funded compared to the research attempting to understand the potential dangers. Significantly, field tests of transgenic plants are presently not even independently monitored. This is a major concern to Australian agriculture and means that we must be concerned about the genes we are incorporating in the populations of cells and organisms and their relations.

These are valid concerns - gene flow to wild relatives has been recorded in quinona, squash, carrot, maize, sorghum, sunflower, strawberries and sugar beet[11] and there have been 16 reported international cases of genetic exchange between crops resistant to herbicides, insects and viruses and wild relatives.[12] Such genetic pollution is now receiving recognition and serious consideration by international governmental regulatory agencies. It was concluded by the United Kingdom's

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[10] Rissler J & Mellon M, *Perils Amidst the Promise: Ecological Risks of Trangenic Crops in a Global Market,* Union of Concerned Scientists, Cambridge MA, 1993 at page 4 of 8.
http://binas.unido.or.at/binas/Library/ucs/section5.2.html accessed 1 June 1999.

[11] Gray AJ & Raybould A F, 'Reducing transgene escape routes', *Nature* Vol 392 16 April 1998 at page 654.

[12] Brookes M, 'Running Wild', *New Scientist,* 31 October 1998 at page 41

> Advisory Committee on Releases to the Environment (ACRE), Department of the Environment, Transport and the Regions that cross-pollination between adjacent crops of fodder maize and sweet corn can occur.[13]
>
> This is also a concern in Australia. The Genetic Manipulation Advisory Committee (GMAC) 1997-98 Annual report documents an incident where transgenic lupins modified for herbicide resistance were inadvertently released. In Australia no crossing occurs with other species in this genus and the possibility of genes entering the naturalised races of lupin are very low. However, similar release of a transformed subterranean clover is very likely and under selective pressures and over a period of time as short as several years the likelihood of an outcross is very likely (it is a matter of numbers…). This may have significant implications for Australian primary producers and the wider Australian community.
>
> The consequences of this "imprecise" technology are likely to significantly affect primary producer access to the benefits of the technology. An assessment of the exact impact is difficult because the mechanisms are poorly understood and they are not being investigated. I am particularly concerned about the long term consequences to the environment and its ability to sustain viable and productive agriculture.

An open letter from World Scientists to all Governments concerning Genetically Modified Organisms Submitted to the UN Commission on Sustainable Agriculture in New York (April 24-May 5 2000) outlined further concerns by scientists from a plethora of disciplines about the potential risks and misuse of genetic technologies, corroborating at an international level the diversity of concerned expert opinion noted by the Chair's report.

4. Principles & Objectives of the Office of the Gene Technology Regulator

4.1 *Objectives of the Bill*

The Object of the Gene Technology Bill 2000 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.[14]

The Australian Democrats support these objectives, though consider that stipulation in regulation of relating principles is required to adequately ensure the protection of public health and safety and the environment.

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[13] Department of the Environment, Transport and the Regions *Advisory Committee on Releases to the Environment*, Advice for the Secretary of State, 23 June 1998: Genetically Modified maize in National List Trials Adjacent to an Organic Farm in Devon. http://www.environment.detr.gov.uk/acre/advice01.htm, accessed 8 March 1999

[14] s3 at page 2.

The Chair's Report states at 3.76 that:

> The Committee considers that while the protection of the environment is important, it should not detract from the paramount objective of protecting the health and safety of people. The Committee supports the placement of the OGTR in the Health and Aged Care portfolio.

The Australian Democrats maintain that environmental protection and public health and safety are synonymous and can not be conflicting objectives.

Furthermore, the Democrats maintain that the Commonwealth Environment Minister must play an active role in the regulation of gene technologies in Australia to ensure that the environment is appropriately considered in Office of the Gene Technology Regulatory (OGTR) decisions. In its current form, the Bill does not provide such involvement and, therefore, does not provide adequate protection for the environment.

4.2 *Role of the Environment Minister*

The Democrats note the commitment given on behalf of the government by the Environment Minister, Senator Hill to the Senate during the original passage of the Environment Protection and Biodiversity Conservation Act 1999 (EPBC Act) on 22 June, 1999 that "matters that affect the environment will be referred to the environment minister for assessment and advice by that independent regulator. That will ultimately be provided for through an amendment to this legislation (the EPBC Act), when it passes in conjunction with the law that is going to be put in place to set up the new GTR." This government commitment, provided immediately before the Senate vote on the EPBC Act legislation, has clearly not been met.

The Australian Democrats put on the Parliamentary record on June 2000 our concerns regarding the June 13 Federal Cabinet decision to minimise the role of the Environment Minister in gene technology regulation in Australia.

> Under the proposed amendments [to the EPBC Act], which of course the Australian Democrats confirmed last year, we saw the environment minister—actually the environment minister, I should acknowledge, is on record as endeavouring to honour them—saying that he supported the role of the environment minister in relation to an environmental assessment of GMs before they were released. Under the EPBC Act a licence to deal with a GMO was required to be issued by the Gene Technology Regulator, the GTR. This application, if involving a deliberate release of a GMO into the environment—I think it is clause 43(b)—was required to be referred to the environment minister, who could then stipulate specific requirements to protect the environment if the minister believed that that release posed a significant risk of harm to the environment. The environment minister could accredit an assessment process for the GTR to pursue or direct an assessment on preliminary documentation if considered `a controlled action under part 7 of the EPBC Act, clause 43(c)'.

> With respect to the environmental assessment under clause 43(f), the environment minister could provide advice to the GTR which must be considered by the GTR when considering the licence application. Let us compare this now to the new proposal by cabinet which I think has no amendments to incorporate GMOs into the EPBC Act. The act that was designed to ensure the most comprehensive environmental assessment at a Commonwealth level has now been completely undermined—and with it, of course, the role of the environment minister in the approval of GMs and GMO releases. The new proposal, under the auspices of the health minister and the department, does not begin to make up for the ground lost by the rejection of the Democrats' original proposal. The draft substitute amendments to the Gene Technology Bill 2000 do not require the environment minister's input in matters of deliberate release to the environment, nor do they stipulate adherence to any advice that the minister may volunteer if he or she deems it appropriate to offer.
>
> The Democrats are on record a number of times in the past week or so as saying that we regard the latest cabinet proposal as inadequate; and we will be seeking to rectify the situation when the bill is debated in this place. What is also questionable is the extent of the power of proposed amendments to the Gene Technology Bill 2000 without reciprocal amendments to the EPBC Act, putting the protection of the environment under the bill into further doubt. We know that consumers, through the health department's consultations on the Gene Technology Bill, are saying that they want environmental and health matters to be given equal weighting when discussing the release of GMOs. Yet basically it is a slap in the face to those people who participated in those public consultations.
>
> The role of the environment minister and the role of the environment in terms of assessing the risks and benefits of GMOs has been completely undermined. The federal cabinet's decision of 13 June, which did decide to undermine the environment minister's role in the regulation process, can be construed as being in conflict with the objectives of the bill as it currently stands...[15]

The Australian Democrats maintain that amendment to the Bill and the EPBC Act must be undertaken to ensure the adequate protection of the environment from gene technologies and that operation of the OGTR is in keeping with the Bills objectives.

4.3 *Precaution: an approach or principle?*

[15] N Stott Despoja, Matter of Public Interest: Genetically Modified Organisms, *Senate Hansard*, 21 June 2000 at pager 15318

The Chair's Report reflects, at 3.25, the wide variety of precautionary approaches and principles contained in international agreements, domestic law and environmental legal theory:

> The differing forms of the precautionary principle also impacts on the scope of the principles application, with some conventions and statements limited to toxic substances control, while others include any government policy with the potential to cause environmental degradation.

Epidemiologist and biochemist, Dr Judy Carman, of the Public Health Association of Australia, commenting on the current use of caution and a precautionary approach in approval of genetically modified food products by the ANZFA in an interview with *the Age* stated:

> "The precautionary principle that could be described as 'unsafe until proven to be safe', has been around for centuries to guide us in conditions of uncertainty. Yet ANZFA has officially adopted the opposite approach; that is, they permit 18.7 million Australians to eat GM foods based on a 'safe until proven unsafe' philosophy."[16]

The ANZFA's current objectives do not incorporate the precautionary principle, despite the recommendations of public health and medical groups in the Senate Community Affairs References Committees' Inquiry into the Australia New Zealand Food Authority Amendment Bill 1999.

Attempts by the Senate minor parties to amend the Bill in the Senate to include a comprehensive precautionary principle were not supported by the Opposition and Coalition parties.

The absence of the precautionary principle in the ANZFA's objectives increases the exigency for its inclusion in the objectives of the OGTR.

The Chair's Report states at 3.72 and 3.73:

> *The Committee considers that the precautionary approach would be underpinned in the Bill if the precautionary principle appeared as one of the objects consistent with the way it appears in the Environment Protection and Biodiversity Conservation Act. The Committee does not support the precautionary principle being made a specific test in the licensing provisions.*
>
> *The Committee considers that there is a balance between the risks to the community versus the rights of a company, and strongly considers that, in keeping with a precautionary approach, the onus of proving that GMOs are not harmful should rest with the proponents of the technology.*

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[16] G Strong, 'GM-food tests 'inadequate', *The Age* 28 October, 2000. http://theage.com.au/news/2001029/A13301-2000Oct28.html

The Australian Democrats do not consider the inclusion of a precautionary 'approach' as preferable to the precautionary principle and support the Chair's recommendation that the Objectives of the Bill contain the same words that appear in the EPBC Act 1999 in relation to the precautionary principle.

The Australian Democrats maintain that stipulation of specific preventative standards and safeguard measures is essential to the protection of public health and the environment, and to ensure public confidence in domestic gene technology regulation.

Furthermore, the Australian Democrats strongly question the adequacy of the regulatory system as stipulated by the Gene Technology Bill 2000; Gene Technology (Consequential Amendments) Bill 2000; Gene Technology (Licence Charges) Bill 2000 and related regulations to effectively review and assess declarations by parties with commercial interests in the technology that it is safe (as deemed in keeping by the Chair with a precautionary approach).

The Chair's Report states (at 3.64)

> While there is clearly consensus on the need to ensure a cautious approach to the development and adoption of gene technologies, there is also acknowledgment of the need to ensure the continuation of research and development on the basis of current scientific understanding of potential risks: [The] Regulator's deliberations must be based on sound, consistent and reproducible scientific and technical data generated according to world best practice standards.[17]

The Australian Democrats, while supporting risk assessment and decision making based on reproducible scientific and technical data, believe that such scientific standards and assessment will not be able to be guaranteed under the proposed regulatory regime as the system does not provide for independent testing of such data in all cases.

At present, the ANZFA is responsible for assessment and approval of genetically modified organisms for farm production and public consumption.

The Australian Democrats have previously commented on the ANZFA's lack of testing facilities and the inadequacy of its reliance on applicant scientific data in the approval of genetically modified food products.[18] This situation will not be rectified under the gene technology regulation system proposed.

The findings of a study conducted for the Public Health Association of Australia support this concern.

Scientists conducting the study examined procedures surrounding applications from US-based Monsanto for release of food produced from:

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[17] Submission No 42, p.4 (Floringene Limited and Nugrain Pty Ltd). See also, *Committee Hansard, 23.08.00* p.184

[18] Including, N Stott Despoja, Press Release 00/357: *Democrats call for ANZFA labs not just glossy PR*, 19 June 2000. http://www.democrats.org.au/media/display.htm?id=659

(i) insect-protected corn line MON 810[19];

(ii) glyphosate-tolerant corn line GA21[20]; and, or

(iii) glyphosate-tolerant canola line GT73.[21]

The Public Health Association's review of the glyphosate-tolerant canola found that the canola when fed to laboratory rats, in one instance, caused liver enlargement up to 16%. However, this finding did not warrant further investigation by the applicant.

It is recognised that the percentage of modified DNA ingested by the rats in the mash preparation administered in the laboratory experiment was significantly higher than that which humans would ingest with the consumption of highly-refined canola oil. However, this raises further questions, including:

(i) the scientific rigour of the tests conducted by applicants;[22]

(ii) the standard of current tests constructed to extrapolate valuable information regarding possible human health effects;

(iii) the suitability of commercial interests to determine test models and procedures;

(iv) the value of animal models to ascertain possible human health effects; and,

(v) the right to cause animal distress for unusable test information.

These questions are sustained by the Public Health Association of Australia's review of the tests data submitted for application A346 for the insect resistant corn line MON810 finding:

(i) the *Bt* protein (produced from the insertion of the *cry1(A)b* gene into the corn genome) designed to rupture the gut of lepidopteran insects had not been tested on humans; and,

(ii) testing procedures did not include the ingestion of raw plants or waste material by other organisms in the human food chain and whether human ingestion of such organisms posed a health risk.

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[19] Australia New Zealand Food Authority Application A346, Food produced from insect-protected corn line MON 810. Draft risk analysis report at: http://www.anzfa.gov.au/documents/gen10_00.htm

[20] Australia New Zealand Food Authority Application A362, *Food derived from glyphosate-tolerant corn line GA21*, Draft risk analysis report at: http://www.anzfa.gov.au/documents/gen12_00.htm.

[21] Australia New Zealand Food Authority Application A363, *Food produced from glyphosate-tolerant canola line GT73*. Draft risk analysis report at: http://www.anzfa.gov.au/documents/gen13_00.htm

[22] Reports state that test replication for canola line GT73 was too small to constitute a statistically significant sample size. The composition of only two samples were analysed. Scientists from the Public Health Association of Australia stated "with such low numbers it is almost a foregone conclusion that a statistically significant difference will not be found between the GM food and the non-GM food". See G Strong, 'GM Food tests 'inadequate', *The Age*, 28 October 2000 http://www.theage.com.au/news/20001029/A13301-2000Oct28.html.

The scientific data supporting Application A362 for 'Round-up ready' corn acknowledged that the line possessed a modified protein in which two amino acids differed from those found in non-modified corn. However, further details of these differing amino acids were not supplied on the grounds of commercial in-confidence.

4.3 *ECOLOGICAL SUSTAINABILITY*

The Australian Conservation Foundation's Gene Ethics Network recommended:

> The Objects of the GT Bill 2000 should also be amended to include the principle of ecological sustainability, to ensure genetically engineered organisms do not contribute to the long-term destabilisation and decline of our food and fibre production systems, the natural environment and biological diversity.

The Australian Democrats support the inclusion of ecological sustainable principles in the regulation and promotion of gene technologies in Australia.

5. State 'opt-out' clause

The Democrats believe that a successful gene technology regulatory system must allow choice for consumers. This choice is facilitated most effectively by an 'opt out' provision for states with clear interests and concerns primarily in the regulation of agricultural GMOs. An 'opt-out' clause provides domestic market differentiation and clear 'safehavens' for GM free production which consumers can clearly identify and place confidence in.

A state 'opt out' clause would not prevent industry pursuing isolated identity preserved production lines in States or Territories pursuing GMO production and processing, though allow for areas with natural geographic or other advantages to pursue GM-free products.

The Democrats have acknowledged that a moratorium would have to be carefully considered as a moratorium may hinder positive Australian innovation and ecological sustainable gene technology applications.[23]

Section 99 provides that:

> The Commonwealth shall not, by any law or regulation of trade, commerce, or revenue, give preference to one State or any part thereof over another State or any part thereof.

While the Australian Government Solicitor provided advice that there was:

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[23] N Stott Despoja, Press Release 00/357 'Democrats call for ANZFA labs not just glossy PR', 19 June 2000. http://www.democrats.org.au/media/display.htm?id=659

> ...a significant possibility that Commonwealth legislation to regulate GMOs would be regarded as a law of trade and commerce for the purposes of section 99 and the opt-out provision in that legislation would infringe that constitutional limitation.[24]

The Democrats acknowledge the legal advice supplied to the Tasmanian Government concluding that an 'opt out' provision for States and Territories from the regulatory system, as proposed under the OGTR, is in keeping with WTO requirements:

> The advice obtained indicates that the opt-out as proposed in Principle 7(d) probably would not offend against section 92 of the Constitution. Section 92 of the Constitution requires that trade, commerce and intercourse between the States be free. In order for a law to discriminate against interstate trade it must be protectionist in the relevant sense, by placing a discriminatory burden on trade in order to protect trade within the State (*Cole v Whitfield (1988) 165 CLR 360* is authority for this proposition).
>
> Accordingly, where a state has declined to allow release within its own territory of a GMO, that would apply to trade within the State and trade with other States, therefore the law would not be protectionist in the relevant sense.
>
> In any event, legal authority exists for the principle that laws for the protection from a real danger or threat, or some other legitimate object of a State, not offend section 92, if the law is appropriate for the achievement of that objective.
>
> Section 99
> In order to offend section 99 of the Constitution, two elements must be made out. Firstly a law or regulation must be one of trade, commerce or revenue. Legal opinion obtained by Tasmania suggests that, as the laws in the *Gene Technology Bill 2000* are to regulate the safe release of GMOs within Australia, it is not a law that can be classed as 'trade or commerce' for the purposes of section 99.
>
> World Trade Organisation Agreements
> As yet no jurisprudence exists on GMOs in the context of World Trade Organisation (WTO) Agreements.[25]

The Australian Democrats, therefore, maintain that a State and Territory 'opt out' provision is the most appropriate mechanism to ensure domestic and export market diversity while effectively containing the impact of gene technologies on the environment.

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[24] IOGTR, Submission No.77 at page 159

[25] Tasmanian Government, Submission 89 at page 12-14.

6. The Gene Technology Regulator

> This will be a position of great power, not only within the scientific community but also with immense responsibilities for the long-term safety of the Australian and world environment, given that GMOs, once released, may not be able to be recalled.[26]

The Australian Democrats believe that, in order to maximise the likelihood of public confidence in Australia's gene technology regulatory system the Gene Technology Regulator should be required to possess the following characteristics and abilities:

(i) *Independence*;
The Regulator must be at arms length from Government its research wing the CSIRO and independent of sectoral interests (ie, not holding employment with sectoral interests a minimum of 5 years before assuming the position, and not being employed by a sectoral interest for more than 5 years in total).

The position must be of a fixed, non-renuable tenure to ensure independence.

(ii) *Contributor to public debate*;

The Regulator must be able to make public his or her views on any issue relating to gene technology and its regulation.

(iii) *Powerful 'watchdog'*

The regulator must able to have the power to provide a Commissioner/Ombudsman of gene technology service. The regulator must possess wide ranging powers to commission research and surveillance and propose legislation to ensure public and environmental safety, monitor and enforce responsible application of gene technology.

7. Public Participation & the Community Consultative Committee

> It is of course, impossible to neatly separate the technical, community, ethical and environmental aspects of the new technology. This was eventually recognised, even by the early biased GMAC, and specialists in most such issues were eventually appointed to GMAC. Thus the committee structure, or the committee responsibilities, proposed under the present Bill must be changed – either a single committee should be empowered to cover all aspects listed in the Bill or all three committees should consider and report to the Regulator on all applications for GM work.[27]

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[26] A Gibbs, submission 70 at page 2.

[27] A Gibbs, Submission No 70, at page 2.

The Gene Technology Technical Advisory Committee (GTTAC), The GT Community Consultative Committee (GTCCG) and the Gene Technology Ethics Committee (GTEC) are the engines of the new regulatory authority and will over see public participation in the regulation of Australian gene technology.

> they [the committees] will considerably diminish public involvement in gene technology regulation compared with the existing GMAC system[28]

The Australian Democrats, therefore, conclude for the afore-mentioned reasons that the regulatory system, outlined in the Gene Technology Bill 2000, does not provide the protection that the community requires and as a result fails to provide community confidence, domestically or internationally, on which Australia's biotechnology research community and related agri-industries rely.

7. ***Summary of Recommendations contained in the Chair's Report;***

The Australian Democrats support the recommendations contained in the Chair's Report with the following exceptions and comments:

CHAPTER 3

the relevant State and Territory animal welfare legislation and the NHMRC code of practice for the care and use of animals for scientific purposes, be examined to determine whether more stringent provisions need to be applied with respect to animals and genetic modification.

(i) The Australian Democrats believe current animal welfare legislation and NHMRC codes of practice are inadequate to ensure the ethical scientific use of animals, as they are often not enforceable

The Australian Democrats support increasing regulation of genetic modification practices and testing involving animals, increasing animal welfare protection and translating the NHMRCs current voluntary 'guidelines' into law.

that an independent organisation conduct a national public education campaign to provide information on the benfits and risks of gene technology, drawing on, but not limited to, the expertise of scientists, primary producers, academics and consumer organisations.

(ii) The Australian Democrats consider such a role as integral to an effective regulator. Rather than another independent entity provide such information, the Australian Democrats recommend that Bill be amended

[28] *Ibid.*

to ensure that the Regulator is first and foremost, the protector of public health and the environment, and instigator of public interest and independent information distribution.

CHAPTER 4

that an individual who has worked for a regulated entity be precluded from holding the office of Gene Technology until the expiration of a two-year period.

(iii) The Australian Democrats consider this recommendation worthy of consideration and further examination.

In some cases the passing of two years, after a life career in a regulated scientific body, may not remove the shared knowledge, political and ethical values and vested interests established in a career of such standing.

Similarly employment in an industry does not guarantee sympathy with certain industry practices or directions.

The Australian Democrats further recommend:

(iv) That the Bill be amended to require that the Gene Technology Community Consultative Group is a Committee of equal standing and funding to the GTTAC and and GTEC.

(v) That the Bill be amended to grant the Gene Technology Community Consultative Committee greater public participation powers.

(vi) That the Regulator accept State and Territory self-determination to quarantine against genetically modified organisms or to 'opt-out' of the OGTR if deemed desirable and to facilitate dialogue and agreements between states to pursue GM-differentiated products.

(vii) That the ANZFA is fitted with the independent laboratory facilities to review and test applications for release of genetically modified food products.

Senator Stott Despoja
Deputy Leader Australian Democrats
Spokesperson for Biotechnology
Full Member of the Committee for
the purposes of the Inquiry

Senator Andrew Bartlett
Spokesperson for the Environment
Participating Member for this Inquiry

SUPPLEMENTARY REPORT

THE GENE TECHNOLOGY BILL 2000

AUSTRALIAN GREENS SENATOR BOB BROWN

I support the vast majority of the recommendations made by the Senate Committee on the Gene Technology Bill 2000 (**"Bill"**). The report's recommendations constitute a significant improvement on the original Bill. The recommendation to include the Precautionary Principle in the Objects of the Bill is an essential recognition of the significant risks inherent in gene technology. However the report's recommendations do not match the degree of uncertainty that surrounds GMOs and their release into the wider environment.

The risk to human health and the environment posed by gene technology is poorly understood and is the subject of scientific controversy at the highest levels. Furthermore, the economic risk that GMOs pose to Australia is underestimated. I strongly object to the assumption that the adoption of GE will have automatic benefits for Australia's farming community, while internationally the consumer preference for GE-free is expanding rapidly.

In many cases, for example in the need for all GMOs to be licensed, for proponents to obtain adequate insurance to cover any consequences of their GMO releases, and for there to be disclosure provisions, the recommendations are not sufficiently strong to meet the Bill's central object. Recommendations suggesting rather than prescribing appropriate action are inadequate given the significant shortcomings in the self-regulating industry's *modus operandi* to date. In other critical areas such as the need for a five-year freeze and to sign and implement the Biosafety Protocol, where clear recommendations for action are required, the report is silent.

In order to achieve the Bill's object 'to protect health and safety of people and to protect the environment' the following recommendations should be added to the report:

A five-year freeze

I support a moratorium, of at least five years, to apply to the import of all GM products and the release of all GMOs in Australia. The Australian environment and economy should not be subject to the risks that the release of GMOs poses in a climate of great uncertainty. Once released, self-replicating GMOs offer no possibility for recall. No evidence exists on the long-term impacts to human health of the consumption of GE foods or to the environment of the release of GMOs. Time is required to evaluate the practical experience of other countries that have adopted GE. Time is also required to observe the market response to GMOs. If the international consumer preference for GE-free continues to grow (especially in key Australian markets such as Europe, Asia and the Middle East), there may be a significant cost

associated with exposing Australian farmers to the risk of losing their GE-free status permanently.

Recommendation

That Australia implement a 5-year freeze on the import of all GM products and the release of all GMOs.

The Biosafety Protocol

The Biosafety Protocol has been agreed to by 130 countries. The Protocol will establish internationally agreed environmental protection measures for trade in GMOs and promote informed handling of GMOs to minimise risks associated with oversight. As a member in good standing of the United Nations Convention on Biodiversity, and as a trade partner of many countries increasingly concerned about the GE status of imports, it is essential that Australia sign and implement the Biosafety Protocol as soon as possible.

Recommendation

That Australia sign and implement the Biosafety Protocol.

State, Territory and Local Government Opt-out Clauses

The Bill makes no provision for State, Territory or local governments to prohibit the release of GMOs within their jurisdictions. Communities should have the right to determine whether they are willing to accept the risks associated with the release of GMOs. It is important to have a centralised regulatory system where the primary responsibility for regulation of GMOs rests within the Gene Technology Regulator ("**Regulator**"). However State, Territory and Local Governments must have the power to prevent the release of GMOs in their jurisdictions where they determine that the proposed dealing is inappropriate.

Recommendation

That the Bill be amended to provide State, Territory and local governments with the explicit power to prohibit dealings with any GMOs or GM products within their respective jurisdictions.

A One-Stop Shop (the OGTR to be responsible for all GMOs)

I am concerned that the creation of a multi-layered regulatory system may result in inadequate government oversight being provided for certain dealings with GMOs and GM products. The Bill's provision for extensive exemptions from license requirement (for example for tertiary institutions and State agencies) is unacceptable.

Recommendation

That the Bill be amended to require all dealings with GMOs (including transgenic GMOs involving human DNA) to be licensed by the Regulator. There should be a single licensing procedure that applies to all GMOs. The Bill should be amended to remove all exemption provisions and the provisions relating to notifiable low risk dealings and the GMO Register. The definition of GMOs should be amended to ensure that all GMOs are required to adhere to the licensing procedure.

Recommendation

That prior to the enactment of the Bill, further consideration be given to the feasibility of introducing a 'one-stop shop' model, having regard to the operational effectiveness of the proposed 'gap-filler' arrangements. If the 'gap-filler' arrangements are retained, the Bill should be amended to require the Regulator to consult with existing regulatory agencies about all proposed dealings with GMOs and GM products. The Bill should be amended to ensure that the Regulator and all State, Territory and local governments have the power to prevent the approval of a dealing with a GMO or GM product by another regulatory agency which they consider is appropriate.

Insurance for GMO dealings

The persons involved in the development, use and release of GMOs and GM products should be responsible for the adverse effects that these dealings have on the environment and on the interests of other members of the community. Distribution of the costs associated with the use of gene technology amongst those persons who benefit from its application is dependent upon the availability of suitable insurance.

The Insurance Council of Australia has noted that:

"There is a lack of reliable loss experience history (associated with genetic engineering) and means for calculation of likely loss patterns. This absence of data inevitably promotes a fundamental doubt over the insurability of such risks."[1]

So persons involved in the development, use and release of GMOs and GM products may not have satisfactory insurance.

Recommendation

That the Bill be amended to require all persons responsible for dealings with GMOs to have insurance to cover the risks associated with the dealings.

Recovery for loss and environmental harm

Primary producers who are reliant on their GE-free status should not suffer economically as a result of genetic contamination from dealings with GMOs and GM products. Organic and conventional non-GE primary producers may have difficulties

[1] Submission No.1, p.2 (Insurance Council of Australia)

recovering damages for genetic contamination in tort. Persons should have the right to recover adequate compensation for loss or damage suffered as a consequence of genetic contamination.

Recommendation

That the Bill be amended to ensure that persons who suffer loss or damage as a consequence of a breach of the Act have the right to recover compensation in an action against the persons responsible.

Recommendation

That the Bill be amended to ensure that persons responsible for the release of GMOs into the environment are liable for any consequent damage to the environment.

Recommendation

That the Bill be amended to provide for the establishment of a compensation fund for the purposes of:

(a) compensating persons who suffer loss or damage as a result of the development, use or release of GMOs and GM products; and

(b) remedying any damage done to the environment as a result of the development, use or release of GMOs or GM products.

This fund should be financed from contributions made from those involved in the development, use and distribution of GMOs and GM products.

Full Site Disclosure of all GMO dealings

The recommendations made by the Committee do not guarantee that commercial in confidence information will not compromise the objectives of the Bill and the transparency of the regulatory regime. Anything short of full disclosure of all dealings with GMOs is unacceptable.

Recommendation

That the Bill be amended to require all applications for the approval of a dealing with a GMO to disclose the size and location of the proposal, and to require that these details be made publicly available.

Direct notification of a proposed GMO dealing involving intentional release to local residents and producers

Non-GE producers are exposed to the economic risk of genetic contamination by all GMO releases. It is therefore necessary that all persons residing or involved in agricultural industry within the distance over which GMO gene exchange could possibly take place are directly notified of all proposed dealings involving an

intentional release of a GMO into the environment. Furthermore, these persons should have the opportunity to make submissions on the proposed GMO dealing.

Recommendation

That the Bill be amended to require the Regulator to notify all persons who reside within a 15km radius of the location of a proposed dealing involving the intentional release of a GMO into the environment of the proposal, and invite their submissions on the proposal.

Senator Bob Brown
(AG, Tasmania)

APPENDIX 1

ORGANISATIONS AND INDIVIDUALS WHO PRESENTED WRITTEN PUBLIC SUBMISSIONS AND SUPPLEMENTARY INFORMATION TO THE COMMITTEE

1 Insurance Council of Australia (NSW)

2 Mr David de Havelland (NSW)

3 NT Bio Dynamic Network (NT)

4 Mrs S Stafford (SA)

5 National Council of Women of Australia (VIC)

6 Consumers' Association of South Australia Inc (SA)

Tabled at public hearing 22.8.00

- The safety of GE foods : Reasons to expect hazards and the risk for their appearance

7 Ms Dorothy Pottage (VIC)

8 Serve-Ag Pty Ltd (TAS)

Supplementary information

- Answers to questions on notice from hearing on 23 August
- Response to questions from hearing on 23 August, dated 21.9.00, including paper on Agricultural Biotechnology by George Bruening

9 Heritage Seed Curators Australia Inc (SA)

Tabled at public hearing 22.8.00

- Human Insulin Problems
- Countries with No to GE

Supplementary information

- Herbicide resistance is out of control say Canola farmers, copy of article from Cropchoice News, provided 23.8.00

10 Tasmanian Alkaloids Pty Ltd (TAS)

Tabled at public hearing 23.8.00

- Tasmanian Alkaloids, information brochure
- Poppy Growers Bulletin, No.41, August 2000

11 Canberra Consumers Inc (ACT)

12 Dr Sam Bridgeford (NSW)

13 Mr Andrew Walker-Morison (VIC)

14 Mr Elton Cleary (TAS)

15 Mr Bob Holderness-Roddam (TAS)

16 Mr Arnold Ward (SA)

17 National Genetic Awareness Alliance (VIC)

18 Mr George McLean (ACT)

19 The Environment Centre of WA (WA)

20 Ms Lisa McDermott (QLD)

21 Ms Ute Mueller (TAS)

22 Mr Greg Whitten (TAS)

23 Australian Law Reform Commission (NSW)

24 Bio-Dynamics Tasmania (TAS)

25 Mr Andrew Macintosh (TAS)

Supplementary information

- Several documents regarding the risks associated with the use of gene technology

26 Southern Cross University (NSW)

27 Ms Vicki Brooke (NSW)

28 Ms Patsy Hemsworth (VIC)

29 Mr Dallas Fraser and Mr David Lowe (QLD)

30 Mr James Langmead (TAS)

31 J Grevillea (NSW)

32 Avcare – National Association for Crop Production and Animal Health (ACT)

Tabled at public hearing 25.8.00

- The Precautionary Principle - 'Nothing ventured, nothing gained"? Avcare Insights, Vol 1, 2000
- Precautionary Principle, Dr Elizabeth Whelan, American Council on Science and Health, 23 May 2000
- Avcare Guidelines for GM Crop Field Trials in Australia, July 2000
- Agrifood Awareness Australia, information folder
- ACIL Fact Sheets: Gene Technology

(This material was also provided in information folders on 1 October)

Supplementary information

- Insurance coverage of member companies, dated 8.9.00
- Supplementary submission, dated 26.9.00

33 Ms Toshi Knell (NSW)

34 Australian Centre for Environmental Law (ACT)

35 GE-Free Tasmania (TAS)

36 Valley Seeds Pty Ltd (VIC)

37 Mr Rick Calitz (TAS)

38 Mr Jesse Sleeman (SA)

39 Department of Primary Industries, Water and Environment (TAS)

Supplementary information

- Letter from Minister supporting statement at hearing, dated 12.9.00

40 Australian Conservation Foundation (VIC)

41 Grains Research and Development Corporation (ACT)

42 Florigene Limited and Nugrain Pty Ltd (VIC)

43 Agrifood Awareness Australia (ACT)

44 Seed Industry of Australia (ACT)

45 Ms Kathy Liddell (VIC)

46 Mr Niko Antalffy (NSW)

47 Ms Ieva Gay (NSW)

48 Ms Sharon Kyriacou (NT)

49 Mr Ian Dowden and Ms Kathleen Canning (TAS)

50 Consumer Food Network of the Consumers' Federation of Australia (QLD)

51 Friends of the Earth (Fitzroy) (VIC)

52 Mr Michael Dickson (NSW)

53 Professor Richard Roush, Waite Institute, University of Adelaide (SA)

Supplementary information

- Response to questions from hearing on 22 August, dated 22.9.00

54 Organic Federation of Australia Inc (VIC)

Tabled at public hearing 23.8.00

- Collection of articles and graphs

Supplementary information

- GM genes 'can spread to people and animals', copy of article from Independent, provided 23 August 2000
- Premium for 150 000 tons of Aussie Canola, copy of article from Cropchoice News, provided 24 August 2000
- Segregation costs in California applied to GE rice, provided 8 September 2000

55 Ms Leila Huebner (VIC)

Supplementary information

- Supplementary submission, dated 12.9.00

56 Australian United Fresh Fruit & Vegetable Association Ltd and Fresh Produce Watch (NSW)

57 Mr John Todd (NSW)

58 Australian Biotechnology Association (VIC)

Tabled at public hearing 24.8.00

- Summary of the overwhelming broad scientific consensus that 'genetic modification' poses no strictly distinct risks over conventional breeding
- Guidelines for EU application of the Precautionary Principle

Supplementary information

- Information provided 25 August 2000:

  GM-food: Secret Scientists or Obfuscatory Opponents? David Tribe;

  Applying the Precautionary Principle to Genetically Modified Crops, Indur M. Goklany, Policy Study No 157, August 2000, CSAB, Washington University

in St. Louis, with News Release;

World Food Prospects: Critical Issues for the Early Twenty-First Century, Per Pinstrup-Andersen et al, IFPRI, October 1999, and

Assorted graphs from IFPRI report.

- Comprehensive precaution versus tunnel vision precaution, provided 26 August.
- Information provided 28 August:

  Public Good Research Example – nutriceutical/functional food;

  The Political Economy of Agricultural Biotechnology for the Developing World, Klaus M Leisinger.
- Information provided 29 August:

  Documentation of herbicide tolerant mutant plant varieties on the market in Australia and elsewhere;

  Comments relating to BSE.
- Information provided 30 August:

  Documentation of the low risks of possible movement from antibiotic resistance markers from GM-food to gut bacteria;

  Comments on mobile DNA and risks, and transposable elements and retroelements;

  Health GMO release example, copy of draft paper 'Vaccination against typhoid fever: potential for a GMO release'.
- Perspective on food policy importance of GMOs in India and the Third World in general, provided 31 August.
- Further comments on the status of the 'precautionary principle' in International Law, provided 3 September.
- Examples of moving genes, provided 6 September.
- Comments re liability, provided 9 September.

59 Meat and Livestock Australia Limited (NSW)

60 District Council of Grant (SA)

61 Aventis CropScience Australia Pty Ltd (VIC)

Tabled at public hearing 23.8.00

- Licence agreement, dated 16.9.99
- Revised licence, dated 5.6.00
- Tasmanian Quarantine Act Declaration, legal advice by Deacons, dated 15.8.00
- In Vigor Hybrids, Seed Production Overview, AgroEvo
- Crop biotachnology and genetic improvement, Aventis
- New ideas for Australian agriculture and beyond, Avenits

Supplementary information

- Response to questions from hearing on 22 August 2000, dated 5.9.00

62 Australian Cotton Growers Research Association and Cotton Research & Development Corporation (NSW)

63 AWB Ltd (VIC)

64 Mr Patrick Hockey (VIC)

65 Mr Adrian McKinley (NSW)

66 M/s Strider (NT)

67 Mr Graig Gange-Holloway (VIC)

68 Ms Herminie Swainston (NSW)

69 Friends of the Earth (Perth, WA Group) (WA)

70 Professor Adrian Gibbs (ACT)

71 Australian Food and Grocery Council (ACT)

Supplementary information

- Response to questions from hearing on 25 August 2000, dated 28.9.00

72 Mr Patrick M Guerin (NSW)

73 Ms Janet Ablitt (VIC)

74 Ms Josephine Firns (SA)

75 Ms Nannette George (VIC)

76 NSW Farmers' Association (NSW)

77 Department of Health and Aged Care (ACT)

(Interim Office of the Gene Technology Regulator)

Tabled at public hearing 14.8.00

- Part 2: Term of Reference J relating to 'opt-out' provision for States and Territories
- International comparisons relating to different uses with GMOs and GM products
- Copies of overheads used at hearing

Document provided 18.8.00

- Report to the Minister for Health and Aged Care, Alleged breach by Aventis CropScience, dated 28.6.00 (publication authorised by Committee on 22.8.00)

Tabled at public hearing 25.8.00

- Answers to questions on notice from hearing on 14 August
- Draft Gene Technology Regulations 2000, August 2000, and Explanatory Guide
- Draft Model State legislation
- Gene Technology regulations in Australia will be among world's best practice, media release, IOGTR, 25 August 2000
- Report to Minister on alleged breach by Aventis, advice from Australian Government Solicitor, 1 August 2000

Supplementary information

- Response to questions from hearing on 25 August, dated 18 September (publication of Attachment A authorised by Committee on 12.10.00)
- Report 'A model for cost-recovery in the Office of the Gene Technology Regulator', KPMG Consulting, dated September 2000, provided on 5 October
- Responses to questions dated: 18 August; 26 September; 3 October; 5 October; 11 October and 17 October 2000
- Additional information dated 12.10.00

78 Institute of Public Affairs Ltd (VIC)

79 Mr Kim Healy (VIC)

80 Mr Scott Molloy (QLD)

81 South Australian Farmers Federation (SA)

82 Environs Kimberley (WA)

83 Mr Steven Bailie (QLD)

84 Queensland Government (QLD)

Supplementary information

- Additional information following the hearing 25 August 2000 dated 1.9.00

85 ACF GeneEthics Network (VIC)

Tabled at public hearing 24.8.00

- Media release, Goats with human genes unregulated, 24.8.00
- Assorted letters and articles
- Powers of Local Councils to regulate GEOs, letter from NSW Environmental Defender's Office, dated 12.8.00
- First Australian Consensus Conference, Lay Panel report, March 1999
- Genetic engineering and liability insurance, Swiss reinsurance

Supplementary information

- Response to questions from hearing on 24 August, dated 11.9.00

86 World Wide Fund for Nature and The Humane Society International (ACT)

87 Mr and Mrs Richard Underwood (VIC)

88 National Farmers' Federation (ACT)

89 Tasmanian Government (TAS)

90 DuPont Technical Centre (NSW)

Tabled at public hearing 25.8.00

- Seeds of opportunity: An assessment of the benefits, safety, and oversight of plant genomics and agricultural biotechnology, Committee on Science, US House of Representatives, 13 April 2000

91 Western Australian Government (WA)

92 Ms Teresa Sutton (VIC)

93 Dr Kate Clinch-Jones (SA)

94 Monsanto Australia Ltd (VIC)

95 Mr Dick Adams MP (TAS)

96 Ms Fiona Murdoch (QLD)

97 Mr Edward Nieman (WA)

98 Novartis Australia Pty Ltd (NSW)

99 Ms Kathy Harris (NSW)

100 Professor Peter Gresshoff (QLD)

101 Ms Frances Murrell (VIC)

102 CSIRO (ACT)

Supplementary information

- Rabobank Group: Code of Conduct on Genetic Modification, material from net site, provided 29 August 2000.
- Precautionary principle/approach in overseas GT legislation, Canadian paper, provided 30 August 2000
- The precautionary principle: Further references, provided 8 September
- Response to questions from hearing on 25 August, dated 20 September
- 'Angst ascendant? Changing consumer attitudes to biotechnology', Dr K Baghurst, received 18 October 2000
- Copy of overheads – Changing consumer attitudes to biotechnology – Dr K Baghurst, received 18 October 2000

103 National Health and Medical Research Council (NHMRC) (ACT)

104 Dow AgroSciences (NSW)

105 Australian Cotton Co-operative Research Centre (NSW)

106 Gene Ethics Network - Perth (WA)

107 Food Industry Council of Tasmania (TAS)

108 Ms Margaret Waspe (VIC)

Supplementary information

- Additional information dated 29.8.00
- Additional information dated 12.9.00

109 Dr Anne Campbell (ACT)

110 South Australian Government (SA)

111 Dr I Furzer (NSW)

112 Ms Margaret Zehntner (NT)

113 Ms Margretta Sculthorp (NSW)

114 Ms Brenda J Rosser (TAS)

115 Victorian Government (VIC)

116 Mr Nicholas Tonti-Filippini (VIC)

117 Mr and Mrs de Burgh-Day (TAS)

118 GeneEthics Sydney (NSW)

119 Mr and Mrs L Mendoza (VIC)

120 Ms Cristina Jovellan

121 Ms Kirrily Jordan (NSW)

122 Residents Against Genetically Engineered Food (NSW)

123 Ms Anne Redsell (VIC)

124 Mr and Mrs M Blake (WA)

125 Mr Steven Bailie (QLD)

Additional Information

Dr T J Higgins, Chief Research Scientist, CSIRO Plant Industry – Additional information following presentation given to the Committee on 14 August, dated 8 September 2000.

APPENDIX 2

WITNESSES WHO APPEARED BEFORE THE COMMITTEE AT PUBLIC HEARINGS

Monday, 14 August 2000 at 9.05 am, Senate Committee Room 2S3, Parliament House, Canberra

Dr T J Higgins, Project Leader, Plant Industry, CSIRO
(Background briefing on gene technology and genetic modification)

Department of Health and Aged Care

Mr David Borthwick, Deputy Secretary, Department of Health and Aged Care

Ms Elizabeth Cain, Head, Interim Office of the Gene Technology Regulator (IOGTR)

Mr Terry Slater, National Manager, Therapeutic Goods Administration

Dr Andina Faragher, Secretary, Genetic Manipulation Advisory Committee

Ms Andrea Matthews, Partner, Matthews Pegg Consulting, Legal/Policy Adviser to IOGTR

Dr Sue Meek, Executive Director, Science and Technology, Department of Commerce and Industry, Western Australia

Mr Denzil Scrivens, Acting Director, Economic Policy, Department of the Premier and Cabinet, Queensland

Mr Peter Cronin, Principal Policy Officer, Economic Policy, Department of the Premier and Cabinet, Queensland

Tuesday, 22 August 2000 at 9.10 am, Ballroom 4, Stamford Grand Hotel, Moseley Square, Glenelg, Adelaide

South Australian Farmers Federation

Mr Gary Burgess, Vice-Chair, GMO Task Force

Heritage Seed Curators Australia Inc

Mr Bill Hankin, Vice-President

Ms Leila Huebner

Professor Richard Roush, Director, Cooperative Research Centre for Weed Management

Consumer's Association of South Australia

Mrs Elaine Attwood, Food Policy Officer, and National Adviser, Consumers Affairs, National Council of Women of Australia

Aventis CropScience Pty Ltd

Mr Oliver Duroni, Managing Director

Ms Naomi Stevens, Public & Government Affairs Manager

Mr George Brownbill, Government Relations Consultant, Acil Consulting

Wednesday, 23 August 2000 at 9.10 am, Antarctic Cooperative Research Centre Centenary Building, University of Tasmania, Hobart

Organic Federation of Australia Inc

Mr Scott Kinnear, Chairperson

Mr Tony Scherer, Member

GE-Free Tasmania

Mr Greg Whitten

Mr Andrew Macintosh

Ms Georgia Miller

Serve-Ag Pty Ltd

Mr Buz Green, Chief Executive

Tasmanian Alkaloids Pty Ltd

Mr Brian Hartnett, Managing Director

Tasmanian Government
Department of Primary Industries, Water and Environment

Hon David Llewellyn, Minister for Primary Industries, Water and Environment

Mr Glenn Appleyard, General Manager, Food, Agriculture and Fisheries Division

Mr Rodney Gobbey, Director, Food Quality and Safety

Ms Marion March, Policy Analyst, Food Quality and Safety

Mr Carl Fulford-Smith, Senior Policy Analyst, Department of Premier and Cabinet

Thursday, 24 August 2000 at 9.10 am, Conference Room, CSIRO Biomolecular Research Institute, 343 Royal Parade, Parkville, Melbourne

Australian Biotechnology Association

Dr David Tribe, Vice President and Director

National Genetic Awareness Alliance

Ms Margaret Jackson, Convenor

Ms Maureen Minchin, President Victorian Branch, Australian Lactation Consultants Association

AWB Ltd

Mr Gerard McMullen, Manager, Quality & Assurance

Mr Andrew McConville, Government Relations Manager

Australian Conservation Foundation

Mr Michael Kerr, Legal Adviser, ACF

ACF GeneEthics Network

Mr Bob Phelps, Director

Florigene Ltd and Nugrain Pty. Ltd

Dr Michael Dalling, Director, Florigene, Director Nugrain

Friday, 25 August 2000 at 9.05 am, Senate Committee Room 2S3, Parliament House, Canberra

Australian Centre for Environmental Law

Mr Donald Anton, Director

Avcare Ltd.

Mr Claude Gauchat, Executive Director

Mr Colin Sharpe, Director, Scientific & Regulatory Affairs (Crop Production)

Dr William Blowes, Member, Biotechnology Committee – Avcare, and Monsanto

Mr George Brownbill, Government Relations Consultant, ACIL Consulting

Mr Leo Hyde, Research & Development Manager, DuPont (Australia) Pty Ltd

Dr Matt Cahill, Regulatory Specialist, Dow AgroSciences Aust. Ltd

Mr Rowley Winten, Development Manager, Novartis CP Protection A/Asia Pty Ltd

Australian Food and Grocery Council

Dr Geoffrey Annison, Director, Scientific and Technical

Mr Tony Downer, Assistant Director, Scientific and Technical

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Mr Terry Slater, National Manager, Therapeutic Goods Administration

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APPENDIX 3

REGULATION OF GENE TECHNOLOGY – INTERNATIONAL COMPARISONS

- European Community
- United Kingdom
- Germany
- New Zealand
- Japan
- South Africa
- United States of America
- Canada

Document provided by the IOGTR

Regulation of Gene Technology in the

EUROPEAN COMMUNITY

SUMMARY

- The EC has issued a number of directives that relate to different uses with GMOs and GM products.
- In relation to the use of GMOs, there are three relevant directives:
  - contained use of GM micro-organisms;
  - deliberate release of GMOs into the environment and placing on the market; and
  - protection of workers from the risks of exposure to biological agents.
- In relation to GM products, there are also a number of relevant directives:
  - additives in feeding stuffs;
  - medicinal products; and
  - novel food.

Contained work with GMOs	
Responsible agency	• The Council of the European Communities.
Legislation	• Council Directive 90/219/EEC for contained use of genetically modified micro-organisms.
Intentional releases of GMOs in the environment	
Responsible agency	• The Council of the European Communities.
Legislation	• Council Directive 90/220/EEC regulates the deliberate release of GM microorganisms into the environment.
Coverage of the legislation	• The deliberate release of GMOs into the environment.

Assessment process for intentional releases of a GMO into the environment (field trials and general releases)	• Member states must ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise form the deliberate release or placing on the market of GMOs. • Member states shall designate a competent authority responsible for carrying out the requirements of the Directive. • A person must submit notification about the proposed release including a technical dossier with all of the information annexed to the Directive and an evaluation of the impacts. • The competent authority must examine the application for compliance with the directive and evaluate the risks posed by the release – this must be a science based consideration. • The competent authority may consult on any aspect of the proposed deliberate release. • A notification may only proceed with the release having received written consent and in conformity with any conditions required in the consent. • The competent authority shall send to the commission the results of the decision and the Commission shall forward summaries to other Member States.
Consideration of ethical issues	• The Directive does not make any reference to the need for ethical matters to be considered.
Public consultation on applications	• The Directive provides that the competent authority may consult on any application in relation to a deliberate release. There is not, however, any express or mandatory requirement for public consultation.
Conditions that may be applied	• The Directive provides that competent authorities may grant approvals subject to conditions.
Monitoring, surveillance and enforcement powers	• The Directive provides that Member States shall ensure that the competent authority organises inspections and other control measures as appropriate to ensure compliance with the Directive.
Penalties	• The Directive does not include any penalties as it is up to individual Members States as to how they implement the Directive (through legislation) and the penalties imposed.

Liability for contamination	• The EC directive does not deal explicitly with liability, including liability for contamination. • To ascertain liability, the general law in each jurisdiction would need to be applied. However, the EC has published a White Paper on Environmental Liability which is relevant.
Policy and Governance issues	
Expert Committees	• Not applicable
Research	• Not applicable
Other	
The precautionary principle	• The Directive does not explicitly reference the precautionary principle
Cost recovery	• Not applicable
Moratorium	• Not applicable
Other	• Amendments to the Directive have recently been proposed. The EC is yet to vote on the amendments.

REGULATION OF GENE TECHNOLOGY IN THE

UNITED KINGDOM

<table>
<tr><td colspan="2">SUMMARY

• The UK has implemented EC Directive 90/110/EC through Part VI of the Environment Protection Act 1990 and the issuance of the following regulations:
- Genetically Modified Organisms (Contained Use) Regulations 1992, as amended in 1996 and 1998;
- Genetically Modified Organisms (Deliberate Release) Regulations 1992 (SI 1992/3280); and
- Genetically Modified Organisms (Deliberate Release) Regulations 1995 (SI 1995/304).
• There appears to be no statutory requirements for an interface between the regulation of GMOs and GM products.</td></tr>
<tr><td colspan="2">Contained work with GMOs</td></tr>
<tr><td>Responsible Agency</td><td>• The Health and Safety Executive (HSE). The HSE shapes and implements policy for the Health and Safety Commission, whose members are appointed by the Secretary of State for the Environment.</td></tr>
<tr><td>Legislation</td><td>• Genetically Modified Organisms (Contained Use) Regulations 1992, as amended in 1996 and 1998.

• Contained use is defined as any operation in which organisms are genetically modified or in which GMOs are cultured, stored, used, transported, destroyed or disposed of and where physical barriers (possibly combined with chemical and/or biological barriers) are used to limit their contact with the general population and the environment. General release includes field trials for research purposes, and commercial releases of GMOs.

• The Contained Use Regulations require persons who intend to carry out any act in which organisms are genetically modified, or intend to culture, store or use GMOs to:
(a) carry out (and keep records of) risk assessments beforehand, where specified; and
(b) notify the Health and Safety Executive of their proposals and;
(c) for certain activities, to obtain written consent.</td></tr>
</table>

Intentional releases of GMOs in the environment	
Responsible agency	• The Department of the Environment, Transport and the Regions (DETR) for consent for marketing or release of a GMO.
Legislation	• Part VI of Environment Protection Act 1990: Genetically Modified Organisms (Deliberate Release) Regulations 1992 (SI 1992/3280) and the Genetically Modified Organisms (Deliberate Release) Regulations 1995 (SI 1995/304). • The regulations implement EC Directive 90/110/EC.
Coverage of legislation	• The culturing storage, use, transport, destruction, disposal, release (field trials for research purposes and commercial releases) into the environment or marketing of GMOs. GMO is defined as an organism that has been altered by genetic modification.
Assessment process for intentional releases of a GMO into the environment (field trials and general releases)	• The Deliberate Release Regulations requires that everyone who intends to release GMOs to the environment, or to sell products consisting of or containing GMOs, must first obtain a consent from the Department of the Environment. • Application must be made to the Department of the Environment. • Application must include a risk assessment prepared by the applicant. • The Department audits the application to ensure that the risk to human health and the environment has been minimised. • The Department seeks the advice of expert committees. Various advisory committees have been set up to examine the risk assessment and management procedures set out in applications and advise whether the work/release should proceed or work procedures amended. For example: - higher risk contained use applications are reviewed by the Advisory Committee on Genetic Modification; and - general release applications are reviewed by the Advisory Committee on Releases to the Environment (ACRE). ACRE carries out an assessment of the application and advises on the risks posed to human health and the environment, whether a consent should be granted and whether any risk management of the release should be required as a condition of consent. Once the assessment of the application is complete, the final decision rests with the Secretary of State for the Environment and the Minister of Agriculture, Fisheries and Food. Release may only take place with the consent of both the Secretary of State for the Environment and the Minister of Agriculture, Fisheries and Food.

Consideration of ethical issues	• Ethics issues are not directly considered in relation to each application, however, ethicists have been placed on advisory committees.
Public consultation on applications	• There appear to be no statutory requirements for public consultation.
Conditions that may be applied	• Conditions can be placed on general releases. • Requirements for post-release monitoring and reporting can be imposed as a condition of release.
Monitoring, surveillance and enforcement powers	• Auditing of research and marketing releases is undertaken by specialist inspectors of the HSE on behalf of DETR, to ensure conditions of consent are complied with. Inspectors can take action where breaches are detected (including fines).
Penalties	• Information is not available at this time
Liability for contamination	• Liability for environmental damage is generally imposed by general statute, and examples include land contamination, waste disposal, and water pollution. However, there is no specific statute dealing with liability for contamination by GMOs, and plaintiffs must look to the common law or general statutes for remedies.
Policy and Governance issues	
Expert Committees	• Following a review on biotechnology regulation in 1999, the UK Government decided to establish two new bio-technology specific bodies in order to create a more strategic advisory structure. The Human Genetics Commission is to advise on gene technology and its impact on humans, and the Agriculture and Environment Biotechnology Commission is to advise on all other aspects of biotechnology except food.
Research	• DETR contracts out specific research projects investigating the risks associated with GMOs.
Other	
The precautionary principle	• There is no direct reference to the precautionary principle in the Regulations.
Cost recovery	• There is a level of cost recovery – further information is being sought on the precise level of cost recovery imposed.
Moratorium	• The UK Government initially entered into a voluntary agreement with industry that no GM crops will be grown commercially in the UK for at least 2 years. In the mean-time, farm-scale field trials will be conducted to assess the safety of GMOs. Until these tests demonstrate that the risk is minimal, no GMOs will be allowed to be released in the UK. In November 1999, companies agreed to wait until the end of a 3.3 million pound government-funded experiment to see if GM crops damage wildlife more than conventional crops before growing crops commercially. The trial ends in 2002, delaying the commercial growing of GM crops in Britain for another 3 years.

REGULATION OF GENE TECHNOLOGY IN
GERMANY

SUMMARY

- Research with GMOs and release of GMOs into the environment in Germany is regulated under one piece of legislation – the *Genetic Engineering Act.*
- There appears to be no statutory link (or one-stop shop) between legislation to regulate GMOs and GM products (such as GM therapeutics and agricultural and veterinary chemicals).
- Note: It was not possible to obtain a copy of the *Genetic Engineering Act* in English and as such all of the information contained in this report is based on summary information including that published on Biotrack Online by the relevant German authorities.

Contained work with GMOs and intentional releases of GMOs into the environment

Responsible agency	• Federal Ministry of Health (the Robert Koch-Institut - RKI) – for the licensing of and release of GMOs and the marketing of products containing them. • The Federal States (for contained work).
Legislation	• The Genetic Engineering Act.
Coverage of the legislation	• Recombinant micro-organisms, viruses, cells, plants, animals and plasmid vectors. • This Act regulates GMOs in closed systems (laboratory and production areas), field experiments with GMOs and the placing on the market of products containing GMOs. Reproductive medicine and the use of somatic-genetic therapeutic procedures in humans are not covered by the legislation.
Assessment process for intentional releases of a GMO into the environment (field trials and general releases)	• Regulation is risk-based – the law divides work with rDNA into four safety levels (class one being the lowest level of risk), with activities considered to be of higher risk subject to more stringent requirements. For example: - commercial work in class one need only be notified to the authorities (no permissions needed); - academic research in all four classes need only be notified to the authorities (no permissions needed); and - commercial work in classes 2, 3 or 4 requires permission.

	• Applications for release of a GMO (including field trials) must be made to the RKI. • The RKI seeks advice from: - the Federal Environment Agency and Federal Biological Research Centre for Agriculture and Forestry and, in the case of releases of animals, the Federal Research Centre for Virus Diseases of Animals; - the Advisory Committee for Biological Safety; and - the competent authority of the State in which the GMO is proposed to be used. • The RKI makes decisions in agreement with: the Federal Environmental Agency (Federal Ministry of Environment); the Federal Biological Research Center for Agriculture and Forestry (Federal Ministry of Food, Agriculture and Forestry) and the Federal Research Center for Virus Diseases of Animals (in the case of GM vertebrates or GM micro-organisms that are applied to vertebrates). • In relation to contained uses of GMOs, the States are responsible for assessing applications under the legislation. The responsible authorities of the States seek advice from the Central Advisory Committee for Biological Safety and inform the RKI of their decisions.
Consideration of ethical issues	• On the basis of the information available, it does not appear that ethics are taken into account as part of the decision making process on individual applications.
Consultation on applications	• On the basis of the information available, it does not appear that there is any statutory requirement for public consultation on individual applications.
Conditions that may be applied	• A series of regulations have been issued under the Genetic Engineering Act specifying requirements, procedures and safety precautions to be observed. For example: - Regulations on Containment Levels and Safety Measures for Genetic Operations in Genetic Engineering Installations; - Regulations on the Advisory Committee for Biological Safety; - Regulations on the Keeping of Records for Genetic Operations; and - Regulations on Hearing Procedures and Regulations on Application and Notification Documents.
Monitoring, surveillance and enforcement powers	• There are significant monitoring and enforcement powers available under the legislation.
Penalties	• A maximum fine of $1,000,000 or a prison term of 3 years.

Liability for contamination	• The Act imposes a strict liability regime for any damage caused by the deliberate release of GMOs. • On the basis of secondary sources, it is understood that the legislation provides that the producer of a GMO is strictly liable for any damage caused by the release of the GMO. Liability is limited to DM 160 million (AUD 127 million).
Policy and Governance issues	
Expert Committees	• The **Central Advisory Committee for Biological Safety** (Zentrale Kommission für die Biologische Sicherheit - ZKBS) was established in 1978, in conjunction with the development of guidelines on the protection against hazards from in-vitro recombinant nucleic acids. After the Genetic Engineering Act came into force, the Central Advisory Committee for Biological Safety was constituted as an institution. The Committee consists of thirty scientific or technical experts and experts from other relevant fields (15 members and 15 deputy members) who work on an honorary basis. The members are either experts in the fields of microbiology, cell biology, virology, genetics, hygiene, ecology and technical safety which are, in most cases, familiar with the methods of genetic engineering or experts from trade unions, occupational safety, economy, research-promoting organizations and environmental protection. • The Committee undertakes safety evaluation of GMOs, and provides advice to the States and other institutions dealing with GMOs. This applies to experimental research in the laboratory, operations for production purposes in industrial fermentation facilities, and also the release and the placing on the market of GMOs. • Work of the Central Advisory Committee for Biological Safety is supported by its Secretariat at the Centre for Gene Technology at the RKI.
Research	• No information available at this time.
Other	
The precautionary principle	• No information available at this time.
Cost recovery	• No information available at this time.
Moratorium	• Chancellor Schroeder recently proposed a 3-year program to explore the possible environmental and health impacts of gene technology and to increase consumer trust in gene products Industry would be required to give an undertaking only to use genetically modified seed and plants and to cooperate with the scientific and government sector.

REGULATION OF GENE TECHNOLOGY IN
NEW ZEALAND

SUMMARY

- One piece of legislation covers research with GMOs and release of GMOs into the environment in New Zealand – the *Hazardous Substances and New Organisms Act 1996* (HSNO Act).
- There appears to be no statutory link (or one-stop shop) between legislation to regulate GMOs and GM products (such as GM therapeutics and agricultural and veterinary chemicals).

Contained work with GMOs and intentional releases of GMOs in the environment

Responsible agency	• Environmental Risk Management Authority (ERMA)
Legislation	• *Hazardous Substances and New Organisms Act* (HSNO Act)
Coverage of the legislation	• The legislation covers the importation, development, field testing and release from containment of new organisms. • A new organism includes any organism in which any of the genes or other genetic material: (a) Have been modified by *in vitro* techniques; or (b) are inherited, or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by *in vitro* techniques. The term *in vitro* is not defined.
Assessment process for intentional releases of a GMO into the environment (field trials and general releases)	• Any person importing or releasing a 'new organism' into the environment must apply to the ERMA for approval. Approval may be given if the new organism is not likely to cause: - any significant displacement of any native species within its natural habitat; - any significant deterioration of natural habitats; - any significant adverse effects on New Zealand's inherent genetic diversity; and - disease, become parasitic or become a vector for human, animal or plant disease. • In addition, the positive effects of the GMO must outweigh the adverse effects of the GMO.

	For release of GMOs into the environment
	• The HSNO Act describes a specific procedure which must be followed in relation to each application. When ERMA receives an application it must:
	- inform the Minister for the Environment and any government department or crown entity that is likely to express an interest in the application;
	- in relation to applications involving new organisms, inform the Department of Conservation and any regional council that is likely to express an interest;
	- if the application is to field test or release a GMO (ie if the GMO is not to be used in containment), publicly notify the application (in relation to an application for contained work, ERMA may publicly notify the application if it considers that there is likely to be significant public interest). The public notice invites people to make submissions on the application. All submissions must be received by the date specified in the public notice, and this date must be no longer than 30 working days after the public notification was advertised. ERMA may also call a hearing to consider the application and any submissions made;
	- Consider the application and any submissions made in accordance with documented assessment methodology;
	- Consider the following principles:
	  - safeguarding the life supporting capacity of air, water and ecosystems; and
	  - maintaining and enhancing the capacity of people and communities to provide for their own economic, social and cultural well being, and for the reasonable foreseeable needs of future generations;
	- consider:
	  - the sustainability of all flora and fauna;
	  - the intrinsic value of ecosystems;
	  - public health;
	  - the relationship of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga;
	  - economic and related values; and
	  - New Zealand's international obligations.
	
	For low risk contained work
	• The Act allows ERMA to delegate assessment decisions in these cases. For example, approval decisions may be delegated to approved biological safety committees attached to research institutions. The definition of "low risk" in this case is set out in regulations made under section 41.

Consideration of ethical issues	• No specific mention is made of ethical concerns, except in relation to Maori concerns. However, it is possible that ethical concerns could be addressed when weighing up the positive and adverse effects of an application, especially as section 5 provides that persons exercising functions under the Act should recognise and provide for the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social and cultural wellbeing. However, harm (or adverse effects) would need to be established.
Public consultation on applications	• Refer to assessment process. ERMA must publicly consult on all applications for release into the environment for a period of no longer than 30 days. • ERMA may consult on applications for use of GMOs in contained settings if ERMA considers that there is likely to be significant public interest on the issue.
Protection of confidential commercial information	• Provides some protection for commercial in confidence information
Conditions that may be applied	• There is no provision for conditions to be imposed on general release approvals in relation to GMOs. • Persons with approvals to undertake contained GMO research and field trials can have monitoring and inspection controls placed on them. It is also an offence for a manufacturer, developer or importer of a GMO to knowingly fail to report any significant adverse effect of a GMO.
Monitoring, surveillance and enforcement powers	• Enforcement officers can be appointed under the Act to promote and monitor compliance with the provisions of the Act. • Enforcement officers have powers of entry for inspection without consent to monitor the conditions in a premises or to determine the nature of any organism in the premises. Officers have extensive seizure powers and powers to take samples, open containers, conduct examinations and inquiries, and to require the production of documents. Enforcement officers can issue compliance orders to require persons to cease, or prohibit persons from commencing, anything which will, or is likely to, contravene the Act.
Offences/Penalties	• One of the key offences under the Act is manufacturing or developing a GMO in contravention of the Act (maximum penalty of $500,000 or up to 3 months imprisonment and $50,000 for every day on which the offence continues). • Similar penalties for offences such as failing to comply with any controls in relation to an approval.

Liability for contamination	• The *HSNO Act* does not address the issue of liability for contamination by GMOs and therefore it would be necessary for plaintiffs to seek relief under common law. • Tort law in New Zealand operates in a similar fashion to Australian law. To establish the tort of negligence a plaintiff would need to show the existence of a duty of care, a breach of that duty, causation of damages, proximity, and damage.
Policy and Governance issues	
Expert Committees	• The Act does not establish any overarching expert scientific, community or ethics committees. The legislation does however acknowledge the roles of Institutional Biosafety Committees. The IBCs can be approved by ERMA and delegated authority to approve low risk containment work. • ERMA has appointed a non-statutory advisory committee, Nga Kaihautu Tikanga Taiao, to provide ERMA, on request, with information on Maori issues in relation to individual applications.
Research undertaken by Regulator	• It is not a statutory function of ERMA to conduct, or commission, research.
Other	
The precautionary principle	• Section 7 of the Act states that all persons exercising functions, powers and duties under this Act shall take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects.
Cost recovery	• ERMA applies cost recovery and levies charges for services such as searching the register, submitting applications, auditing and conducting public hearings.
Moratorium	• On 17 April 2000, the Government announced a four-person Royal Commission headed by former Chief Justice, Sir Thomas Eichelbaum, to inquire into genetic modification. • The Royal Commission's chief objective is to inquire into and report on the strategic options available to enable New Zealand to address genetic modification now and in the future. It may also recommend any changes in the current legislative, regulatory, policy or institutional arrangements for addressing genetic modification technologies and products in New Zealand. • The Commission will have 12 months to report. • The Government also announced that a voluntary moratorium on all applications for the release of genetically modified organisms is to be negotiated between the government and relevant industry and research groups (with industry groups already expressing agreement with this approach). The moratorium will also apply to field testing of GMOs, but with some exemptions (to be determined on a case by case basis by the Minister for the Environment). The moratorium will be in force for the length of the Commission's inquiry.

REGULATION OF GENE TECHNOLOGY IN
JAPAN

SUMMARY

- Controls on gene technology are essentially voluntary and different aspects of gene technology are overseen by different portfolios:
- Ministry of Agriculture Forestry and Fisheries – oversee GMOs for use in agriculture;
- Science and Research Agency – oversees experimentation in all research facilities other than University research facilities;
- Monbusho (Ministry of Education, Sports and Culture) - oversees experimentation in University research facilities; and
- In relation to GM products, the Ministry for Health and Welfare approves GM products such as pharmaceuticals, medical treatments and foods.

For contained work with GMOs	
Responsible agency	• Science and Research Agency - for experimentation in all research facilities other than University research facilities. • Monbusho (Ministry of Education, Sports and Culture) - for experimentation in University research facilities.
Guidelines (no legislation)	• Voluntary guidelines: - "Guidelines for rDNA Experimentation" (for experimentation in facilities other than university facilities) and; - "Guidelines for rDNA Experimentation in University Research Facilities".
For intentional releases of GMOs in the environment	
Responsible agency	• Ministry of Agriculture, Forestry and Fisheries (MAFF).
Guidelines (no legislation)	• "Guidelines for application of recombinant DNA organisms in Agriculture, Forestry, Fisheries, the Food Industry and other related industries". • The system is based on administrative guidance with no underpinning legislation.
Coverage of the guidelines	• The release, production and use in agro-industries of rDNA organisms in both open systems (without specific measures of containment) and simulated model environments (e.g. experimental applications of rDNA in a

	restricted area).
Assessment process for intentional releases of a GMO into the environment (field trials and general releases)	• Any person who wishes to utilize rDNA crop plants in agriculture must conduct safety assessments in accordance with the guidelines. • Before organisms can be applied to open systems or a simulated model environment, the developer may request the approval of the MAFF to confirm that the safety assessments satisfy the requirements of the Guidelines. Safety assessments undertaken by proponents are examined by scientific advisory committees underpinning MAFF. • The guidelines set out how safety is to be confirmed. For example the guidelines set out: - the way of conducting simulations (including requirements for facilities, experimental equipment, cultivation, storage, transport etc); - the information required for a safety evaluation of an organism (conducted by the proponent); and - the institution of management systems including appointment of a safety officer, an operations administrator, a safety operations manager and a safe operations committee. • When a safety assessment has been conducted in accordance with the guidelines, a person may request the Minister of Agriculture, Forestry and Fisheries to approve the safety criteria regarding safety assessment and procedures utilised to ensure compliance with the guidelines.
Consideration of ethical issues	• No reference to ethics in the guidelines.
Public consultation on applications	• Not required.
Protection of confidential commercial information	• Information not available.
Conditions that may be applied	• The guidelines set out the requirements for various releases (eg education, handling, reporting etc).
Monitoring, surveillance and enforcement powers	• The system is a voluntary one and as such there are no enforcement provisions.
Penalties	• No penalties as the system is a voluntary one.

Liability for contamination	• Plaintiffs must seek redress for contamination by GMOs under general law.
Policy and Governance issues	
Expert Committees	• Information not available at this time.
Research undertaken by the Regulator	• There is no statutory provision for research to be undertaken on risks posed by GMOs. • However, significant research budgets across various portfolios. For example in 1998 in the Ministry of International Trade and Industry alone, over AUD$100m was dedicated to biotechnology R&D, AUD$500,000 to bioindustry safety assurance measures, AUD$2.2m to research into conservation and biodiversity.
Other	
The precautionary principle	• No reference to the precautionary principle in the Guidelines.
Cost recovery	• Information not available – but as the system is based on voluntary compliance with guidelines it is unlikely that there is a cost recovery regime.
Moratorium	• No moratorium.

REGULATION OF GENE TECHNOLOGY IN
SOUTH AFRICA

<table>
<tr><td colspan="2">SUMMARY

• One piece of legislation regulates the contained use of GMOs, trial releases of GMOs and general releases in South Africa.
• The relationship with GM product regulators is not clear.</td></tr>
<tr><td colspan="2">Contained work with GMOs and intentional releases of GMOs in the environment</td></tr>
<tr><td>Responsible agency</td><td>• The Minister’s delegate (the Registrar) on the advice of the Executive Council for GMOs</td></tr>
<tr><td>Legislation</td><td>• Genetically Modified Organisms Act 1997</td></tr>
<tr><td>Coverage of the legislation</td><td>• The Act covers GMOs, the development, production, release, use and application of GMOs (including viruses and bacteriophages) and the use of gene therapy (but not human gene therapy).
• A GMO is defined as an organism, the genes or genetic material of which have been modified in a way that does not occur naturally through mating or natural recombination or both. ‘Organism’ means a biological entity, cellular or non-cellular, capable of metabolism, replication, reproduction or of transferring genetic material and includes a microorganism.</td></tr>
<tr><td>Assessment process for intentional releases of a GMO into the environment
(field trials and general releases)</td><td>• Distinctions are drawn between ‘contained use’, ‘trial use’ and ‘general release’ of GMOs.
• A permit is required to use facilities for the development, production, use or application of GMOs, or to release such organisms into the environment.
• Permit applications must be submitted to the Registrar.
• The registrar seeks advice from the Executive Council on GMOs.
• The Council, through the Registrar, may request the applicant to submit a risk assessment and, where required, an assessment of the impact on the environment of the activity for which a permit is being sought.
• The Council, after consideration of the submitted assessments, authorises the Registrar to issue a permit.
• In coming to its decision, the Council must consult the Advisory committee (discussed below).</td></tr>
</table>

Consideration of ethical issues	• Ethical issues are not addressed in the legislation.
Public consultation on applications	• There is no public consultation requirement in the legislation
Protection of confidential commercial information	• No person shall disclose information acquired by them in performance of duties under the Act, except in certain circumstances. • The Council will decide, after consultation with an applicant, which information will be kept confidential, but this cannot include descriptions of GMOs, the purpose of contained use or release, the location of use (although it is not clear what level of detail is necessary), methods and plans for monitoring of GMOs and for emergency measures, and the risk assessment. • However, the information can be withheld if it is in order to protect the intellectual property of the applicant.
Conditions that may be applied	• The Executive Council may approve permit applications subject to such terms and conditions as the Council may deem necessary.
Monitoring, surveillance and enforcement powers	• Under the Act, the Executive Council can require the Registrar to arrange for the inspection of facilities where activities with or release of GMOs are being undertaken, or the inspection of all activities which the Registrar deems necessary to ensure that the terms and conditions attached to a permit are being complied with. • Inspectors may conduct an investigation to determine whether the provision of the Act are being complied with. However, they can only do so on the authority of a warrant. • During working hours, inspectors may also, without a warrant, enter any place or facility registered in terms of the Act in order to open containers, examine GMO material and inspect activities and records in connection with GMOs (monitoring power). • The Registrar may also authorise inspectors to destroy GMOs where the registrar has ascertained or suspects on reasonable grounds that GMOs are being imported, used or produced contrary to the provisions of the Act or the conditions of a permit.
Penalties	• It is an offence under the Act to contravene or fail to comply with any condition, restriction, prohibition, reservation or directive imposed or issued in terms of the Act, or to obstruct and hinder an inspector, or to refuse or fail to furnish information or give an explanation or reply to the best of your ability. • Penalty for first conviction is a fine (no maximum limit prescribed) or maximum imprisonment period of 2 years. • Penalty for subsequent offences is a fine or maximum imprisonment of 4 years.

Liability for contamination	• Section 17 of the Act provides that the liability for damage caused by the use or release of a GMO shall be borne by the user concerned. Clarification of the impact of this provision is currently being sought.
Policy and Governance issues	
Expert Committees	• **Executive Council for Genetically Modified Organisms:** consists of no more than eight members appointed by the Minister. It is essentially a bureaucratic committee established under the legislation and comprising one member from the Departments of Agriculture, Arts, Culture, Science and Technology, Environmental Affairs and Tourism, Health, Labour, and Trade and Industry who has knowledge of the implications of GMOs for their respective Departments, and any 2 other persons. The Council advises the Minister on all aspects concerning the development, production, use, application and release of GMOs, and ensures that such activities are performed in accordance with the provisions of the Act • **National advisory body:** advises, on request or of its own accord, the Minister, Executive Council, other Ministries and appropriate bodies on matters concerning genetic modification of organisms. This includes advice on all aspects relating to the introduction of GMOs into the environment and the contained use of GMOs, and on proposals for specific activities or projects concerning the genetic modification of organisms and the import and export of GMOs, and advice on proposed guidelines. The Committee must also liaise through relevant Departments, with international groups and organisations concerned with biosafety. The Committee may invite written comments from knowledgeable persons on any aspect that is within the Committee's brief. The Committee is to consist of no more than 10 persons appointed by the Minister (on recommendation of the Council, and for a period not exceeding 5 years), with no more than eight being knowledgeable persons in those fields of science applicable to the development and release of GMOs, and two being from the public sector with a knowledge of ecological matters and GMOs.
Research	• No information available at this time.
Other	
The precautionary principle	• The Precautionary Principle is not referred to in the Act
Cost recovery	• There is provision in the Act for regulations to provide for application fees. No confirmation has been received at this stage regarding whether fees have been prescribed.
Moratorium	• No moratorium.

REGULATION OF GENE TECHNOLOGY IN THE UNITED STATES

SUMMARY

- Several pieces of legislation regulate GMOs:
  - *Federal Plant Pest Act – 7 USC 7B;*
  - *Federal Insecticide, Fungicide, and Rodenticide Act – 7 USC 136;*
  - *Federal Food, Drug and Cosmetic Act – 21 USC 9;*
  - *Toxic Substances Control Act – 15 USC 53.*
- The system requires permits to be issued by the relevant regulatory authority. Depending on the nature of the GMO, permits may be required from more than one authority. In general:

- the US Department of Agriculture Animal and Plant Health Inspection Service (APHIS) - has the broadest authority over transgenic plants and has responsibility for determining whether such a plant poses a threat directly or indirectly as a plant pest;
- the US Environmental Protection Agency (EPA) regulates microbial and plant pesticides, new uses of existing pesticides and novel microorganisms; and
- the US Food and Drug Administration (FDA) is responsible for ensuring the safety of all food (by enforcing tolerances in food set by EPA), feed, and human and veterinary drugs.

- *There is no statutory link between each of the regulators.*

Contained work with GMOs

Responsible Agency	• National Institute of Health (NIH).
Legislation	• There is no special regulatory system for ensuring the safe use of biotechnology in the laboratory or factory where the organism is not to be released into the environment (ie: contained use). Voluntary guidelines - the NIH's *Guidelines for Research Involving Recombinant DNA Molecules* - are implemented by most users of the technology.

Intentional releases of GMOs in the environment	
Responsible agency	• The US Department of Agriculture Animal and Plant Health Inspection Service (for plant pests, plants and veterinary biologics). • The U.S. Environmental Protection Agency (for microbial/plant pesticides, new uses of existing pesticides and novel micro-organisms).
Legislation	• *Federal Plant Pest Act*; and • *Federal Insecticide, Fungicide and Rodenticide Act* • *National Environment Protection Act*
Coverage of the legislation	• Field testing, moving, importing and commercial release of organisms and products altered or produced through genetic engineering which are plant pests or may become plant pests • 'Genetic engineering' is defined as the genetic modification of organisms by recombinant DNA techniques. There is no definition of 'recombinant DNA techniques'.
Assessment process for intentional release of a GMO into the environment (field trials and general releases)	• Developer submits data to the APHIS (notification to APHIS of an environmental release must be at least 120 days prior to release). • Data must demonstrate that the plant is safe to release and is not itself a plant pest or potential noxious weed. • The APHIS conducts an assessment in accordance with the *National Environmental Protection Act.* • APHIS has a two tiered level of risk – lower risk GMOs need only be notified to the agency, while other releases require a permit. • In assessing an application for a permit, the APHIS: - examines the results of any field trial (field trial results must be submitted to APHIS within 6 months of the termination of a field trial); - must be satisfied that the benefits of the proposal outweigh the costs; - may require the preparation of an environmental impact statement in addition to an environmental assessment; - must seek public comment on a proposal if a person has submitted to the APHIS a petition to seek a determination that a particular GMO should not be regulated under the legislation. APHIS then makes a decision to approve the petition in whole or in part, or to deny the petition; and - must consult Departments of Agriculture in the States where release is planned.

	• If the GMO is also a plant pesticide then EPA approval is also required under the *Federal Insecticide, Fungicide and Rodenticide Act* as pesticide is broadly defined to include plants modified by biotechnology to resist disease. The EPA may also treat micro-organisms as subject to the *Toxic Substances Control Act* • A "determination of non-regulated" status is issued by APHIS if the crop is not a plant pest allowing the crop to be released without restriction. EPA would also issue approval.
Consideration of ethical issues	• The only matter considered by APHIS is whether the plant is a plant pest or has the potential to be a plant pest. Ethics, trade and social issues are not taken into account.
Public consultation on applications	• The APHIS must only seek public comment on a proposal if a person has submitted to the APHIS a petition to seek a determination that a particular GMO should not be regulated under the legislation. APHIS then makes a decision to approve the petition in whole or in part, or to deny the petition.
Protection of confidential commercial information	• Each of the relevant pieces of legislation provide for the protection of confidential commercial information. • Proponents applying to APHIS for a permit must provide two copies of their application, one with confidential business information passages marked and the other with these passages removed.
Conditions that may be applied	• APHIS permits are subject to several conditions prescribed in the regulations, including: - Separation of the GMO from other organisms; - Treatment of material accompanying the GMO; - Compliance with measures prescribed by APHIS which are necessary to prevent the accidental or unauthorized release of the GMO; - the requirement that the GMO be subject to the application of remedial measures determined by APHIS to be necessary to prevent the spread of plant pests; - the maintenance of the GMO only in the areas prescribed in the permit; and - inspectors must be allowed access, during regular business hours, to places where the GMO is located, and to records relating to the introduction of the GMO. • In addition, the permit holder can be subject to any other conditions APHIS deems as necessary to prevent the dissemination and establishment of plant pests. Permit can be withdrawn if non-compliance with these conditions is identified.
Monitoring, surveillance and enforcement powers	• Once permission for the cultivation of a transgenic crop has been granted, progress is monitored. The system does not rely on significant enforcement powers as the regulatory system is based on 'permits, testing and tolerance setting'
Offences/Penalties	• Violations relating to plant pests can incur criminal or civil penalties. • Any person who violates the regulations, or who forges or counterfeits any permit can be punished criminally by

	a fine not exceeding $5000 or by imprisonment not exceeding 1 year, or both. Such violations may also be dealt with civilly with the maximum fine being $1000.
Liability for contamination	• There is no strict liability regime for recovery by third parties; third parties must rely on the common law or remedies available under general environment protection legislation.
Policy and Governance issues	
Committees	• Information about Committees is currently being clarified but there are no statutory committees that examine GMOs specifically.
Research	• Information about research is currently being clarified but there is no statutory requirements for the Regulator to undertake research on GMOs.
Other	
The precautionary principle	• The legislation does not reference the Precautionary Principle.
Cost recovery	• There is capacity for some cost recovery – For example, permit applications carry a charge but the services of inspectors during regular assigned hours and at usual places of duty are furnished without cost while overtime for inspectors does carry a cost.
Moratorium	• No moratorium.

REGULATION OF GENE TECHNOLOGY IN
CANADA

SUMMARY

- Canada does not have a single piece of legislation that regulates GMOs. Most of the legislation applicable to biotechnology addresses specific product categories, and pertains both to biological and non-biological processes and products.
- The main agencies involved in the regulation of GMOs are Agriculture Canada, Environment Canada and Health and Welfare Canada. The relevant legislation includes:
  - *Canadian Environment Protection Act 1999 (CEPA)* (covers those uses not covered by other legislation);
  - *Feeds Act* (feeds);
  - *Fertilisers Act* (supplements);
  - *Health of Animals Act* (veterinary biologics);
  - *Seeds Act* (plants with novel traits);
  - *Pest Control Products Act* (microbial pest control agents); and
  - *Food and Drugs Act* (drugs, cosmetics, medical devices, and novel foods).
- Environment Canada oversee all intentional releases of GMOs into the environment and as such this summary will focus on this.

Contained work with GMOs	
Type of regulation	• Contained research involving GMOs is not covered by the Environment Protection Act. • Laboratory research in Canada is covered by the US NIH's *Guidelines for Research Involving Recombinant DNA Molecules*.
Intentional releases of GMOs in the environment	
Responsible Agency	• Environment Canada.
Legislation	• Canadian Environment Protection Act 1999 (CEPA).

Coverage of the legislation	• Substances that are new (ie not on the list of Domestic Substances) cannot be manufactured or imported unless approval is granted from the Minister. • Substance is defined as any distinguishable kind of organic or inorganic matter, whether animate or inanimate, and includes any matter that is capable of being dispersed in the environment or of being transformed in the environment into matter that is capable of being so dispersed or that is capable of causing such transformation in the environment. 'Living organism' is defined as a substance that is an animate product of biotechnology.
Assessment process for intentional releases of a GMO into the environment (field trials and general releases)	• The Minister must be notified if someone wishes to manufacture or import a new substance that is not on the Domestic Substances List (if it is on the list no approval is necessary). • Information relevant to the assessment must be provided to the Minister. • All proposals undergo a single 60-day public consultation period where interested parties may bring forward additional scientific evidence to support or refute the Minister's decision. • After taking into account any advice provided, the Minister must decide whether the substance is toxic or capable of becoming toxic. • If the Minister decides that the organism is not toxic or capable of becoming toxic, the Minister can place the organism on the Domestic Substance Register but cannot impose any conditions. • If the Minister decides that the organism is toxic or capable of becoming toxic, then the Minister can: (a) permit its manufacture or importation subject to any conditions the Minister may specify; or (b) can prohibit its import or manufacture. • The final decision of the Minister must be published.
Consideration of ethical issues	• In making a decision Ministers may only determine whether the substance is toxic or capable of becoming toxic. Ethics, trade, social and other issues may not be taken into account.
Public consultation on applications	• All proposals for release of a GMO into the environment undergo a single 60-day public consultation period where interested parties may bring forward additional scientific evidence to support or refute the Minister's decision.
Protection of confidential commercial information	• An applicant may request that information be treated as confidential. • The Minister must not disclose any information in respect of which a request for confidentiality has been made unless: - it is in the public interest; or - it is disclosed under an agreement between the Government of Canada and any other government of Canada or government of a foreign state etc and the agency agrees to keep the information confidential.
Conditions that may be applied	• Where the Minister suspects that a living organism is toxic or capable of being toxic, the Minister for the

	Environment may permit the manufacture or import of the living organisms subject to any conditions that the Minister may specify.
Monitoring, surveillance and enforcement powers	• Enforcement officers may be appointed under the CEPA. • Enforcement officers have the power to enter and inspect premises where a substance can be found, for the purposes of the Act. Officers have been given wide powers of inspection, including opening receptacles and packages, examining records, taking samples and conducting tests. CEPA also allows officers to act without warrants in emergencies. Officers may seize or detain anything which caused a contravention to occur, or which will provide evidence of the contravention, however they can only do so if it is required for evidence, analysis or it is in the public interest to do so. • Officers may also issue environmental protection compliance orders to owners and managers and persons contributing to contraventions which must be complied with (orders can include reporting requirements, and to cease operating).
Penalties	• A maximum fine of $1,000,000 or a prison term of 3 years exists (if convicted on indictment) for persons who contravene a provision of the Act or regulations, an order or direction under the Act or an obligation or a prohibition arising from the Act or regulations, or who knowingly provide false or misleading information. • For summary conviction it is $300,000 or 6 months. • If, in committing the offence, a person intentionally or recklessly causes a disaster that results in loss of the use of the environment, or shows wanton disregard for the lives or safety of other persons and thereby causes a risk of death or harm to another person, the maximum prison term increases to 5 years and there can be an unlimited fine imposed. • Each day the offence is committed is a separate offence. The CEPA also sets down criteria which the Court must look at when sentencing, including harm caused, the costs of any remedy actions, intention, and any property, benefit or advantage to the offender. • Despite the maximum amount of any fine under the legislation, a court may impose an additional fine equal to the court's estimation of the amount of property, benefit or advantage derived by the offender from their actions. Instead of convicting an offender, or in addition to other punishments, a court may make an order requiring the offender to do or refrain from doing certain action (eg: requiring the offender to take any action to remedy or avoid harm, prepare and implement a pollution prevention plan, carry out environmental effects monitoring, compensate the Minister, pay an amount to environmental, health or other groups or to scholarships for students enrolled in environmental studies, or publish the facts relating to the incident).

Liability for contamination	The CEPA provides for two types of action: (1) <u>Environmental Protection Actions.</u> Any Canadian citizen can apply for an investigation of an alleged offence in contravention of the legislation – this is called an "Environmental Protection Action" (EPA). An EPA can only be bought if: (a) the Ministers investigation was inadequate or non-existent; and (b) there was an alleged breach of the Act; and (c) the alleged breach is causing significant harm to the environment. An EPA may not be bought if the alleged conduct was: (a) taken to correct or mitigate harm or risk of harm to the environment or human plant or animal life; (b) taken to protect national security; or (c) was reasonable and consistent with public safety. Defences to an EPA include: (a) due diligence; (b) authorisation by another act of parliament; (c) an officially induced mistake of law; and (d) any other defences available under general law. In addition, an action may be dismissed if it is not in the public interest. The only relief that is available if an EPA is successful is an injunction (stopping the defendant from doing something or forcing them to do something) or an order to the parties to negotiate a plan to correct or mitigate the harm to the environment etc, costs of the action. There can be no award of damages in the event of a successful EPA. This action does not assist individuals effected by contamination to seek damages for loss suffered; rather it enables them to bring an action if there has been a breach of the Act, to stop the activity continuing. (2) <u>Common law actions</u> The Act explicitly reiterates the common law right for a third party who has suffered damage to go to court to seek damages for such loss. The action that may be brought (and the damages able to be recovered) will depend entirely on the application of ordinary principles of law (nuisance, negligence etc). The Canadian Environment Protection Act does not establish any statutory right to recover for loss or damage or any strict liability regime. At the time of preparing this document, no successful actions for contamination have been brought under common law in Canada.

Policy and Governance issues	
Committees	• **Canadian Biotechnology Advisory Committee (CBAC):** is a non-statutory committee established by the federal government to provide advice to a Coordinating Committee of federal ministers on broad policy issues associated with the ethical, social, regulatory, economic, scientific, environmental and health aspects of biotechnology. CBAC is made up of 21 members drawn from the scientific, business, general public, ethics and environmental communities. • The CEPA establishes a **National Advisory Committee** that can provide both technical and policy advice to the Minister on: - proposed regulations for toxic substances; - proposed regulations on environmental emergencies; - a co-operative coordinated approach to the management of toxic substances; and - any other matter or mutual interest. • This Committee looks at all environmental issues not just biotechnology.
Research	• The Minister for the Environment and Minister for Health must both undertake research and studies into environmental contamination arising from disturbances of ecosystems by human activity, and the role of substances in illnesses or health problems, respectively.
Other	
The precautionary principle	• The preamble to CEPA states that 'whereas the Government of Canada is committed to implementing the precautionary principle that, 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 environmental damage.
Cost recovery	• Fees are attached to notifications to CEPA. The Canadian Government may also recover all costs of, and incidental to, taking reasonable measures to prevent releases that endanger the environment and public safety, or to remedy any dangerous situation or reduce or mitigate any danger to the environment or to human life that results, or may result, from the release of a toxic substance in breach of conditions (although there is a 5 year limitation period).
Moratorium	• No moratorium.

APPENDIX 4

SELECTED STATEMENTS OF THE PRECAUTIONARY PRINCIPLE/APPROACH

A. Statements From Conventions[1]

1. Montreal Protocol on Substances That Deplete The Ozone Layer (Preamble, paragraph 6) (as amended in 1990)

Determined to protect the ozone layer by taking precautionary measures to control equitably total global emissions of substances that deplete it, with the ultimate objective of their elimination on the basis of developments in scientific knowledge, taking into account technical and economic considerations and bearing in mind the developmental needs of developing countries.

2. London Convention 1972 (Resolution LDC. 44/14) (1991)

AGREES that in implementing the London Dumping Convention the Contracting Parties shall be guided by a precautionary approach to environmental protection whereby appropriate preventive measures are taken when there is reason to believe that substances or energy introduced in the marine environment are likely to cause harm even when there is no conclusive evidence to prove a causal relation between inputs and their effects;

AGREES FURTHER that Contracting Parties shall take all necessary steps to ensure the effective implementation of the precautionary approach to environmental protection and to this end they shall:

(a) encourage prevention of pollution at the source, by the application of clean production methods, including raw materials selection, product substitution and clean production technologies and processes and waste minimization throughout society;

(b) evaluate the environmental and economic consequences of alternative methods of waste management, including long-term consequences;

(c) encourage and use as fully as possible scientific and socio-economic research in order to achieve an improved understanding on which to base long-range policy options;

(d) endeavour to reduce risk and scientific uncertainty relating to proposed disposal operations; and

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1 All extracts from A taken from the CEPA website: http://www.ec.gc.ca/cepa/ip18/e18_01.html#J11).

(e) continue to take measures to ensure that potential adverse impacts of any dumping are minimized, and that adequate monitoring is provided for early detection and mitigation of these impacts...

3. U.N. Framework Convention on Climate Change (Article 3(3)) (1992)

The Parties should take precautionary measures to anticipate, prevent or minimise the causes of climate change and mitigate its adverse effects. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing such measures, taking into account that policies and measures to deal with climate change should be cost effective so as to ensure global benefits at the lowest possible cost...

4. Convention on the Protection of the Marine Environment of the Baltic Sea Area (Article 3(2)) (1992)

The Contracting Parties shall apply the precautionary principle, i.e., to take preventative measures when there is reason to assume that substances or energy introduced, directly or indirectly, into the marine environment may create hazards to human health, harm living resources and marine ecosystems, damage amenities or interfere with other legitimate uses of the sea even when there is no conclusive evidence of a causal relationship between inputs and their alleged effects.

5. Convention for the Protection of the Marine Environment of The North-East Atlantic (Article 2(2)(a)) (1992)

The Contracting Parties shall apply:

(a) The precautionary principle, by virtue of which preventive measures are to be taken when there are reasonable grounds for concern that substances or energy introduced, directly or indirectly, into the marine environment may bring about hazards to human health, harm living resources and marine ecosystems, damage amenities or interfere with other legitimate uses of the sea, even when there is no conclusive evidence of a causal relationship between the inputs and the effects...

6. Treaty on European Union (Article 130r(2)) (1992)

Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay. Environmental protection requirements must be integrated into the definition and implementation of other Community policies.

B. Non-Treaty Statements[2]

1. Declaration of the Second North Sea Conference (Paragraphs VII and XVI.1) (1987)

Accepting that, in order to protect the North Sea from possible damaging effects of the most dangerous substances, a precautionary approach is necessary which may require action to control inputs of such substances even before a causal link has been established by absolutely clear scientific evidence...

[The participants] accept the principle of safeguarding the marine ecosystem of the North Sea by reducing polluting emissions of substances that are persistent, toxic and liable to bioaccumulate at source, by the use of the best available technology and other appropriate measures. This applies especially when there is reason to assume that certain damage or harmful effects on the living resources of the sea are likely to be caused by such substances, even where there is no scientific evidence to prove a causal link between emissions and effects ("the principle of precautionary action")...

2. UNEP Governing Council Recommendation (12th Meeting, May 25, 1989)

Recognizing that waiting for scientific proof regarding the impact of pollutants discharged into the marine environment may result in irreversible damage to the marine environment and in human suffering.

Also aware that policies allowing uncontrolled discharges of pollutants continue to pose unknown risks...

The UNEP Governing Council ecommended that all Governments adopt the 'principle of precautionary action' as the basis of their policy with regard to the prevention and elimination of marine pollution.

3. Bergen Declaration (Paragraph 7) (1990)

In order to achieve sustainable development, policies must be based on the precautionary principle. Environmental measures must anticipate, prevent and attack the causes of environmental degradation. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation.

4. Declaration of the Third International Conference on the Protection of the North Sea (Preamble) (1990)

[The participants] will continue to apply the precautionary principle, that is to take action to avoid potentially damaging impacts of substances that are persistent, toxic

2 Extracts Nos.1-4 from B taken from the CEPA website: http://www.ec.gc.ca/cepa/ip18/e18_01.html#J11) and No.5 taken from *Avcare Insights*, p.3.

and liable to bioaccumulate even where there is no scientific evidence to prove a causal link between emissions and effects.

5. Agenda 21 (Oceans Chapter 17, Paragraph 17.21) (1992)

A precautionary and anticipatory rather than a reactive approach is necessary to prevent the degradation of the marine environment. This requires, *inter alia*, the adoption of precautionary measures, environmental impact assessments, clean production techniques, recycling, waste audits and minimization, construction and/or improvement of sewage treatment facilities, quality management criteria for the proper handling or hazardous substances, and a comprehensive approach to damaging impacts from air, land and water. Any management framework must include the improvement of coastal human settlements and the integrated management and development of coastal areas.

When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if the cause and effect relationship are not fully established scientifically.

Press release on Wingspread Conference, February 1998.

APPENDIX 5

APPROVAL PROCESSES FOR THE INTENTIONAL RELEASE OF GENETICALLY MODIFIED PLANTS INTO THE ENVIRONMENT

Attachment C

COMPARISON OF REGULATION IN RELATION TO THE APPROVAL PROCESS FOR THE INTENTIONAL RELEASE OF GENETICALLY MODIFIED PLANTS INTO THE ENVIRONMENT

	United States	**Canada**	**New Zealand**	**EU**	**United Kingdom**
Relevant legislation	Federal Plant Pest Act and Federal Insecticide, Fungicide and Rodenticide Act	Canadian Environmental Protection Act	The Hazardous Substances and New Organisms Act	Council Directive 90/220/EEC	Environment Protection Act 1990 Part VI, the Genetically Modified Organisms (Deliberate Release) Regulations 1992 (SI 1992/3280) and the Genetically Modified Organisms (Deliberate Release) Regulations 1995 (SI 1995/304).
Relevant Regulatory authority	The US Department of Agriculture Animal and Plant Health Inspection Service (for plant pests, plants and veterinary biologics) The U.S. Environmental Protection Agency (for microbial/plant pesticides, new uses of existing pesticides and novel micro-organisms).	Environment Canada	Environmental Risk Management Authority (ERMA)	The Council of the European Communities Member states must designate a competent authority responsible for carrying out the requirements of the Directive.	The Department of the Environment, Transport and Regions
Coverage	Field testing, moving, importing and commercial release of organisms and products altered or produced	Manufacture or import of new substances (i.e. that are not on the list of Domestic Substances). Substances include living	Importation, development, field testing and release of new organisms. All GMOs are considered to be new	The deliberate release of GM micro-organisms into the environment	The culturing storage, use, transport, destruction, disposal, release (field trials for research purposes and commercial releases) into the environment or

	through genetic engineering which are plant pests or may become plant pests	organisms that are an animate product of biotechnology.	organisms.		marketing of GMOs.
Assessment process	Developer submits data to the USDA Animal and Plant Health Inspection Service Data must demonstrate that the plant is safe to release and is not itself a plant pest or potential noxious weed. The USDA conducts an assessment in accordance with the *National Environmental Protection Act.* If the GMO is also a plant pesticide then EPA approval is also required under the *Federal Insecticide, Fungicide and Rodenticide Act* as pesticide is broadly defined to include plants modified by biotechnology to resist disease. The EPA may also treat micro-organisms as subject to the Toxic	The Minister must be notified if someone wishes to manufacture or import a new substance that is not on the Domestic Substances List (if it is on the list no approval is necessary). Information relevant to the assessment must be provided to the Minister. Assessment is undertaken by Environment Canada who may utilise external advice	Any person importing or releasing a 'new organism' into the environment must apply to the ERMA for approval. The organism is assessed according to whether it is likley to cause: - any significant displacement of any native species within its natural habitat; - any significant deterioration of natural habitats; - any significant adverse effects on New Zealand's inherent genetic diversity; and - disease, become parasitic or become a vector for human, animal or plant disease. The positive effects of the	A person must submit notification about the proposed release including all of the information required by the Directive and an evaluation of the impacts. The competent authority must examine the application for compliance with the directive and evaluate the risks posed by the release – this must be a science based consideration. The competent authority may consult on any aspect of the proposed deliberate release.	Application must be made to the Department of the Environment. Application must include a risk assessment prepared by the applicant. The Advisory Committee on Releases to the Environment (ACRE) carries out an assessment of the application and advises on the risks posed to human health and the environment, whether a consent should be granted and whether any risk management of the release should be required as a condition of consent.

	Substances Control Act		organism must outweigh the adverse effects of the organism and any inseparable organism.		
Approvals	A "determination of non-regulated" status is issued by APHIS if the crop is not a plant pest allowing the crop to be released without restriction. EPA would also issue approval.	Minister decides whether the substance is toxic or capable of becoming toxic. If the organism is not toxic or capable of becoming toxic, the Minister can place the organism on the Domestic Substance Register but cannot impose any conditions. If the organism is toxic or capable of becoming toxic, the Minister can permit its manufacture or importation subject to conditions or can prohibit its import or manufacture.	Approval for release can only be granted without conditions.	Consent to release may be granted with conditions The competent authority must send to the commission the results of the decision and the Commission must forward summaries to other Member States.	Release may only take place with the consent of the Secretary of State for the Environment and the Minister of Agriculture, Fisheries and Food. Consent may be subject to risk management conditions.

Enforcement	Once permission for the cultivation of their transgenic crops has been granted, progress is monitored. The system does not rely on significant enforcement powers as the regulatory system is based on 'permits, testing and tolerance setting'.	The Minister can appoint enforcement officers to investigate alleged offences against the Act. The enforcement officers have broad powers including to search, seize etc.	Considerable powers of enforcement and inspection including search and seizure powers.	Member states shall ensure that the competently authority organises inspections and other control measures as appropriate to ensure compliance with the Directive.	Specialist inspectors may be appointed on behalf of DETR.