

STATUTORY REVIEW

of the *Gene Technology Act 2000*
and The Gene Technology Agreement

The Chair
Gene Technology Ministerial Council

Dear Minister

As members of the Independent Review of the *Gene Technology Act 2000* we are pleased to submit our report to you as Chair of the Gene Technology Ministerial Council.

In summary, we believe that the Act and the national regulatory scheme have worked well over the last five years, and no major changes are required. We have recommended a number of changes intended to improve the operation of the Act at the margin.

We would like to thank all those who took part in the Review, either by providing submissions or other information to us or by taking part in consultations.

We commend the report to you and your Ministerial colleagues.

Yours sincerely



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List of acronyms and abbreviations

AAT	Administrative Appeals Tribunal
The Act	<i>The Gene Technology Act 2000</i>
ACVM Act	<i>The Agricultural Compounds and Veterinary Medicines Act 1997</i>
AD(JR) Act	<i>Administrative Decisions (Judicial Review) Act 1977</i>
AHEC	Australian Health Ethics Committee
ANAO	Australian National Audit Office
APVMA	Australian Pesticides and Veterinary Medicines Authority
AQIS	Australian Quarantine and Inspection Service
CCI	Confidential Commercial Information
COAG	Council of Australian Governments
CSCG	Commonwealth State Consultative Group on Gene Technology
DIR	Dealing involving intentional release
DNA	Deoxyribonucleic acid
DNIR	Dealing not involving intentional release
DPP	Director of Public Prosecutions
EPBC Act	<i>Environment Protection and Biodiversity Conservation Act 1999</i>
FSANZ	Food Standards Australia New Zealand
GM	Genetically modified
GMAC	Genetic Manipulation Advisory Committee
GMO(s)	Genetically Modified Organism(s)
GTCCC	Gene Technology Community Consultative Committee
GTEC	Gene Technology Ethics Committee
GTIMS	Gene Technology Information Management System
GTMC	Gene Technology Ministerial Council
GTRAP	Gene and Related Therapies Advisory Panel
GTTAC	Gene Technology Technical Advisory Committee
IBC	Institutional Biosafety Committee
ICA	Insurance Council of Australia
IGA	Inter-governmental Agreement on Gene Technology

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IGAE	Australian Inter-governmental Agreement on the Environment
NHMRC	National Health and Medical Research Council
NGOs	Non-government organisations
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NLRD	Notifiable Low Risk Dealing
OCS	Office of Chemical Safety
Other regulatory agencies	Commonwealth agencies involved in regulating products (FSANZ, AQIS, NICNAS, APVMA, TGA)
OGTR	Office of the Gene Technology Regulator
OECD	Organisation for Economic Co-operation and Development
PC1–4	Physical containment Levels 1–4 (PC4 provides the greatest degree of containment)
Prescribed agencies	Agencies that must be consulted by the Regulator when developing a RARMP (FSANZ, AQIS, NHMRC, NICNAS, APVMA, TGA)
RAF	Risk Assessment Framework
RARMP	Risk assessment and risk management plan
RNA	Ribonucleic acid
RNAi	Ribonucleic acid interference
States	Australian States and Territories
The Regulator	Gene Technology Regulator
The Review	<i>Gene Technology Act 2000</i> Review Panel
TGA	Therapeutic Goods Administration
ToR	Term of reference
TRIPs	Trade-Related Aspects of Intellectual Property Rights
WHO	World Health Organization

Background

The *Gene Technology Act 2000* (the Act) is the Australian Government's component of the nationally consistent regulatory scheme for gene technology in Australia. The Act was passed following extensive public consultation and inquiries by Parliamentary committees.

Section 194 of the Act required an independent review of the operation of the Act, including the structure of the Office of the Gene Technology Regulator (the OGTR), to be undertaken and tabled in Parliament by 21 June 2006, the fifth anniversary of the Act coming into force.

The Gene Technology Ministerial Council (GTMC), which oversees the cooperative national legislative scheme, appointed the independent panel and issued terms of reference for the Review in May 2005. The terms of reference are set out in chapter 1.

Conduct of the Review

The Review prepared five issues papers based on the key issues raised in the nearly 300 submissions received in response to the terms of reference. Extensive national public and stakeholder consultation was carried out to ensure that the Review heard, first hand, the diverse range of community views in relation to the Act.

In addition to conducting public forums and stakeholder meetings, the Review visited contained laboratories and field trial sites. In undertaking the review and deciding recommendations, the Review considered material including the submissions received, the issues raised during consultations, the experience of the first four years of operation of the Act, emerging trends and international developments in gene technology and a range of reports and related literature.

Scope of the Act

While the Review heard a high level of support for the existing scope of the Act with its focus on health and safety of people and the environment, some stakeholders were concerned that the scope of the Act should be widened. In particular, non-government organisations (NGOs) and farmers opposed to the introduction of genetically modified (GM) crops argued that the scope of the Act should be broadened to include economic, social and marketing impacts so that the impact on farmers who choose not to grow GM crops is considered under the Act. As discussed in chapter 3, the Review concluded that the existing scope of the Act should be maintained.

Act achieving its object

The Review also found that the object of the Act — the protection of the health and safety of people and the environment — is being achieved. It found the Act to be rigorous with a high level of transparency in relation to the regulatory system. It also found that the regulatory framework set out in the Act is appropriate and is being applied effectively. However, the operational experience of the first four years has highlighted the need for some amendments to the regulatory system.

Operation of the Act

One of the strengths of the Act is the consultation required with States, prescribed agencies, the Environment Minister, the Gene Technology Technical Advisory Committee (GTTAC), relevant local councils and the public in respect of the Risk Assessment and Risk Management Plan (RARMP) as part of the licence approval process. This consultation is designed to ensure that all relevant issues are presented to the Regulator for consideration in her decision whether to issue a licence.

The Review concluded that the consultative structure and process generally worked well, but that it could be improved by ensuring that GTTAC's membership includes members with primary expertise in public health and environmental risk assessment, combining the Gene Technology Ethics Committee (GTEC) and the Gene Technology Community Consultative Committee (GTCCC) and no longer requiring the National Health and Medical Research Council (NHMRC) to be consulted on all dealings involving intentional release (DIR) applications. Details of these recommendations are in chapter 5.

The Review heard a range of views on the timing and duration of the assessment of applications by the Regulator. It concluded that there was a case for distinguishing between field trials and commercial releases of Genetically Modified Organisms (GMOs), reducing the time limit for assessing field trial applications but extending it for commercial releases. It also recommended that a time limit be introduced for consideration of licence variations.

and the Gene Technology Agreement

A number of submissions called for more stringent application of the Regulator's enforcement powers. After considering the issue in the light of the enforcement guidelines followed by the Regulator, the Review concluded that the powers are appropriate and used proportionately. The Review recommended amendments to the Act to allow the Regulator to direct licence-holders to comply with the Act in all circumstances, and to issue temporary permits to persons inadvertently finding themselves dealing with unlicensed GMOs so that these GMOs could be dealt with in accordance with the Act.

Regulatory burden

Many submissions from the research community suggested that the regulatory burden imposed by the Act was not commensurate with the risk posed by dealings with GMOs by researchers. In discussions with researchers the Review also heard that the different guidelines for laboratory certification used by the Regulator and Australian Quarantine and Inspection Service (AQIS) caused a number of practical problems. The Review recommended (chapter 6) lessening the burden of compliance by removing any requirement to report on dealings with GMOs exempted by regulation and reducing the requirement to report on Notifiable Low Risk Dealings (NLRDs) to an annual report. It also recommended that the Regulator and AQIS work on harmonising certification requirements and introducing a system of single audits.

Interface with other systems

The Review was told in submissions and discussions with industry that there was a sense of overlap and duplication between the Regulator and the other regulatory agencies. Examination of the legislation and discussions with the other regulatory agencies led the Review to conclude that the agencies worked very well together to minimise duplication and ensure consistency and coherence. The Review believed that to some extent this outcome reflected the personalities of the various regulators, and recommended (chapter 7) that a forum should be established to formalise these arrangements.

A number of submissions to the Review called for a "one-stop shop" to regulate all aspects of GMOs, including their use as foodstuffs, agricultural chemicals or medicines. The Review considered that there was no evidence of failure under the current system, and concluded that the system should be maintained.

Finally, the Review examined the extent of overlap between the Act and other legislation, including State legislation. Given that State legislation was outside the scope of the Review, the Review recommended that the Regulator should take steps to align her requirements with those of Standards Australia as far as practicable.

Changing circumstances

The Review was not told of any development in the last four years which had cast doubt on the Act's flexibility to deal with changing circumstances and emerging technologies. It recommended (chapter 8) that the Act should be reviewed again in five years to ensure that it continues to accommodate emerging trends. The Review also examined the gene technology regulatory frameworks in a number of countries including Australia's major trading partners and competitors. It did not identify any features in overseas systems that could be adopted to enhance the operation of the Australian system. Indeed, the Review concluded that the Australian system is one of the most rigorous, transparent and accessible.

The Inter-governmental Agreement

The major issue raised with the Review in relation to the Inter-governmental Agreement on Gene Technology (IGA) was the extent to which State moratoria on the growing of GM crops had undermined the nationally consistent framework which the IGA was intended to support. As discussed in chapter 9, industry, many farming and research groups were critical of the moratoria as halting the path to market for GMO food crops approved for commercial release by the Regulator, creating regulatory uncertainty, stopping further investment in GMO food crops and limiting Australian farmers' ability to compete internationally. On the other hand, NGOs and farming groups opposed to GMOs supported the moratoria, arguing that the States should have the right to decide not to allow GM crops to be grown if growing them would threaten markets for non-GM crops.

The Review noted that there was no evidence of adverse impacts on markets, and concluded that the moratoria were having detrimental rather than beneficial impacts. It recommended that all jurisdictions should reaffirm their commitment to a nationally consistent scheme, including a nationally consistent approach to market considerations, and work together to develop a national co-existence framework.

LIST OF RECOMMENDATIONS

Chapter Three: Scope of the Act (Term of Reference 1)

Review the scope of the Act to determine whether the policy objectives remain valid; and consider other issues, technologies or organisms that may be included in the scope of the Act, including:

- a) *consideration of economic, marketing and trade, cultural and social impacts, and re-examine how ethical issues are considered*
- b) *the definitions in the Act, including of the environment, and the need for the definition of other terms, including health*
- c) *consideration of the technologies and organisms covered by the Act*
- d) *consideration of a trait based or novel organism based regulatory scope*

Recommendation 3.1:

The Review concluded that the policy objectives remain valid and recommends that the scope of the Act should be maintained.

Recommendation 3.2:

The Review recommends that the definitions in the Act remain unchanged.

Chapter Four: Act Achieving Objects (Term of Reference 2)

Investigate whether the object of the Act is being achieved and whether the regulatory framework stipulated in section 4 of the Act is still appropriate.

Recommendation 4.1:

The Review concluded that the object of the Act is being achieved and recommends that the principles of the regulatory framework stipulated in section 4 be maintained. (Some legislative amendments may be required to accommodate the remainder of the recommendations in this chapter).

Recommendation 4.2:

The Review recommends that the Act be amended to include powers for the relevant Minister to issue a special licence in an emergency (similar to provisions in other relevant regulatory schemes).

Recommendation 4.3:

The Review recommends that the Regulator continue to participate actively in the development of international guidance on acceptable data packages.

Recommendation 4.4:

The Review recommends that technical amendments suggested by the Regulator should be made to improve the workability of the Act.

Chapter Five: Operation of the Act (Terms of Reference 3, 4 and 5)

3. Examine the structure and effectiveness of the OGTR.
4. Review the consultation provisions of the Act including:
 - a) *their effectiveness with respect to their costs and benefits, including the value of advice received, and the transparency and accountability they provide;*
 - b) *the functions and roles of the statutory advisory committees;*
 - c) *the statutory timeframes for applications under the Act; and*
 - d) *the stakeholders included in consultations for various applications under the Act.*
5. Determine whether the powers of the Act allow enforcement of compliance which is effective and appropriate to the circumstances, including instances where GMOs may be detected that are present unintentionally.

(Term of Reference 3)

The Review noted that the issues raised in TOR 3 were recently the subject of an intensive and thorough review by the Australian National Audit Office (ANAO). The Review has not made recommendations additional to those of the ANAO.

Recommendation 5.1 (ToR 4):

The Review recommends that GTTAC should include members whose primary expertise is in public health and in environmental risk assessment.

Recommendation 5.2 (ToR 4):

The Review recommends that GTEC and GTCCC be combined into one advisory committee, with the combined functions of the two committees.

Recommendation 5.3 (ToR 4):

The Review recommends that a function of the new single statutory committee include providing advice within the confines of the Act, on the request of the Regulator or the GTMC, on community consultation and risk communication matters for the DIR commercial licence application process.

Recommendation 5.4 (ToR 4):

The Review recommends that, in light of the NHMRC's practical experience as a prescribed agency, its role be changed from a prescribed agency to one where the Regulator can seek its advice as appropriate.

Recommendation 5.5 (ToR 4):

The Review recommends that section 49 should be deleted and that sections 51–52 should be amended to:

- require the Regulator to identify whether or not the GMO poses a significant risk to the health and safety of people or the environment as part of the preparation of the RARMP;
- where the Regulator gives notice of a decision that a GMO may pose a significant risk that a second round of public consultation be required on any amendments that the Regulator makes to the RARMP after the initial round of public consultation currently required under section 52. This additional consultation period should be 20 working days.

Recommendation 5.6 (ToR 4):

The Review recommends that the DIR category be split to distinguish between field trial and commercial release licences.

Recommendation 5.7 (ToR 4):

The Review recommends that DIR field trial licences be subject to a statutory time frame of 150 working days or 170 working days for a GMO that the Regulator assesses may pose a significant risk.

Recommendation 5.8 (ToR 4):

The Review recommends that the statutory time frame for commercial DIR licences be extended to 255 working days (this is consistent with other relevant regulatory systems) to ensure that the Regulator has adequate time for assessment and public consultation.

Recommendation 5.9 (ToR 4):

The Review recommends that a 90 working day statutory time frame be applied to variations for licences and there be an explicit power to allow a licence-holder to apply for a variation.

The restrictions on a variation should be that:

- a variation cannot turn a DNIR into a DIR;
- a variation cannot turn a field trial into a commercial release;
- the variation must be able to be assessed under the original RARMP;
- for a variation involving a new location of the field trial it can only be approved where the Regulator is satisfied that appropriate local councils have been consulted; and
- the Act should permit the regulations to prescribe other limitations.

Recommendation 5.10 (ToR 5):

The Review recommends that the Act be amended so that the Regulator has the power to direct a licence-holder, or a person covered by a licence, if she believes they are not complying with the Act or the Regulations to take reasonable steps to comply with the Act or Regulations.

Recommendation 5.11 (ToR 5):

The Review recommends amending the Act to allow the Regulator to grant a temporary permit to persons who find themselves inadvertently dealing with an unlicensed GMO for the purpose of disposing of the GMO in a manner which protects health and safety of people and the environment.

Chapter Six: Regulatory Burden (Terms of Reference 6 and 7)

6. Examine whether compliance and administrative costs, including information requirements, for organisations working in gene technology are reasonable and justified compared to benefits achieved and possible alternatives to legislation.
7. Review the system of approvals and the application of regulatory requirements commensurate to the level of risk.

Recommendation 6.1:

The Review recommends that there should be no legislative requirements on exempt dealings beyond listing in the Regulations. The Regulator should undertake regular reviews of the listing to ensure it remains current.

Recommendation 6.2:

The Review recommends that the requirement to notify NLRDs to the Regulator within 14 days be removed and replaced with a requirement to include a report of all NLRDs conducted in the last 12 months in the accredited organisation's annual report, and to maintain an up-to-date list for inspection and auditing purposes.

Recommendation 6.3:

The Review recommends that the OGTR certification guidelines and the AQIS guidelines be harmonised as far as possible and that the OGTR and AQIS establish a system of single audits to meet the needs of both organisations as soon as practicable.

Recommendation 6.4:

The Review recommends that the harmonisation exercise be used as an opportunity to ensure that the outcome focussed language in the certification guidelines is used to the maximum extent possible.

Recommendation 6.5:

The Review recommends that the Regulator develop information and guidance for accredited organisations on obtaining certification variations.

Recommendation 6.6:

The Review recommends the removal of the requirement in the accreditation guidelines for the reporting of exempt dealings in the annual report of an accredited organisation.

Chapter Seven: Interface with Other Systems (Terms of Reference 8 and 9)

8. Examine the nationally consistent scheme for gene technology regulation in Australia and identify any need for, and ways to achieve, improvements in its consistency, efficiency and coordination.
9. Examine the interface between the Act and other Acts and schemes (either Australian Government or State and Territory) that regulate gene technology and gene technology products. Identify any discrepancies including regulatory gaps and areas needing consistency and harmonisation of provisions.

(Note: recommendations in relation to harmonisation between AQIS and OGTR are dealt with under chapter 6 — Regulatory burden)

Recommendation 7.1:

The Review recommends the establishment of a regulators' forum to exchange information between the prescribed agencies and the Regulator, to ensure that duplication is minimised and the systems work seamlessly between each other.

Recommendation 7.2:

In the special case of Australian Standards that apply to laboratory facilities, the Review recommends that the Regulator actively participates in every opportunity for review so as to align her requirements with those of Standards Australia.

Chapter Eight: Changing Circumstances (Term of Reference 10)

10. Examine emerging trends and international developments in biotechnology and its regulation and whether the regulatory system stipulated by the Act is flexible enough to accommodate changing circumstances

Recommendation 8.1:

The Review recommends the Act be reviewed in five years to ensure that it continues to accommodate emerging trends.

Chapter Nine: IGA Achieving its Aims (Term of Reference 12)

12. Investigate whether the Inter-governmental Agreement on Gene Technology is achieving the aims listed in its Recitals

Recommendation 9.1:

The Review recommends that the Commonwealth and States through the GTMC reconfirm their commitment to a nationally consistent scheme for gene technology, including a nationally consistent transparent approach to market considerations as soon as practicable.

Recommendation 9.2:

The Review recommends that the Commonwealth and States work together to develop a national framework for co-existence for non-GM and GM crops to address market considerations.

Recommendation 9.3:

The Review recommends that the IGA be amended to provide capacity for the Commonwealth to declare a thing to be a GMO by regulation for a limited period in an emergency. This would be notified to GTMC in the first instance. It is recommended that GTMC must agree to the Regulations before they are submitted to the Executive Council for renewal.

Note: Changes to the Legislation (Term of Reference 11)

Suggested changes to the legislation are included, where appropriate, in the above recommendations.

INTRODUCTION AND TERMS OF REFERENCE

In May 2005 the GTMC issued the following terms of reference for the Review:

The *Gene Technology Act 2000* (Commonwealth) (the Act) is the Australian Government's component of the nationally consistent regulatory scheme for gene technology in Australia. The object of the Act is to protect the health and safety of people and the environment from risks posed by, or as a result of, gene technology by identifying those risks and managing them by regulating certain dealings with genetically modified organisms (GMOs). The Act establishes a regulatory framework through which its object is to be achieved. This framework provides for a precautionary approach and an efficient and effective system for the application of gene technologies that operates in conjunction with other Australian Government and State regulatory schemes relevant to GMOs and GM products.

Section 194 of the Act stipulates that the Ministerial Council for Gene Technology must cause an independent review of the operation of the Act, including the structure of the Office of the Gene Technology Regulator (OGTR), as soon as possible after the fourth anniversary of commencement of the Act. The Act states that the review must be undertaken by people the Ministerial Council agrees possess appropriate qualifications, and include people who are not employed by the Commonwealth or a Commonwealth authority. The report of the review must be tabled in each House of the Parliament within 12 months after the fourth anniversary of the commencement of the Act.

In establishing this review to examine the operation of the Act, the Ministerial Council is aware of the Australian Government's position on biotechnology, as outlined in the National Biotechnology Strategy: Consistent with safeguarding human health and ensuring environmental protection, that Australia capture the benefits of biotechnology for the Australian community, industry and the

environment. The Ministerial Council is also aware that there are a range of concerns amongst stakeholders and the public regarding gene technology and its regulation in Australia.

Having particular regard to

- a) The National Biotechnology Strategy,
- b) the Senate Community Affairs Reference Committee Report on the Gene Technology Bill 2000,
- c) the House of Representatives Committee on Primary Industries and Regional Services Report 2000, and
- d) the experience of the first 4 years of the operation of the Act, including the recent review of the Gene Technology Regulations 2001, and noting the object and regulatory framework set out in the Act, the Ministerial Council has established the following terms of reference for the review of the operation of Act:

Terms of Reference

Scope of Act

1. Review the scope of the Act to determine whether the policy objectives remain valid; and consider other issues, technologies or organisms that may be included in the scope of the Act, including:
 - a) consideration of economic, marketing and trade, cultural and social impacts, and re-examine how ethical issues are considered
 - b) the definitions in the Act, including of the environment, and the need for the definition of other terms, including health
 - c) consideration of the technologies and organisms covered by the Act
 - d) consideration of a trait based or novel organism based regulatory scope

Act achieving objects

2. Investigate whether the object of the Act is being achieved and whether the regulatory framework stipulated in section 4 of the Act is still appropriate.

Operation of the Act

3. Examine the structure and effectiveness of the OGTR.
4. Review the consultation provisions of the Act including:
 - a) their effectiveness with respect to their costs and benefits, including the value of advice received, and the transparency and accountability they provide
 - b) the functions and roles of the statutory advisory committees
 - c) the statutory time frames for applications under the Act
 - d) the stakeholders included in consultations for various applications under the Act
5. Determine whether the powers of the Act allow enforcement of compliance which is effective and appropriate to the circumstances, including instances where GMOs may be detected that are present unintentionally.

Regulatory Burden

6. Examine whether compliance and administrative costs, including information requirements, for organisations working in gene technology are reasonable and justified compared to benefits achieved and possible alternatives to legislation.
7. Review the system of approvals and the application of regulatory requirements commensurate to the level of risk.

Interface with other systems

8. Examine the nationally consistent scheme for gene technology regulation in Australia and identify any need for, and ways to achieve, improvements in its consistency, efficiency and coordination.
9. Examine the interface between the Act and other Acts and schemes (either Australian Government or State and Territory) that regulate gene technology and gene technology products. Identify any discrepancies including regulatory gaps and areas needing consistency and harmonisation of provisions.

Changing circumstances

10. Examine emerging trends and international developments in biotechnology and its regulation and whether the regulatory system stipulated by the Act is flexible enough to accommodate changing circumstances.

Changes to the legislation

11. Recommend amendments to the Act (including consideration of those recommendations made by State or Territory Parliamentary Committees), or alternatives to legislation, which improve the effectiveness, efficiency, fairness, timeliness and accessibility of the regulatory system.

IGA achieving its aims

12. Investigate whether the Intergovernmental Agreement on Gene Technology is achieving the aims listed in its Recitals.

The persons undertaking the review are to advertise nationally, consult with key interest groups and affected parties, receive submissions, and take into account overseas experience. Those consulted should include State and Territory Governments, the Gene Technology Advisory Committees, the Australian Government authorities and agencies prescribed by the Gene Technology Regulations 2001, including the Environment Minister, as well as the public.

Process

Call for submissions

The GTMC released the terms of reference for the review and some background information on the gene technology regulatory system when it made a call for submissions in May 2005. At this time, the GTMC also announced the appointment of an independent panel of three people, Ms Susan Timbs, Ms Kathryn Adams and Mr Murray Rogers, to conduct the review (see Appendix 1 for details of the panel members).

Nearly 300 submissions were received (see Appendix 2 for a list of individuals and organisations that made submissions to the Review).

Issues papers

The Review analysed the submissions and identified a number of key issues raised in relation to the gene technology regulatory system. This led to the development of a series of five issues papers, which were released in early October 2005. The issues papers provided a factual statement of how the legislation and regulatory arrangements work followed by some views that were indicative of the issues raised in the submissions. Extracts from some submissions were included in the issue papers to give an indication of the opinions held by different groups.

The five issues papers and the terms of reference they addressed were:

Issue paper	Term of reference (ToR)
Issues paper 1: Scope and efficacy of the Act	ToR 1 — Review the scope of the Act to determine whether the policy objectives remain valid; and consider other issues, technologies or organisms that may be included in the scope of the Act; ToR 2 — Investigate whether the object of the Act is being achieved and whether the regulatory framework stipulated in section 4 of the Act is still appropriate.
Issues paper 2: Operation of the Act	ToR 3 — Examine the structure and effectiveness of the OGTR (Office of the Gene Technology Regulator); ToR 4 — Review the consultation provisions of the Act; ToR 5 — Determine whether the powers of the Act allow enforcement of compliance which is effective and appropriate to the circumstances including instances where genetically modified organisms (GMOs) may be detected that are present unintentionally.

Issue paper	Term of reference (ToR)
Issues paper 3: Regulatory burden of the Act	ToR 6 — Examine whether compliance and administrative costs, including information requirements, for organisations working in gene technology are reasonable and justified compared to benefits achieved and possible alternatives to legislation; ToR 7 — Review the system of approvals and the application of regulatory requirements commensurate to the level of risk.
Issues paper 4: The Act as part of a wider regulatory framework	ToR 8 — Examine the nationally consistent scheme for gene technology regulation in Australia and identify any need for, and ways to achieve, improvements in its consistency, efficiency and coordination; ToR 9 — Examine the interface between the Act and other acts and schemes (either Australian Government or State and Territory) that regulate gene technology and gene technology products. Identify any discrepancies, including regulatory gaps and areas needing consistency and harmonisation of provisions; ToR 12 — Investigate whether the Intergovernmental Agreement on Gene Technology is achieving the aims listed in its Recitals.
Issues paper 5: An international perspective	ToR 10 — Examine emerging trends and international developments in biotechnology and its regulation and whether the regulatory system stipulated by the Act is flexible enough to accommodate changing circumstances.

National consultation

The issues papers served as the basis for the national public and stakeholder consultation process, which took place around Australia in October, November and December 2005 and January 2006. Public consultations began in Canberra on 21 October, followed by the Clare Valley and Adelaide on 23–25 October, Perth on 26–27 October, Brisbane and Townsville on 31 October–2 November, Narrabri and Sydney on 6–8 November, Melbourne and Horsham on 14–16 November, Hobart on 17–18 November and Darwin on 2 December.

These consultations consisted of a forum at each location which was open to the general public. In each State capital city, meetings were held with key stakeholder groups (see Appendix 3 for a list of people who attended these consultations). The consultations allowed the Review to hear, first hand, a range of views of interested parties, including State governments, industry, researchers, farm groups, NGOs and consumers.

The Review met with the Regulator, the prescribed Australian Government agencies that also have responsibilities relevant to the regulation of GMOs and GM products, the Environment Minister and the statutory committees under the Act. In addition, the Review made a series of visits to contained laboratories and field trial sites.

Matters considered by the Review

The Review was cognisant that the policy positions reflected in the Act were reached after extensive public and stakeholder consultation prior to the passing of the Act.

The key focus of the Review was on issues that have emerged or changed significantly since the Act was passed and on matters arising from the practical operation of the Act.

The Review took into consideration the following matters:

- the submissions in relation to the terms of reference;
- the issues raised during consultations;
- the report from the Western Australia Legislative Council's Standing Committee on Environment and Public Affairs¹;
- the experience of the first 4 years of the operation of the Act, including the recent review of the Gene Technology Regulations 2001;
- practical operational issues that have been encountered in the first 4 years;
- technological change since 2001 and emerging trends in technology;
- emerging trends and international developments in biotechnology and its regulation; and
- reports and related literature.

Form of recommendations

Having considered the list of matters above, the Review was left in no doubt of the wide variety of strongly held opinions on whether the current regulatory system is adequate to address the risks presented by GMOs. While the Review carefully considered the merits of each proposal to change the legislation, it has only formulated specific recommendations where it concluded that changes were warranted. Where the Review concluded that no change was warranted, the report sets out the Review's reasoning for this view.

Acknowledgments

The Review panel would particularly like to acknowledge the time, effort and assistance of those people who lodged submissions and participated in the consultation process.

The Review would also like to acknowledge the work undertaken and assistance provided by the Secretariat.

1 Tabled in the Western Australian Parliament in July 2003

BACKGROUND ON GENE TECHNOLOGY

What is gene technology?

Gene technology involves the modification of organisms by the direct incorporation, deletion or alteration of one or more genes or genetic sequences to introduce or alter a specific characteristic or characteristics. Organisms modified using gene technology are GMOs and GM products are things, other than a GMO, derived or produced from a GMO.

There are a variety of current and potential applications of gene technology including:

- medical research, for example, basic research in biology and medicine with micro-organisms and transgenic animals (primarily mice and zebra fish at present);
- agricultural biotechnology, for example, genetic modification of crops to introduce pest resistance, virus resistance or herbicide tolerance or salt tolerance;
- therapeutics applications that involve the modification of micro-organisms to produce insulin, or the modification of crops or animals to produce proteins of therapeutic value;
- industrial applications that modify micro-organisms to produce particular enzymes.

Development of the gene technology regulatory system

The oversight of gene technology in Australia began on a voluntary basis with the formation of the Committee on Recombinant DNA that was set up by the Australian Academy of Science in the mid-1970s. This was followed by the Recombinant DNA Monitoring Committee which was established in 1981 in the federal Department of Science. These two committees comprised a range of scientific experts that effectively

provided a peer review assessment of proposals to conduct experiments with GMOs between 1975 and 1987.

The work of these organisations was consolidated into the Genetic Manipulation Advisory Committee (GMAC) in 1987. GMAC was an administrative body founded on the initiative of the then Minister for Industry, Technology and Commerce. It was funded federally and charged with the task of assessing risks to human health and the environment in connection with gene technology and providing advice to proponents on how risks associated with work with GMOs could be managed. It also provided advice to statutory agencies responsible for product approvals that contained GMOs, or contained things that were derived from GMOs.

While GMAC had no statutory powers or functions its advice was consistently sought and complied with by Australian researchers. Although GMAC had no enforcement powers, compliance with its recommendations was a condition of research and development funding from the Australian Government.

With the advent of significant advances in the application of the technology, increased commercial involvement, and elevated community concern about GMOs, in November 1998, the Australian Government, together with the States, initiated a cooperative process to develop a uniform, national approach to the regulation of gene technology. The Commonwealth State Consultative Group on Gene Technology (CSCG) prepared a paper entitled 'Regulation of Gene Technology' and sought public and other stakeholder comment. These consultations contributed to the preparation of a discussion paper by the CSCG entitled 'Proposed national regulatory system for genetically modified organisms — How should it work?'

The discussion paper was advertised widely in 1999 in national, State, and regional newspapers; mailed directly to over 2500 individuals and organisations representing a wide range of interests and all MPs and Senators in the Australian Parliament; and posted on the interim OGTR website. More than 200 written submissions were received. This initial development of the Act was informed by Australia's first consensus conference where a range of community representatives were invited to provide comment on the management of GMOs.

In December 1999 a draft Gene Technology Bill 2000 and accompanying Explanatory Memorandum were released for public comment. Public forums were held in all capital cities and a number of regional centres. Over 750 people attended and more than 160 written submissions were received. Such extensive consultation in the development of the regulatory scheme reflects the emphasis placed on community input and participation in the decision making process in relation to gene technology. This process generated strong agreement about what should be included and excluded from the scope of the legislation. In setting up the regulatory scheme the government sought to recognise and balance both the potential of gene technology to contribute to society and community concerns over the development and deployment of the technology.

and the Gene Technology Agreement

On 21 June 2001 the Act and the Gene Technology Regulations 2001 (the Regulations) came into effect, establishing the national legislative scheme for the regulation of gene technology in Australia. The Act establishes an independent statutory office holder (the Regulator), who is charged with administering the Act and making decisions about the development and use of GMOs under the Act (see Appendix 4: The Application Approval Process, and Appendix 5: Structure of the Office of the Gene Technology Regulator).

The Gene Technology Ministerial Council and the Gene Technology Intergovernmental Agreement

The implementation of the legislation and the role of the Regulator are overseen by the GTMC. The GTMC was established by the IGA between the Australian Government and the governments of all States. The IGA also commits State governments to enacting corresponding State legislation. The entire text of the IGA can be found at Appendix 6 to this report.

Functions conferred upon the GTMC by the IGA are to:

- a. issue policy principles, policy guidelines and codes of practice to govern the activities of the Regulator and the operation of the Scheme (the 'Scheme' refers to the national legislative scheme 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);
- b. approve proposed regulations for the purpose of the Scheme;
- c. approve the appointment (and, if necessary, the dismissal) of the Regulator, and of the chairpersons of the GTTAC, GTCCC, and GTEC, and advise the responsible Commonwealth Minister on the appointment of the members of those bodies;
- d. ensure coordination with other Ministerial Councils on matters relating to gene technology and, in particular, harmonisation of regulatory processes relating to GM products;
- e. oversee generally the implementation of the Scheme;
- f. consider and, if thought fit, agree on proposed changes to the Scheme;
- g. initiate a review of the Scheme in accordance with the specifications of the IGA; and
- h. perform any other function conferred on the GTMC by the IGA.

In summary, the role of the GTMC is to provide policy input into the implementation and operation of the regulatory scheme. In addition, the GTMC provides advice to the Australian Government Minister for Health and Ageing on the appointment of the Regulator and appointment of members of the Gene Technology Committees (see below). The GTMC is supported by the Gene Technology Standing Committee comprised of senior Commonwealth and state department officials, and the Regulator is supported by the OGTR.

The Act provides for the GTMC to issue policy principles dealing with ethical issues relating to GMOs and the recognition of areas designated under State law for the purpose of preserving the identity of either GM crops or non-GM crops for marketing purposes (section 21).

The GTMC issued its first policy principle on 31 July 2003: the *Gene Technology (Recognition of Designated Areas) Principle 2003* which came into effect on 5 September 2003. This principle allows States to preserve the identity of GM or non-GM crops (or both) for marketing purposes.

Coordination with other regulatory agencies and NHMRC

Australia's gene technology regulatory system does not operate in isolation, but rather as part of an integrated legislative framework. While the Regulator must consider risks to health and safety of people and the environment relating to the development and use of GMOs, other agencies with complementary expertise have responsibility for regulating GMOs or GM products as part of a broader or different mandate (in this report these groups are referred to as other regulatory agencies).

During the development of the gene technology legislation, it was determined that the activities of the Regulator should not override existing legislation or result in duplication. The Act was seen as a means of addressing areas of gene technology not currently covered by existing legislation. The Act thus incorporates a requirement for the Regulator to consult with other agencies on applications for DIRs, and was accompanied by consequential amendments of the other relevant Acts, relating to mutual consultation and exchange of information regarding their assessments and approvals.

Accordingly, where other agencies approve non-viable (i.e. unable to reproduce) products derived from GMOs, advice on these decisions is supplied to the Regulator for placing on the GMO record.

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There are situations where approval of particular dealings with a GMO will require approval by both the Regulator and another regulatory body. The respective roles of these agencies are listed along with the relevant legislation in Table 1. For example, while the Regulator licences the release of a GMO that is used in human medicine into the environment, the Therapeutic Goods Administration (TGA) would have to authorise its dispensation to people.

Similarly, while the Regulator must approve the environmental release of GM insecticidal or herbicide-tolerant plants into the environment, the Australian Pesticides and Veterinary Medicines Authority (APVMA), which is responsible for the regulation of all agricultural chemicals, must register the insecticidal gene or approve the application of the herbicide to which the GM plants are tolerant.

Although the focus and responsibility of other agencies which regulate products that are, or are derived from, GMOs are distinct from those of the Regulator, all the agencies have a policy of aligning the decision making processes so far as is practicable. They work closely together to ensure thorough coordinated assessments of parallel applications are undertaken and, wherever possible, that the timing of decisions by both agencies coincide. An example of where this cannot apply is when Food Standards Australia New Zealand (FSANZ) is asked to assess the safety of a GM product that will be imported for use in human food before an application to grow the GMO from which it was derived in Australia is submitted to the Regulator.

While not strictly a regulatory agency, the NHMRC is also included in the list of prescribed agencies with which the Regulator must consult. The NHMRC has a number of committees which deal with matters that relate to the work of the Regulator. For example, there is cross-membership between the Gene and Related Therapies Advisory Panel of the NHMRC and the GTTAC. There is also cross-membership between the Australian Health Ethics Committee (AHEC) of the NHMRC and the GTEC.

Table 1: Other Commonwealth Agencies in Australia with a role in regulating gene technology

GM products	Agency	Portfolio	Scope	Relevant Legislation
GMO dealings	OGTR Gene Technology Regulator and Office	Health and Ageing	OGTR administers a national scheme for the regulation of GMOs in Australia, in order to protect human health and safety and the environment by identifying risks posed by or as a result of gene technology, and to manage those risks by regulating certain dealings with GMOs.	Gene Technology Act 2000
Medicines, medical devices, blood and tissues	TGA Therapeutic Goods Administration	Health and Ageing	TGA administers legislation that provides a national framework for the regulation of therapeutic products in Australia and ensures their quality, safety and efficacy.	Therapeutic Goods Act 1989
Health and Medical Research	NHMRC ¹ National Health and Medical Research Council	Health and Ageing	While not strictly a regulator, NHMRC provides funding for health and medical research, advises the community and governments on a range of health and health-related ethical issues. Through its oversight of the Gene and Related Therapies Research Advisory Panel (GTRAP), the NHMRC has a specific advisory role in relation to human clinical research using gene therapy or GM cells and tissues.	
Food	FSANZ Food Standards Australia and New Zealand	Health and Ageing	FSANZ is responsible for food standards, including mandatory approvals for the safety and labelling of food produced using gene technology before it can be sold.	Food Standards Australia New Zealand Act 1991

GM products	Agency	Portfolio	Scope	Relevant Legislation
Agricultural and Veterinary Chemicals	APVMA Australian Pesticides and Veterinary Medicines Authority	Agriculture, Fisheries and Forestry	APVMA operates the national system that evaluates, registers and regulates all agricultural chemicals (including those that are, or are used on GM crops) and veterinary therapeutic products. Assessments consider human and environmental safety, product efficacy (including insecticide and herbicide resistance management), and trade issues relating to residues.	Agricultural and Veterinary Chemicals (Code) Act 1994; Agricultural and Veterinary Chemicals Administration Act 1994
Industrial Chemicals	NICNAS/OCS National Industrial Chemicals Notification and Assessment Scheme; Office of Chemical Safety	Health and Ageing	NICNAS administers a national notification and assessment scheme to protect the health of the public, workers and the environment from the harmful effects of industrial chemicals.	Industrial Chemicals (Notification and Assessment) Act 1989
Quarantine	AQIS Australian Quarantine and Inspection Service	Agriculture, Fisheries and Forestry	AQIS regulates the importation into Australia of all animal, plant and biological products that may pose a quarantine pest and/or disease risk.	Quarantine Act 1908; Imported Food Control Act 1992

1 NHMRC administers the *Research Involving Human Embryos Act 2002*; however, research with human embryos is excluded from the scope of the Act

SCOPE OF THE ACT

Term of reference 1:

Review the scope of the Act to determine whether the policy objectives remain valid; and consider other issues, technologies or organisms that may be included in the scope of the Act, including:

- a) *consideration of economic, marketing and trade, cultural and social impacts, and re-examine how ethical issues are considered*
- b) *the definitions in the Act, including of the environment, and the need for the definition of other terms, including health*
- c) *consideration of the technologies and organisms covered by the Act*
- d) *consideration of a trait based or novel organism based regulatory scope*

Policy objectives

The policy objective of the Act is set out in section 3, which provides that:

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

The current policy objective was universally endorsed as remaining valid. However, there were views put to the Review to extend the scope beyond the current focus on protection of health and safety of people and the environment, which, if accepted, would create new policy objectives. These matters are discussed below.

Consideration of economic, marketing and trade, cultural and social impacts

There were many submissions and comments during the consultations on the issues raised by paragraph (a) of the ToR: should the Act require consideration of other impacts of GMOs? It should be noted that ethical issues are considered in chapter 5 in the discussion on the committees.

Many submissions to the Review, particularly those from industry, researchers and farming organisations seeking a choice to grow GMOs, supported the scope of the existing policy objective. They argued that health and safety of people and environmental protection were appropriate objectives for a regulatory framework which they saw as rigorous, transparent and science based, and that other impacts should be assessed in other ways.

In relation to marketing and trade impacts, these groups argued that the impacts of a GMO crop were heavily dependent on market conditions in what was essentially a global market, and that these conditions changed quickly. As such, it was considered inappropriate for a point of time assessment of market conditions to inform the decision on whether or not to release a GMO for commercial cropping by producers who wished to use it.

These groups supported their view with examples of how other agricultural issues involving introduction of new varieties had been dealt with outside a legislative framework (see case study below).

Case study: Market correction – Lupini beans

Wild forms of the broadleaf lupin *Lupinus albus* contain high levels of bitter-tasting alkaloids. Once introduced into a sweet variety, outcrossing will cause the bitter gene frequency to increase with each season. In the 1990s the Australian lupins became too bitter and consumers reacted negatively to the product. The *albus* industry put in place a management plan to reduce bitter contamination in sweet crops. The management plan included such protocols as paddocks should be free of any volunteer lupini bean plants for a minimum of 2 years before considering a following *albus* crop and a 2 km isolation from any sweet *albus* crop. After the successful implementation of this management plan, the Australian *albus* is producing sweet lupins again and consumer demand has increased.

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On the other hand, a number of submissions from NGOs, consumer groups and farming groups opposed to the introduction of GMO crops argued that the scope of the Act should be extended to require examination of economic, trade and marketing, and social and cultural impacts in reaching a decision whether or not to approve release of a GMO.

These groups believed that the cultivation of GMOs in Australia would lead to 'contamination' of non-GMO crops, and could lead to erosion of Australia's 'clean, green' image in overseas markets. These effects would lead to difficulties with market access and the prices paid for Australian products, and these economic and market impacts should be taken into account in deciding whether or not to release a GMO.

These views were also expressed in meetings with stakeholders and in public consultations. During these meetings the Review asked participants who supported consideration of economic and market impacts to suggest how these could be reflected in the assessment of specific applications by the Regulator. However, no relevant operational examples were identified.

In considering this issue, the Review also examined the scope of the agencies with a role in regulating gene technology such as National Industrial Chemicals Notification and Assessment (NICNAS), TGA, APVMA, FSANZ and AQIS (referred to as other regulatory agencies in this report). These systems focus on safety, efficacy (where explicit or implicit claims are made about the worth of the product) and international trade (in the case of APVMA).

The Review considered whether there was any basis for concluding that the particular characteristics of GMOs were such that their assessment should be extended but found no compelling case for extension. On balance, the Review concluded that the policy objective of the Act should remain the protection of health and safety of people and the environment.

Benefit assessment

A closely related issue to that of widening the scope of the Act to include economic and other impacts is whether the Regulator should have regard to the benefits as well as the risks of GMOs. While some submissions and participants in consultations argued that the Regulator should have regard to benefits as well as risks, most regarded such an extension as impractical or undesirable.

It was considered impractical on several grounds. Firstly, the existence or scale of many benefits did not become apparent for some years after the GMO was released. Bt cotton was cited as an example of where new benefits are still being identified years after commercial release. Secondly, it would be very difficult to construct a calculus for measuring risk and benefit in the same time frame and dimension. During the

consultations, an individual observed that while it might be possible to make sense of risks and benefits in the same aspect of a GMO's impact on health or the environment, trying to compare risks and benefits across different aspects would lead the Regulator up blind allies and be unworkable.

Many groups opposed to the release of GMOs argued consideration of benefits was undesirable because it might result in presumed benefits outweighing risks. At the same time some proponents of GMOs argued against consideration of benefits on the basis that it would be seen to compromise the scientific approach to risk assessment by the Regulator.

The Review concluded that the risk assessment process contemplated by the Act should not be modified to a risk-benefit assessment.

Efficacy

One submission suggested that for the special case of GM pesticidal crops, the responsibility for assessing the pesticide should be removed from the APVMA so that the sole responsibility for approving these crops would lie with the Regulator. This submission noted that as APVMA currently includes an assessment of efficacy for pesticides, the Regulator should then be required to assess efficacy for this group of GMOs.

The Review found that inclusion of consideration of efficacy was not consistent with the finding that the policy objectives should maintain their focus on health and safety of people and the environment.

Recommendation 3.1: The Review concluded that the policy objectives remain valid and recommends that the scope of the Act should be maintained.

Definitions in the Act

Paragraph (b) of the first ToR requires the Review to examine definitions used in the Act, including in particular the definition of 'the environment' and the lack of a definition of 'health'.

The environment is defined in section 10 of the Act as including:

- (a) ecosystems and their constituent parts; and
- (b) natural and physical resources; and
- (c) the qualities and characteristics of locations, places and areas.

and the Gene Technology Agreement

This differs from section 528 of the *Environment Protection and Biodiversity Conservation Act 1999* (the EPBC Act) which defines the environment as including:

- (a) ecosystems and their constituent parts; and
- (b) natural and physical resources; and
- (c) the qualities and characteristics of locations, places and areas; and
- (d) heritage values of places; and
- (e) the social, economic and cultural aspects of a thing mentioned in paragraph (a), (b) or (c).

A number of submissions to the Review suggested that the Act should be amended to adopt the wider definition in the EPBC Act, implicitly requiring the Regulator to have regard to social, economic and cultural impacts of GMOs.

The Review concluded that given its recommendation that the scope of the Act should not be widened to include economic and social impacts, it followed that the definition of the environment should not be widened.

While the object of the Act is to protect the health and safety of people, the term 'health' is not defined. A number of submissions suggested that the term should be defined, and suggested a definition drawn from the World Health Organization (WHO) constitution:

Health is the state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.

The issue attracted little comment during the consultation phase of the Review. Several individuals suggested that the term should be defined on the basis that clarity is always a good thing; but among this group there was only one supporter of the WHO definition. There were several suggestions that 'absence of disease' was preferable to 'a state of wellbeing'.

The Review noted that the term is not defined anywhere in the Australian statute book. It also noted that no case had been made out that the absence of a definition was leading to uncertainty or ambiguity in the application of the Act. It thus concluded that there is no need to include a definition in the Act.

One submission suggested that the Act should be amended to include a new definition for adventitious presence so that the unintended presence of an unlicensed GMO can be dealt with. The issue of unintended presence and how it can be more effectively managed in the Act is discussed in chapter 5.

Recommendation 3.2: The Review recommends that the definitions in the Act remain unchanged.

Technologies and organisms covered by the Act

Paragraphs (c) and (d) of the first term of reference require the Review to consider the technologies and organisms covered by the Act and to consider a trait based or novel organism based regulatory scope. (Emerging technologies are discussed in chapter 8.)

The Act currently covers GMOs defined (in section 10) as organisms or descendants of organisms that have been modified by gene technology, together with anything declared by regulations made under the Act to be a GMO. It excludes human beings who have undergone somatic cell therapy and organisms declared by regulations not to be GMOs. Gene technology is defined as any technique for the modification of genes or other genetic material, apart from sexual reproduction, homologous recombination and any technique specified in regulations to be excluded from the scope of the Act. This means that the focus of the regulatory system is organisms derived by a particular process (gene technology).

In contrast, New Zealand regulates novel organisms so that the focus of the regulatory system is assessing organisms that have never been seen in New Zealand, whether they are naturally occurring or derived by a technological process. The Canadian system focus is on the traits of the organism. For example, the trait of herbicide tolerance in a crop, whether it occurs naturally or has been put into the crop by a technological process. These regulatory systems are discussed in more detail in chapter 8.

Very few submissions addressed these issues. The Review did not have any evidence presented to it that would necessitate a move to a novel organism approach.

The Review noted that a number of submissions and participants in consultations drew attention to the fact that there was no difference between the effective outcome of gene technology and other plant breeding processes including selective breeding or mutagenesis and yet only gene technology was subject to regulation. For example, tt (triazine tolerant) strains of canola had been developed through non-GM processes, while glyphosate tolerant strains had been developed through gene technology. The outcome was effectively the same: a canola variety unaffected by exposure to a herbicide which controlled weeds in the crop. Under a trait-based approach, tt strains and glyphosate tolerant strains would be subject to the same regulatory regime.

The Review noted that the focus and approach of the Act was thoroughly considered during its development and concluded that there was no evidence presented to warrant changing the current system.

ACT ACHIEVING OBJECTS

Term of reference 2:

Investigate whether the object of the Act is being achieved and whether the regulatory framework stipulated in section 4 of the Act is still appropriate.

Object of Act being achieved

In considering whether or not the object of the Act is being achieved, the Review examined all the terms of reference and then made an overall assessment. Having considered all the material in this report, the Review concluded that the object is being achieved.

An appropriate regulatory framework

Section 4 of the Act provides that:

The object of this Act is to be achieved through a regulatory framework which:

- (aa) provides that where there are threats of serious or irreversible environmental damage, a lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation; and
- (a) provides an efficient and effective system for the application of gene technologies; and
- (b) operates in conjunction with other Commonwealth and State regulatory schemes relevant to GMOs and GM products.

Note: Examples of the schemes mentioned in paragraph (b) are those that regulate food, agricultural and veterinary chemicals, industrial chemicals and therapeutic goods.

This chapter focuses on paragraph 4(aa), known as the precautionary principle; looks at whether or not there is a need to introduce a strict liability regime or mandatory insurance; and assesses whether or not some changes to the regulatory system to address effectiveness and efficiency are required. Other chapters also address efficiency and effectiveness of the system. The operation of the Act in conjunction with other Commonwealth and State regulatory schemes relevant to GMOs and GM products is addressed in chapter 7.

The Review found the Regulator's Risk Analysis Framework (RAF) provided useful context for this term of reference. The RAF was revised and re-issued in January 2005, taking into account the lessons learnt from the first four years of operation of the Act and advice from the GTEC on more effective ways to communicate risk. The Review found that the revised RAF has had a major influence on the structure and format of the Regulator's risk assessment and risk management plans (RARMPs), improving their transparency and accessibility.

Application of the precautionary principle

The version of the precautionary principle cited in section 4 is the same as Principle 15 of the 1992 Rio Declaration on Environment and Development adopted by the United Nations sponsored conference on Environment and Development:

In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. 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 degradation.

The version in the Act differs from the principle enunciated in the Australian Intergovernmental Agreement on the Environment (IGAE), which was concluded in 1992 between the Commonwealth, States and representatives of local government.

The precautionary principle in the IGAE is stated as:

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:

- (i) careful evaluation to avoid, wherever practicable, serious or irreversible damage to the environment;
- (ii) an assessment of the risk-weighted consequences of the various options.

and the Gene Technology Agreement

This version of the principle is incorporated in other Commonwealth statutes dealing with environmental matters (section 391 of the EPBC Act and section 39Z of the *Great Barrier Reef Marine Park Act 1975*). Most State environmental legislation also contains this version of the precautionary principle.

Some submissions called for the wording in the Act to be amended to exclude reference to cost-effective. The Review identified many versions that are used around the world and noted that their underlying theme is a need for a cautious and careful approach to decision-making. The Review noted that negotiation of the IGAE version of the wording pre-dates the Rio version and that Parliament had chosen a form of words with wide international acceptance as the most appropriate for the Act. The Review did not identify any international developments that had occurred since 2000 to suggest a change to the wording was justified.

The Review further found that there are many possible interpretations of the wording and noted that some submissions called on the Regulator to apply the precautionary principle 'more rigorously'.

In her submission the Regulator outlined how she approached the issue:

The Act indicates that the Regulator is required to take protective measures as a prudent and sound response in the face of a lack of full scientific certainty. The approach adopted by the Regulator in addressing s.4(aa) is outlined in the Risk Assessment Framework (RAF) document. Perceived threats should be based on credible scientific hypotheses and have a plausible causal pathway; the seriousness of the threat should be taken into account and measures to prevent damage should not be limited to bans.

The RAF, while emphasising that protective measures should be both commensurate with the risk and sufficient to minimise exposure to harm, also details how a cautious approach is employed in the administration of the Act to achieve protection of people and the environment. These can be grouped into actions taken prior, during and after a proposed dealing.

The 2005 RAF essentially sets out a 'cautionary' understanding of the principle and if applied effectively and consistently, would preclude the release of any GMO that might present 'threats of serious or irreversible environmental damage' without adequate risk mitigation measures as part of the licence conditions.

The Review concluded that:

- the Regulator applies a cautionary approach to licence decisions; and
- the precautionary principle in its current form is still appropriate.

Strict liability for contamination

Many submissions to the Review from NGOs, consumer organisations and farming groups opposed to the introduction of GM crops called for the imposition on licence-holders of strict liability under common law for any damage caused by GMOs (note the Act currently provides for strict liability for offences and this is distinct from strict liability under the law of civil liability).

On the other hand, research, industry, and other farming groups argued that such a requirement was unnecessary because the common law provided effective remedies for persons incurring damage from GMOs. They argued that imposing strict liability on licensees would stop the development and marketing of GMO crops, because licensees would not be willing to accept liability for damages caused by GMO crops regardless of the circumstances in which the GMO crops were planted or cultivated.

In considering this issue the Review noted that the law of torts is a matter for State governments. Any codification of the law to impose strict liability would thus require amendments to State law rather than the Act.

The key reasons put forward for strict liability are discussed below.

1. The common law is deficient in not allowing recovery of damages for pure economic loss that farmers might suffer as a result of unintended presence of GMOs in their crops.

The Review noted that case law was developing to recognise pure economic loss, and that the *Perre v Apand*¹ case decided in the High Court in 1999 covered many of the issues that might be expected to arise concerning losses arising from unintended presence of GMOs in non-GM crops. The *Trade Practices Act 1974* and other consumer protection legislation would also afford redress to persons affected by purchasing seed supposed to be GM-free but containing GM material.

2. It would avoid the need for persons incurring damage from GMOs to initiate legal action.

However, while making licensees of GMOs strictly liable for any damage their GMOs might cause would obviate the need for plaintiffs to prove fault, the Review noted that plaintiffs would still need to demonstrate before a court the causal link between the GMO and the damage they had incurred as well as the extent of their loss in order to receive damages.

In considering the issue, the Review noted that there is no other product in Australia which has attracted a strict liability presumption under the common law. In the

1 [1999] 198 CLR 180

and the Gene Technology Agreement

past, and also in overseas jurisdictions, courts have imposed a strict liability regime in relation to 'superhazardous goods'. Given that the object of the Act is to manage risks to protect health and safety of people and the environment, it is contradictory to categorise any GMO assessed by the Regulator and licensed for intentional release as a superhazardous good.

The Review also noted that applying strict liability to a licensee of a GMO intended for cropping could create a risk that farmers using the GMO would have less incentive to take care to avoid practices that could result in unintended presence in a neighbour's field. While this could be addressed by the licensee imposing strict conditions on the end-user, this would not be as efficient as exposing the end-user to direct liability for incautious use of the GMO. In some circumstances it would be inequitable to impose strict liability on a licensee. For example, if a person deliberately distributed GM seeds across his non-GM neighbour's paddock it would be unfair to require the licensee to bear any liability for the use of their product.

The Review noted that the European Union Directive 2004/35/EC8 on environmental liability specifically excludes civil liability for property damage or economic loss from, for example, adventitious presence of unwanted GM material/traits/species from neighbouring properties in crops or wild relatives.

On balance, the Review concluded that a strict liability regime should not be introduced into the Act.

Compensation fund

A number of groups proposing a strict liability regime drew attention to the recent Danish law establishing a compensation fund for farmers adversely affected by the unintended presence of GMOs in their crops and suggested that a similar regime may be appropriate for Australia.

The Danish scheme is funded through a levy paid by growers of GMOs for areas planted. According to the EU decision authorising the scheme²:

Conditions for receipt of compensation

- 26) Payment of compensation is limited to cases, where GM-material is found in non-GM-crops of the same type as the GM-crops or a closely related type (GM-crops, which can cross into non-GM-crops) in the same cultivation season and within a specifically determined area (distance from GM-crops). With regard to the cultivation of ecological seed corn, the only condition relates to the cultivation season.

2 http://europa.eu.int/comm/secretariat_general/sgb/state_aids/agriculture-2004/n568-04.pdf

- 27) Compensation is only paid out for losses if the occurrence of GM-material in injured crops, as defined above, exceeds a threshold value of 0.9 per cent. This threshold value is the limit under which genetically modified foodstuff and feed stuff do not have to be marked for contents of genetically modified organisms, refer regulation (EF) Number 1829/2003.
- 28) The farmer must apply for compensation no later than 14 days after the occurrence of GM-material has been ascertained. Proof of the occurrence and amount of GM-material must be undertaken by officials or authorised persons.
- 29) Compensation is paid out, regardless of whether the farmer, from whose fields the GM-material has spread, can be identified.
- 30) Only those farmers who have suffered a loss in connection with primary production are entitled to compensation.

Amount of compensation

- 31) The amount of compensation is limited to the price difference between the market price of a crop, which has to be marked for contents of GM-material, and a crop, which does not demand such marking (that is contents of GM-material of under 0.9 percent). The Danish Plant Directorate sets the market price on the basis of monthly statistics from the Food Economics Institute (Fødevareøkonomisk Institut).
- 32) For organic cultivation, compensation may be granted for the time, which is spent on the replanting of acreage, until production again can be sold as organic. This time depends on the type of production and is set by the Danish Law of Ecology Number 118 of 3.3.1999. Compensation only covers the differences between the market price of the products and the price which would have been attained had they been sold as organic products.
- 33) If the producer has entered into a contract about delivery of GM-free products to a certain price, the compensation is based on the difference between this price and the market price. Compensation is however only paid for the part of the product, in which the contents of GM-material is over 0.9 percent, regardless which limit for contents of GM-material, producer and buyer may have agreed upon.
- 34) Compensation from other sources is deducted from the compensation, which is paid out under the support measures in question.

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The Government then seeks reimbursement for the cost of the compensation that has been paid from the farmer from whose fields the GM material emanated (if that person can be identified). If the farmer does not agree to make reimbursement the authorities may pursue the claim in court under standard civil law provisions, where fault must be proven.

The Review noted that the compensation is limited to the difference in market price between the crop that is sold as 'GM free' and a crop that is sold as co-mingled. As no premium has yet been identified for 'GM free' commodities³, the amount of compensation is likely to be minimal.

The Review considered whether there would be any benefits for such a scheme in the Australian context. It concluded that the need for a compensation scheme rested on the presumption that the common law and consumer protection legislation would not prove adequate in dealing with losses covered under the Danish scheme.

Having considered these issues as well as the operation of the common law and consumer protection legislation in Australia, the Review concluded that a mandatory compensation scheme such as the Danish scheme should not be introduced.

Mandatory insurance for GMOs

A related issue to strict liability at common law was mandatory insurance. Sub section 62(3) of the Act provides that licence conditions for the release of GMOs into the environment may:

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

So far the Regulator has not imposed any conditions of this sort.

Many submissions to the Review from groups seeking the imposition of a strict liability regime under common law also called for mandatory insurance for licence holders to cover their obligations under such a regime. On the other hand, groups opposed to strict liability saw no need for mandatory insurance.

In considering this issue the Review noted that there are various mandatory schemes in Australia at present.

Some of these cover particular activities, such as driving a motor vehicle (to the extent of personal injury liability to other people) and employing staff (to the extent to which they are injured in the workplace). The policy rationale for these schemes is to afford protection to people against financial loss arising from personal injury.

³ Foster, M. 2003, *GM Canola: What are its Economics under Australian Conditions?*, Australian Grains Industry 2003, ABARE, Canberra.

Other schemes cover particular services, such as providing legal advice or building houses, to the extent to which there are deficiencies in the advice or the house. Some schemes are intended to protect consumers placing large sums of money in the hands of providers prior to completion of the service.

However, there are no products covered by statutory insurance requirements. Not even the manufacturers of products which can be seen as inherently dangerous, such as chemicals or explosives, are required to hold product liability insurance. The community instead relies on consumer protection legislation, product standards and industry codes of practice to ensure that products generally are fit for sale and to mitigate the risks of harm from potentially dangerous products. The Review sought comment from the Insurance Council of Australia (ICA) and noted that the ICA was not in favour of imposing mandatory insurance because of practical limitations.

On balance, the Review concluded that mandatory product insurance for GMOs should not be required. The Review considered that the Regulator should retain the existing power under the Act to impose such an insurance condition on a particular release if she considered it warranted by specific circumstances.

Recommendation 4.1: The Review concluded that the object of the Act is being achieved and recommends that the principles of the regulatory framework stipulated in section 4 be maintained. (Some legislative amendments may be required to accommodate the remainder of the recommendations in this chapter).

An efficient and effective system for the application of gene technologies

The Review identified a number of changes to the Act that would improve the efficiency and effectiveness of the gene technology regulatory system. These are discussed below.

Emergency approvals

The Regulator pointed out in her submission that she was unable to fast track an approval in an emergency. The Review noted that the Regulator had approved a genetically modified cholera vaccine for release into the environment in conjunction with the relevant approval from the TGA. It is conceivable in the future that genetically modified vaccines (either for human or veterinary use) may be required in an emergency. The current provisions in the Act would mean that such a vaccine (that may have already been approved overseas) could not be released into the environment in Australia without the standard 170 day approval process.

In contrast, the TGA and the APVMA (the relevant product regulators for these vaccines) both have emergency approval mechanisms. The Review identified that most of the other regulatory agencies have provisions for emergency approvals and that generally the power is given to the relevant Minister.

The Review concluded that the lack of emergency approval powers impacted on both the effectiveness of the regulatory system and consistency with the other regulatory groups. The inclusion of emergency approval powers would make the gene technology regulatory system more effective and bring greater consistency. It would be appropriate for this power to be given to the relevant Minister rather than the Regulator.

Recommendation 4.2: The Review recommends that the Act be amended to include powers for the relevant Minister to issue a special licence in an emergency (similar to provisions in relevant regulatory schemes). _____

Rights of appeal and review

The Review noted some submissions sought to give third parties the right to appeal decisions of the Regulator. This issue had been considered during development of the legislation when the Senate Community Affairs References Committee recommended that the Bill be amended to provide for the right of third parties to apply for review of a decision of the Regulator. The Committee believed that the Bill unfairly discriminated against third parties wishing to appeal the grant of licences.⁴

However, the Parliament did not accept this recommendation and the Bill was passed into law without direct provision for third party appeal.

It is important to note the distinction between review by the Administrative Appeals Tribunal (AAT), which examines the merits of an administrative decision and can set aside a decision and replace it with a preferred decision, and review by the Federal Court under the *Administrative Decisions (Judicial Review) Act 1977* (AD(JR) Act), which can only go to defects in the process of decision making and remit a flawed decision to the decision maker for reconsideration.

It is a feature of many legislative schemes that only persons directly affected by a decision can access the AAT. This is intended to limit the possibility of vexatious appeals.

While Division 2 of Part 12 of the Act provides for internal review (section 181) and review by the AAT (section 183) of a wide range of decisions, it limits the right to seek a review to eligible persons. Eligible persons are defined as applicants for or holders of licences, certification or accreditation.

⁴ Senate Community Affairs References Committee, 2000, *A Cautionary Tale: Fish Don't Lay Tomatoes*, November, p.144.

The Review found that the current AAT appeal eligibility provisions are consistent with the legislation administered by the other regulatory agencies, except the *Quarantine Act 1908* (which does not provide for AAT appeals). The Review could not find any justification for distinguishing the Act from the legislation administered by the other regulatory agencies and concluded that the AAT appeal provisions should remain unchanged.

The AD(JR) Act allows ‘aggrieved persons’ access to the Federal Court. Case law has defined an aggrieved person as one who has an interest above that of an ordinary member of the public such that they will suffer a particular disadvantage from the decision beyond that of an ordinary member of the public. This definition has been widened by specific provisions in some legislation. Section 183A of the Act widens the meaning of an aggrieved person to include the States.

The Review looked at the review provisions in the legislation of the other regulatory agencies and confirmed they are similar to the current provisions in the Act (see chapter 7).

The Review also considered the appeal and review mechanisms in the EPBC Act. For environmental assessments, the EPBC Act has appeal provisions that are unusual compared with many other decision-making agencies. Under Part 3 of the EPBC Act, which relates to activities that have a significant impact on matters of national environmental significance, there is no provision for AAT appeals.

However, this part of the EPBC Act provides extended standing for AD(JR) appeals to:

- an individual (Australian citizen) if at any time in the last 2 years they have engaged in a series of activities for protection or conservation of, or research into, the environment, or
- an organisation or incorporated association whose purposes include protection or conservation of, or research into, the environment and, who engaged in a series of activities for those purposes any time in the last 2 years.

The EPBC Act and the Act differ significantly in their process and consultation provisions. Under the Act, consultation is required with the prescribed agencies, the States, the Environment Minister, relevant local councils and GTTAC in addition to the public. This is designed to ensure that all issues relevant to the Regulator’s decision are presented to the Regulator for her consideration.

While the EPBC Act allows for a period of public consultation on the applicant’s environmental impact statement, it does not specifically provide for consultation with the wide group described above. The Review concluded that the appeal and review provisions should remain unchanged.

The type of data required by the Regulator

Some submissions criticised the type of data that the Regulator accepted as part of applications. This data can include unpublished research and in house studies conducted by the applicant. These submissions argued that such data lacked credibility and it followed that decisions of the Regulator based on this data also lacked credibility. The submissions called for the Regulator to restrict the data submitted to peer reviewed and published studies.

The Review heard from the Regulator that in developing her risk assessment and RARMPs she was not restricted to the information provided by the applicant and used a range of other sources such as assessments done by other regulatory agencies and the general scientific literature. She expressed concern at any restriction of accepted data to peer reviewed and published data since this would mean that she did not receive raw data on which to make her own independent analysis.

The Review heard from all the other regulatory agencies that they accept raw data and unpublished studies. These agencies rejected the suggestion of restricting data to peer reviewed and published studies as this would severely limit the value of the information they received. Further, the Review heard that the data requirements of the other regulatory agencies met relevant international standards for datasets.

The Review concluded that the type of data accepted by the Regulator was consistent with the other regulatory agencies. The Review noted that there was not yet any international consensus on datasets for GMOs. An international standard for the type of data needed to evaluate GMOs is under development and the Review heard that the Regulator is participating in this process.

The Review concluded that the data considered by the Regulator should not be limited to peer reviewed and published studies and that the Regulator should continue to participate actively in international initiatives to develop guidance on appropriate datasets.

Recommendation 4.3: The Review recommends that the Regulator continue to participate actively in the development of international guidance on acceptable data packages.

Data protection

Some industry submissions called for improvements in data protection under the Act. Currently, there is provision in sections 184–187 to declare information confidential commercial information (CCI) if it meets certain criteria. In addition, some information provided to the Regulator may be patentable and subject to protection through the patents system.

One submission suggested that the Act may possibly breach Australia's obligations under the international Agreement on Trade-Related Aspects of Intellectual Property rights (TRIPS).

The relevant paragraphs of the TRIPS Agreement are:

Article 39.1... Members shall protect... data submitted to governments or governmental agencies in accordance with paragraph 3.

Article 39.3

Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

The TRIPS Agreement therefore requires that members must protect data submitted to governments against unfair commercial use when that data is required to obtain marketing approval for pharmaceutical or agricultural chemical products which use new chemical entities.

The information that is provided to the Regulator is not required for the purpose of obtaining marketing approval for pharmaceutical or agricultural chemical products that use new chemical entities. Therefore Article 39 of the TRIPS Agreement does not apply.

The Review noted that some of the other regulatory agencies have provisions that protect data by preventing the decision-maker from using information provided by one applicant in the assessment of a similar product without the agreement and knowledge of the first applicant. However, there is no consistency across regulatory systems and the terms of the protection afforded vary greatly.

The Review heard from industry that the limited data protection available under the Act could potentially be an impediment to conducting research in Australia. The Review concluded that, if this happens, it could be counterproductive to the aims of the National Biotechnology Strategy. Therefore it should be kept under close review and consideration should be given to a process for achieving greater consistency across regulatory systems.

Access to information

The Review heard calls to increase the information on applications that was made available to the public. The main concern was the inability to access information declared by the Regulator to be CCI and difficulties experienced in reviewing some applications other than in Canberra.

Currently under the Act, anyone can access the application and supporting documents with any CCI removed. The Review heard that in most cases copies of this information are posted out but it is the Regulator's practice that in the case of an application which runs to several volumes of information, a copy of the completed application form and the list of supporting documents are posted out. In this case the whole supporting material is made available for viewing in a reading room in Canberra or people can request relevant parts of the supporting material to be posted to them. Some people argued this impeded access unnecessarily.

The Review heard that prescribed agencies, the Environment Minister, GTTAC and the States have access to all information in the application including the CCI.

The Review noted that compared with other regulatory agencies and comparable regulatory agencies overseas, the gene technology regulatory system was amongst the most transparent, and that reading rooms in Canberra are also operated by some of the other regulatory agencies. In addition, some of the other regulatory agencies did not make any information on the application available to the public.

The Review considered the approach taken by the Regulator to public access to applications which run to several volumes was pragmatic and cost effective. The Review concluded that the current public access provisions are appropriate and should not be changed.

Regulator's technical amendments

The Regulator also suggested minor amendments to the Act that would improve the workability of the Act but would not change the policy intention of the Act. These amendments are listed in Appendix 7. The Review supports these suggested amendments.

Recommendation 4.4: The Review recommends that technical amendments suggested by the Regulator should be made to improve the workability of the Act.

Term of reference 3, 4 and 5:

3. Examine the structure and effectiveness of the OGTR.
4. Review the consultation provisions of the Act including:
 - a) *their effectiveness with respect to their costs and benefits, including the value of advice received, and the transparency and accountability they provide;*
 - b) *the functions and roles of the statutory advisory committees;*
 - c) *the statutory timeframes for applications under the Act; and*
 - d) *the stakeholders included in consultations for various applications under the Act.*
5. Determine whether the powers of the Act allow enforcement of compliance which is effective and appropriate to the circumstances, including instances where GMOs may be detected that are present unintentionally.

ToR 3 — Structure and effectiveness of the OGTR

The Review noted that the issues raised in ToR 3 were recently the subject of an intensive and thorough review conducted by the Auditor-General (Regulation by the Office of the Gene Technology Regulator, the Auditor-General, Audit Report No 7 2005-06, Performance Audit).

The major conclusions of the performance audit were:

29. Overall, OGTR has developed and implemented policies and procedures for the efficient and effective discharge of selected functions entrusted to it under the *Gene Technology Act 2000*. OGTR has processed applications within the required time frames and has exceeded targets for annual monitoring of DIR field trial sites.

30. OGTR has good information on its costs and resource requirements, although close monitoring of current staffing levels and the risks to attracting and retaining staff is necessary to ensure that it continues to have the staff necessary for it to effectively perform its regulatory functions.

31. Although OGTR reports a significant amount of operational information, there is room for better use of this information in measuring and improving performance.

32. The ANAO has made five recommendations and suggestions for improvement:

- The ANAO recommends that OGTR review and revise its forms and guidance documents in order to facilitate and ensure high level compliance with OGTR information requirements and to facilitate more efficient and effective regulation;
- In order to facilitate and enhance OGTR decision-making, the ANAO recommends that OGTR develop and publish clear guidance to applicants on the process and policies applied by OGTR in assessing applications for variation, cancellation, transfer and suspension;
- The ANAO recommends that OGTR adopt formal mechanisms for the review of its policy, procedure and guidance documents (and maintain records of such reviews), to ensure that they remain consistent and up-to-date;
- In order to provide better information on OGTR monitoring of licences and other instruments, the ANAO recommends that OGTR more fully explain its reported rates of monitoring, including maintaining and publishing information on the number of sites or organisations yet to be visited by OGTR. This will also enable any gaps in OGTR coverage of sites in its monitoring and inspection activities to be more readily identified;

- The ANAO recommends that OGTR seek clarification of its obligations (arising under the Act) to publicly report annual information on its operations. In order to facilitate better use of OGTR performance information and foster confidence in OGTR implementation of the Act, OGTR should assess the need for consolidated annual reporting (internal and/or external) of the performance information provided in its quarterly reports, as well as of other relevant information on its activities throughout the year.

Health has agreed to all recommendations.

The OGTR accepted all five of the ANAO recommendations and is in the process of implementing the improvements.

The Review noted that most users of the regulatory system were complimentary about the overall operation and approach of the OGTR with some minor comments in relation to the timeliness and consistency of advice. The Review considers that these issues have been picked up in the ANAO recommendations and other Review recommendations. Additionally, one submission recommended that the legislation be amended to provide for monitoring of licence-holders and DIR licences every three years. Currently there is no legislative requirement that specifies the frequency of monitoring that must be undertaken and the ANAO has recommended making more information publicly available so that any gaps in the coverage of monitoring activities can be readily identified.

The Review noted that the current arrangements provide the Regulator with the flexibility to design monitoring programs on a case by case basis and take into account the track record in compliance of the licence-holder. Based on the OGTR's adoption of the ANAO's recommendations and the OGTR's monitoring performance, the Review concluded that an amendment to the Act to specify a standard monitoring frequency was not warranted.

Due to the thoroughness of the ANAO review and its assessment of the structure and effectiveness of the OGTR, the Review has not found it necessary to make recommendations additional to those of the ANAO.

The Regulator's interpretation of 'environment'

A number of submissions suggested that the Regulator had adopted a narrow interpretation of the definition of the environment which excluded agricultural systems, roadside verges and other non-natural ecosystems. In her submission the Regulator stated that this was not the case, and that the impact on agricultural and other non-natural ecosystems was taken into account in her risk assessments and decisions.

This issue was also raised in public consultations. However, having examined a number of RARMPs, the Review concluded that the Regulator effectively considers the impact of GMOs on the full range of relevant ecosystems.

How the Regulator deals with public health risks

The Review noted concerns from some members of the public that the Regulator's human health assessment is limited to occupational health and safety risks and that this meant there was a serious gap in the assessment of public health risks. In consultations, the Regulator explained that to assess any given GMO, she identifies all possible human health risks but where she is satisfied that another Commonwealth regulatory agency will consider some or all of the human health risks, she does not duplicate their assessment. Thus, in the case of a GMO that will be used for human consumption, she acknowledges that FSANZ is the appropriate body to do an assessment of the food as consumed. The Regulator considers the remaining human health risks that relate to contact exposure (such as the potential to inhale the GMO or come into direct contact with it). However, for a GMO where no product regulatory agency can be identified, the Regulator would cover all human health risks.

ToR 4 — The Regulator's role in providing information

The Review noted that some stakeholders considered that the Regulator should do more to explain gene technology and to promote the potential benefits from using this technology. The Regulator told the Review that her role was restricted to providing information on the gene technology regulatory system and explaining her decisions. The Review noted that other government agencies such as Biotechnology Australia provide more general information on gene technology and biotechnology and agreed that it was not the Regulator's responsibility to promote gene technology.

With reference to what information is made publicly available via the record of GMO and GM product dealings, one submission recommended that the existing provisions be extended substantially. The Review noted that there is already extensive information made publicly available, and that the extent of the information contained in the record is wider than that available in comparable regulatory systems. The Review thus considered it unnecessary to extend the provisions.

The Review also noted concerns from some stakeholders that there were some human health risks that were not considered by the Regulator, particularly when a GMO was still at the field trial stage. After exploring this issue in depth, the Review concluded that these concerns were a result of miscommunication, as it was clear from examining RARMPs that the Regulator, where relevant, imposed conditions on field trials of GMOs to prohibit GMOs being used as food for animals or humans. This was because at the field trial stage, the GMOs would not usually have undergone an assessment by FSANZ. To avoid these misperceptions the Review suggests that the Regulator clarify the language used in summary documents.

Statutory advisory committees

Roles and functions

The consultation provisions of the Act were a central element of the Review's discussions with the public and stakeholders. There were divided views on the effectiveness and appropriateness of these provisions.

There are currently three statutory advisory committees under the Act — GTTAC, GTEC and GTCCC. Communiqués providing an overview of the matters considered at each of the committees' respective meetings are published on the OGTR website.

GTTAC provides scientific and technical advice, on the request of the Regulator or the GTMC, on:

- gene technology;
- GMOs and GM products;
- applications made under the Act;
- biosafety aspects of gene technology; and
- the need for and content of policy principles, policy guidelines, codes of practice and technical and procedural guidelines.

GTTAC's key role is to provide expert scientific advice to the Regulator on applications and on risk assessment and risk management plans.

GTCCC provides advice at the request of the Regulator or the GTMC on:

- matters of general concern in relation to GMOs; and
- the need for and content of policy principles, policy guidelines, codes of practice and technical and procedural guidelines.

GTCCC's key role is to advise on issues of concern to the community and to ensure that these are addressed in the policy underpinning the regulatory scheme. There is no analogous committee in any other jurisdiction, including internationally.

GTEC provides advice at the request of the Regulator or the GTMC on:

- ethical issues relating to gene technology;
- the need for and content of codes of practice in relation to ethical conduct when dealing with GMOs; and
- the need for and content of policy principles relating to dealings with GMOs that should not be conducted for ethical reasons.

GTEC's key role is to provide advice on the ethical dimensions of dealings involving gene technology.

Many submissions to the Review expressed concerns about the functions and roles of the three statutory advisory committees. The concerns ranged from the appropriateness of the membership to the type of advice that each provides to the Regulator, as well as the transparency in their operations and the appointment processes. In particular, the Review heard repeated concerns about the fact that the GTCCC has not been constituted since October 2004 because of delays in the re-appointment process. For this reason the Review did not have the opportunity to consult with the GTCCC. The Review noted that the appointment process for the committees was not a responsibility of the Regulator and was managed by the GTMC.

GTTAC

Under subsection 50 (3) of the Act, which relates to dealings involving an DIR:

The Regulator must seek advice on matters relevant to the preparation of the risk assessment and the risk management plan from:

- (a) the States; and
- (b) the Gene Technology Technical Advisory Committee; and
- (c) each Commonwealth authority or agency prescribed by the regulations for the purposes of this paragraph; and
- (d) the Environment Minister; and
- (e) any local council that the Regulator considers appropriate.

In practical terms, the Regulator is required to consult with GTTAC twice for DIR applications: on the application itself and in developing the RARMP.

For dealings not involving intentional release of a GMO into the environment (DNIR), subsection 47 (4) specifies that:

The Regulator may consult:

- (a) the States; and
- (b) the Gene Technology Technical Advisory Committee; and
- (c) relevant Commonwealth authorities or agencies; and
- (d) any local council that the Regulator considers appropriate; and
- (e) any other person the Regulator considers appropriate

on any aspect of the application.

The Regulator is effectively allowed more discretion in the choice of groups that are consulted in the case of DNIRs.

Industry, researchers and farm organisations seeking a choice to grow GMO crops were strongly supportive of GTTAC's membership and performance in evaluating licence applications. Neither of the other two committees advise on licence applications. Groups seeking a choice to grow GMOs argued that GTTAC maintains the integrity of the national, science-based, regulatory framework and were not supportive of the other committees being granted extended roles to consider licence applications.

On the other hand, submissions from NGOs, consumer groups and farming groups opposed to the introduction of GMOs argued that GTTAC's membership should include more experts in public health and environmental risk assessment to better reflect the object of the Act.

The Minister can only appoint a person as a member of GTTAC if the Minister is satisfied that the person has skills or experience in one or more areas specified under subsection 100 (5) of the Act. Public health and risk assessment are specified amongst the approximately 20 different areas of expertise. The Review heard that existing members of GTTAC have expertise in the areas of public health and environmental risk assessment, but noted that while members can claim more than one area of expertise, no members have stated that their primary expertise is in the field of public health or environmental risk assessment.

To provide transparency that public health and environmental risk assessment are considered in GTTAC's deliberations, the Review concluded that GTTAC should include members whose primary expertise is in public health and in environmental risk assessment. The issue of advice on public health grounds is also considered in Recommendation 5.4.

Recommendation 5.1: The Review recommends that GTTAC should include members whose primary expertise is in public health and in environmental risk assessment.

GTEC and GTCCC

Across all stakeholder groups, there was little understanding of the function and role of GTEC and GTCCC (which both provide advice at the request of the Regulator and the GTMC) and how the input of GTEC and GTCCC shapes the regulatory system. This was a key theme in the submissions and public consultations with concerns centred on the GTCCC. It was criticised for the polarised views of its membership and its lack of concrete progress. As noted above, the Review did not have an opportunity to hear from GTCCC and was unable to assess these comments given the period since the GTCCC last met.