

The Allen Consulting Group

## **Review of the *Gene Technology Act 2000***

Final report

**August 2011**

Report to the Department of Health and Ageing

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## Abbreviations

APVMA	Australian Pesticides and Veterinary Medicines Authority
AQIS	Australian Quarantine and Inspection Service
DAFF	Department of Agriculture, Fisheries and Forestry
DNIR	Dealings not involving intentional release
DIR	Dealings involving intentional release
EDD	Emergency Dealing Determination
FSANZ	Food Standards Australian New Zealand
GMOs	Genetically modified organisms
GM	Genetically modified
GTEC	(former) Gene Technology Ethics Committee
GTTAC	Gene Technology Technical Advisory Committee
GTCCC	(former) Gene Technology Community Consultative Committee
GTECCC	Gene Technology Ethics and Community Consultative Committee
GTRAP	Gene and Related Therapies Research Advisory Panel
IBC	Institutional Biosafety Committees
NGOs	Non-government organisations
NHMRC	National Medical Health and Medical Research Council
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NLRD	Notifiable low risk dealings
OECD	Organisation for Economic Cooperation and Development
OGTR	Office of the Gene Technology Regulator
PIRSA	Department of Primary Industries and Resources of South Australia
RARMP	Risk Assessment and Risk Management Plan
TGA	Therapeutic Goods Administration
The Act	The Gene Technology Act 2000
The Agreement	The Gene Technology Agreement 2006 (originally signed in 2001)
The Council	The Gene Technology Ministerial Council
The Department	The Department of Health and Ageing
The Regulations	The Gene Technology Regulations
TOR	Terms of Reference
WHO	World Health Organisation

## Executive Summary

The Allen Consulting Group has undertaken this Review of the *Gene Technology Act 2000* (the Act). This Review has investigated emerging trends and international developments in biotechnology and its regulation, the efficiency and effectiveness of the operation of the Act consistently across the national scheme for gene technology regulation in Australia and the interface between the Act and other regulation.

The Review draws on some forty-eight submissions received by the Department from industry, government agencies, researchers, non-government organisations and individuals. In addition, members of the Review team have spoken with key individuals from related regulatory agencies and the chairs of the two advisory committees that operate under the Act.

The Review believes that there is room to improve the harmonisation of Australia's arrangements to regulate gene technology. This would have economic benefits as well as improving the efficiency and effectiveness of the Act.

Table ES 1.1

### SUMMARY REVIEW RESPONSE TO TERMS OF REFERENCE

Term of reference	Finding/comment	Recommendations
1	The national scheme for gene technology regulation in Australia is effective and efficient. However there is scope to improve national consistency in order to fully achieve the aims of the Gene Technology Agreement. Emerging trends and international developments are closely monitored by the Regulator. At this time, there is sufficient flexibility to address new developments in the technology, although the processes that may be needed to implement changes are slow. Some areas of the Act that need to be reconsidered in the light of experience have been identified.	R1, R6, R15
2	The objective of the Act is being achieved and the regulatory framework set out in Section 4 of the Act is operating effectively.	R2, R9, R10, R12
3	To date, the powers of enforcement in the Act have been adequate.	
4	The consultation provisions of the Act are generally working well. The Regulator is making good use of the Internet and email to communicate with stakeholders. The statutory committees are working satisfactorily.	R13, R14
5	The interface between the Act and other related legislation has received a great deal of attention from the Regulator. Other regulatory agencies consulted as part of this review were very positive about cooperation with the Regulator.	R11,
6	The regulatory burden and compliance costs appear justifiable compared with the benefits achieved. The Regulator can reduce regulatory requirements when the risks are considered to have declined although the processes involved are slow.	
7	Recommendations for amendments to the Act and related State and Territory legislation to improve timeliness, efficiency and effectiveness have been proposed (see below).	R3, R4, R5, R7, R8, R16

Source: Allen Consulting Group

### Conclusions

This Review has found that the Act is working well, although there are aspects of its implementation at State and Territory level that need attention. The Office of the Gene Technology Regulator (OGTR) is operating in an effective and efficient manner. The Review considers that current consultation processes in relation to applications under the Act are working well. In particular, OGTR is working well with other regulatory agencies including FSANZ, APVMA and AQIS. The OGTR is providing a rigorous, highly transparent regulatory system.

### Review Recommendations

The Review believes that the recommendations in Table ES 1.2 below will improve the effectiveness and efficiency of the operation of gene technology regulation in Australia.

Table ES 1.2

#### REVIEW RECOMMENDATIONS

No.	Recommendation
R1	The requirement for quarterly reporting to the Commonwealth Minister, to be tabled in Parliament, be discontinued.
R2	All jurisdictions reconfirm their commitment to a national regulatory scheme for gene technology.
R3	Jurisdictions follow the example of NSW and the Northern Territory, automatically adopting changed gene technology regulation by reference to the Commonwealth legislation.
R4	Where the Commonwealth Act has not been adopted by reference, jurisdictions commit to amending legislation at the same time as Commonwealth legislation is amended.
R5	Those jurisdictions with GM moratoria that have not been reviewed in the last three years commit to reviewing them by the end of 2014.
R6	The OGTR continue to be active in OECD and other international fora to stay abreast of international developments in gene technology regulation.
R7	The Ministerial Council review the definition of 'dealings' in the Act with a view to clarifying the scope of the regulatory scheme.
R8	The Ministerial Council review the conditioning of GM products in the Act with a view to clarifying the scope of the regulatory scheme.
R9	The Department of Health and Ageing explore with the Attorney General's Department and the Ministerial Council ways in which the process for amending the gene technology legislation could be streamlined.
R10	The Act be amended so that the Regulator can authorise other appropriate dealings related to inadvertent dealings.
R11	The OGTR continue to provide information to IBCs to assist them in understanding their responsibilities under the Act. IBCs should differentiate this aspect of their work from other activities for which they may also be responsible.
R12	Governments in Australia maintain a science-based precautionary approach to the regulation of gene technology.
R13	The OGTR increase its communications to the general public to raise its profile and build confidence in Australia's regulation of gene technology.
R14	For many DIR applications, advertising in local or state newspapers in the region where the DIR is to occur should be sufficient (given OGTR's established electronic communications channels with interested parties). For issues/licences of national importance it should be sufficient for OGTR to place advertisements in one national newspaper. The OGTR could experiment with using social media to communicate with stakeholders in appropriate situations.
R15	The requirement to include GM products approved by APVMA, TGA, FSANZ and NICNAS in the GMO Record be removed.
R16	Technical amendments, as described in this report, be made to Sections 30, 71, 74 and 138 of the Act.

## Chapter 1

# This report

This report presents the findings of a Review of the *Gene Technology Act 2000* (the Act). This Review was commissioned by the Department of Health and Ageing (the Department) on behalf of the Gene Technology Ministerial Council (the Council). It follows an earlier review conducted in 2006 (the *Statutory Review of the Gene Technology Act 2000 and the Gene Technology Agreement, Commonwealth of Australia 2006a*), which recommended the Act be reviewed again in 2011 to ensure it continues to be current and to reflect and accommodate emerging trends.

At a high level, the current Review has investigated:

- emerging trends and international developments in biotechnology and its regulation;
- the efficiency and effectiveness of the operation of the Act consistently across the national scheme for gene technology regulation in Australia; and
- the interface between the Act and other systems (e.g. other Acts and schemes).

The current Review (the Review) has been informed by submissions from industry, government agencies, research organisations, non-government organisations (NGOs) and other interested parties. The Review's Terms of Reference (TOR) (see Box 1.1) were published on the Department's website<sup>1</sup> on 24 May 2011, with a request that submissions to be provided to the Department by 14 June 2011. In addition, the Review was noted on the website of the Office of the Gene Technology Regulator (OGTR). Some forty-eight submissions were received. Apart from one submission which the author asked to be treated as confidential, the submissions have all been made available on the Department's website.

The remainder of this report is divided into four chapters, as described below.

- *Chapter 2: Gene technology and its applications* provides a brief summary for readers unfamiliar with this technology;
- *Chapter 3: Gene technology and its regulation* sets the context for this Review by providing an overview of the Act, some essential definitions used in the Act and describes the role of other relevant regulatory agencies;
- *Chapter 4: The 2006 Statutory Review* discusses the previous review which was reported in 2006;
- *Chapter 5: Review of the Gene Technology Act* responds in turn to each of this Review's Terms of Reference. It includes some discussion of stakeholders' views.

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<sup>1</sup> <http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-gtmc.htm>

Box 1.1

**REVIEW TERMS OF REFERENCE**

The review must include (but is not limited to) the following.

1. The effectiveness and efficiency of the way that the regulatory scheme operates, taking account of developments since 2005-06 including:
  - a) the national scheme for gene technology regulation in Australia to identify any need for, and opportunities to achieve, improvement in its national consistency, efficiency and effectiveness and coordination; and investigate if the aims of the Agreement to determine these are being achieved;
  - b) emerging trends and international developments in biotechnology and its regulation and whether the regulatory system stipulated by the Act, including definitions within the Act, is flexible enough to accommodate changing circumstances; and
  - c) definitions and provisions within the Act to identify possible areas for enhancement in light of experience with the operation of the regulatory system.
2. Whether the object of the Act is being achieved and whether the regulatory framework stipulated in section 4 of the Act is operating effectively.
3. The powers of the Act to ensure that they are sufficient to enforce compliance.
4. The consultation provisions of the Act to determine:
  - a) their effectiveness with respect to changes in communication modes, such as various social media tools; the costs and benefits, including the value of advice received; and the transparency and accountability that they provide;
  - b) the functions and roles of the statutory advisory committees; and
  - c) the stakeholders for various applications under the Act and the methodology used to engage them.
5. The interface between the Act and other Acts and schemes in Australia (include all States and Territories) that regulate gene technology and its products; and identify any discrepancies, including regulatory gaps and areas needing consistency and harmonisation of provisions.
6. The regulatory burden and whether compliance costs for organisations working in gene technology are reasonable and justified compared to benefits achieved and if the regulatory requirements for classes of approval under the Act are commensurate with the level of risk.

Provision of recommendations for amendments to the Act and the Agreement (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.

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## Chapter 2

# Gene technology and its applications

Gene technology refers to techniques to modify genes or other genetic material of organisms. This may involve 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.

Gene technology can be used to produce genetically modified organisms (GMOs), which are organisms modified by the said techniques to inherit particular traits. While organisms modified using gene technology are called GMOs, genetically modified (GM) products are derived or produced from GMOs. The Gene Technology Act defines a genetically modified organism (GMO) as:

“(a) an organism that has been modified by gene technology; or

(b) an organism that has inherited particular traits from an organism (the initial organism), being traits that occurred in the initial organism because of gene technology; or

(c) anything declared by the regulations to be a genetically modified organism, or that belongs to a class of things declared by the regulations to be genetically modified organisms;

but does not include:

(d) a human being, if the human being is covered by paragraph (a) only because the human being has undergone somatic cell gene therapy; or

(e) an organism declared by the regulations not to be a genetically modified organism, or that belongs to a class of organisms declared by the regulations not to be genetically modified organisms.”

*Gene Technology Act, Section 10*

A GM product is defined as:

“a thing (other than a GMO) derived or produced from a GMO.”

*Gene Technology Act, Section 10*

Gene technology has applications in many areas. Key areas that use gene technology include medical research, industrial and agricultural chemicals, agriculture and pharmaceuticals. The following sections discuss the benefits and risks of gene technology on the key areas of human health, food and agriculture and the environment.

### **Health**

In the area of health, gene technology has enabled:

- the development of more effective therapies for diseases such as cancer and diabetes;
- the production of vaccines for hepatitis B and insulin for diabetics;
- the study of genes that cause genetic diseases that make certain persons prone to heart disease, motor neurone disease and some cancers; and

- genetic testing to look for predisposition to disease or developing a particular condition such as some cancers.

While there are claims of potential health risks associated with the consumption of GMOs or GM products, gene technology and GM foods have not been shown to cause any adverse human health impacts. Examples of health concerns mentioned by some stakeholders include the potential to trigger allergic reactions and the possibility of adverse impacts on health resulting from gene transfer (from GM foods to cells of the body or to bacteria in the gastrointestinal tract). However the World Health Organisation has noted that:

“no allergic effects have been found relative to GM foods currently on the market.”

World Health Organisation, 2011

In addition, Food Standards Australian and New Zealand has stated that:

“to date gene technology has not been shown to introduce any new or altered hazards into the food supply...”

FSANZ, 2011

### ***Food and agriculture***

Gene technology has helped to realise insect resistant and herbicide tolerant crops, as well as improve the efficiency of animal production in Australia. CSIRO (2010) has used gene technology to:

- produce cotton varieties that are resistant to certain insect pests;
- insert a particular gene from algae into crop plants so that they can produce DHA, a ‘healthy oil’ essential for health brain and eye development in infants; and
- investigate whether poultry immunity can be boosted to prevent avian influenza.

Gene technology is also used to improve the efficiency of animal production in Australia. For instance, Cooperative Research Centres, universities and CSIRO have used natural genetic variation in livestock to selectively breed animals that produce more meat, milk and fibre. The development of new vaccines and treatments for preventing and diagnosing livestock diseases are other examples of gene technology applications (CSIRO, 2010).

Potential risks associated with food safety and human consumption are under ongoing surveillance by FSANZ. Concerns expressed about food safety include whether the genetic material could cause adverse health impacts if transferred to human cells, cause allergies, or even be poisonous. Thus far, no adverse human health effects have resulted from consumption of such foods in countries where they have been approved (World Health Organisation, 2011). However, the WHO also notes that the safety of GM foods should be assessed on a case-by-case basis, as different GM organisms introduce genes in different ways, and it is “not possible to make general statements on the safety of all GM foods.”

### ***Environment***

By enabling the production of insect resistant and herbicide tolerant crops, the application of gene technology has resulted in reductions in insecticide application and enabled the use of more environmentally benign herbicides into the environment (Bureau of Rural Sciences 2008). This contributes to the sustainability of land management practices (CSIRO, 2010). Additionally, gene technology can enable the biological control of pests or harmful species. Examples are carp (a highly adaptable fish that competes with other native fish for food resources and contribute to the degradation of waterways) and cane toads (which contributes to a variety of adverse environmental impacts).

Scientists have used gene technology to try to block a specific gene in female carp so that only male fish are produced, in a bid to suppress carp numbers. Gene technology is also being used to find a way to prevent the tadpoles of cane toads from growing into adults. While these applications are still at the laboratory stage, they illustrate the potential for environmental benefits from gene technology that are relevant to Australia.

Although gene technology has the potential to be beneficial to the environment, it carries with it various risks. Potentially, some GMOs could reproduce, spread and multiply in the environment after they are released. In controlling biological pests, for instance, gene technology has to ensure that it involves manipulating only the genes of the specific species, in order to minimise risk to non-target species. Risks are assessed and managed before releasing any biological agents into the environment. Currently, the World Health Organisation is investigating potential adverse GMO impacts on beneficial insects, new plant pathogens, plant biodiversity, crop rotation, and movement of herbicide resistant genes to other plants.

## Chapter 3

# Gene technology and its regulation

The Act and the *Gene Technology Regulations 2001* (the Regulations) provide a foundation for the regulation of gene technology in Australia. The Act established an independent statutory office holder — the Gene Technology Regulator (the Regulator) — who is responsible for administering the national regulatory system for gene technology in accordance with the Act. The Department established the Office of the Gene Technology Regulator to support the Regulator.

The Commonwealth Government and the governments of each of the states and territories have signed an inter-governmental Gene Technology Agreement (the Agreement) (Commonwealth of Australia 2008) the purpose of which was to facilitate a national gene technology regulation scheme. The Agreement also established the Gene Technology Ministerial Council (GTMC) to provide policy input to the implementation and operation of the regulatory scheme. Under this Agreement, the Commonwealth cannot amend its gene technology legislation without GTMC agreement.

The continual development of gene technology across the world makes it incumbent on the Australian regulatory system to keep abreast of technical and regulatory developments across the world. Appendix B presents regulatory framework schemes for other international jurisdictions.

### 3.1 The Gene Technology Act 2000

The Act and its provisions establish a framework to address the overall objective of the Act. The objective of the Act is as follows:

“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 Gene Technology Act 2000, Section 3*

The regulatory framework that aims to achieve this objective:

“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 damage

provides an efficient and effective system for the application of gene technology; and

operates in conjunction with other Commonwealth and State regulatory schemes relevant to GMOs and GM products.”

*The Gene Technology Act 2000, Section 4*

The Act comprises twelve parts. These are listed in Box 3.1 along with a list of the main features of the Act, including circumstances where GMO dealings are allowed and the establishment of risk assessment processes for dealings with GMOs.

## Box 3.1

**THE GENE TECHNOLOGY ACT 2000**

The Gene Technology Act 2000 consists of 12 parts, as shown below. The goal of the Act is to protect the health and safety of people, and to protect the environment. It does this by identifying and managing risks that emerge from dealings with GMOs, using a science-based approach that is grounded in risk assessment and risk management.

- Part 1 — Preliminary
- Part 2 — Interpretation and operation of the Act
- Part 3 — The Gene Technology Regulator
- Part 4 — Regulation of dealings with GMOs
- Part 5 — Licensing system (Part 5A Emergency dealing determinations)
- Part 6 — Regulation of notifiable low risk dealings and dealings on the GMO register
- Part 7 — Certification and accreditation
- Part 8 — The Gene Technology Technical Advisory Committee and the Gene Technology Ethics and Community Consultative Committee
- Part 9 — Administration
- Part 10 — Enforcement
- Part 11 — Powers of inspection
- Part 12 — Miscellaneous

Features of the Act include the following:

- Prohibition of anyone dealing with a GMO (e.g. for research, manufacture, production, commercial release and import) unless the dealing is:
  - Licensed by the Regulator for contained use or involves intentional release into the environment
  - Notifiable low risk dealing (NLRD) or exempt dealing e.g. contained work which has been demonstrated to pose minimal risk to workers, the general public and the environment
  - on the Register of GMOs
  - Specified in an Emergency Dealing Determination
- Establishment of a statutory officer (the Gene Technology Regulator) to make decisions under the legislation;
- Establishment of the Gene Technology Technical Advisory Committee (GTTAC) and the Gene Technology Ethics and Community Consultative Committee (GTECCC). More information on the Gene Technology Advisory Committees is available on the OGTR Gene Technology Committees web page;
- Establishment of a process to assess risks to human health and the environment associated with various dealings with GMOs, including opportunities for public input;
- Extensive powers to allow monitoring and enforcement of the legislation; and
- A centralised, publicly available database of all GMOs and GM products approved in Australia (the Record of GMO and GM product dealings).

Source: Allen Consulting Group

The Act prohibits all dealings with GMOs unless the dealing is:

- a Licensed dealing;
- a Notifiable Low Risk Dealing (NLRD);
- an Exempt dealing;
- included on the GMO Register; or
- specified in an Emergency Dealing Determination (EDD).

The licensing system is based on scientific risk assessment and extensive consultation with expert advisory committees, government agencies and, for intentional releases of GMOs into the environment, the public. The Regulator issues licences for dealings not involving intentional release (DNIR) and dealings involving intentional release (DIR), which are explained below.

- *Dealings not involving intentional release (DNIR)* — these are dealings that take place under specified physical containment conditions in certified facilities to minimise risks to human health and the environment. The dealing requires an assessment of the risks of the dealing and preparation of a risk assessment and risk management plan (RARMP).
- *Dealings involving intentional release (DIR)* — these are dealings that take place outside contained facilities. The Act provides a short process for field trials through the limited controlled release provisions and a longer process with two consultation steps for releases on a wider commercial scale. These dealings also require an assessment of the risks and preparation of a RARMP. They are also subject to external review.

Low-risk dealings that do not require an authorised licence are further explained below.

- *Exempt dealings* — certain types of dealings with GMOs that involve a very low risk (i.e. contained research involving very well understood organisms and processes for creating and studying GMOs). Other than listing in the Regulations, the only legislative requirement for exempt dealings is that they must not involve an intentional release of a GMO into the environment.
- *Notifiable low risk dealings (NLRD)* — the regulations also set out categories of dealings with GMOs which are low risk and which may proceed provided that certain conditions spelt out in the regulations are observed. This includes requirements that the specified dealings be undertaken only in certified contained facilities. Institutional Biosafety Committees (IBCs) verify the proposed dealings and may also have oversight of them on behalf of the institution. NLRDs are notified annually to the Regulator. The conditions under which such dealings must be conducted are clearly set out in the regulations. An NLRD must not involve the intentional release of a GMO into the environment.
- *GMO register* — dealings with GMOs may be entered on the GMO Register once they have been licensed for a certain period of time. Dealings will not be entered onto the Register until the Regulator is satisfied that the dealings are sufficiently safe that they can be undertaken by anyone, and that safety does not depend on oversight by a licence holder.

A further authorised dealing not included above is the *Emergency Dealing Determination* (EDD). For these dealings, the Minister may make an EDD authorising dealings with GMOs for a limited period in an emergency. The Minister must be satisfied that there is an actual or imminent threat to people or the environment, that the EDD would adequately address the threat and that risks posed are able to be managed so as to protect people and the environment. The Minister must receive advice from the Regulator regarding the management of risks.

### 3.2 Gene Technology Regulations

While the Act describes the framework for the Australian system of regulation for GMOs, the Regulations contain additional information about the operation of certain provisions in the Act. In particular, these Regulations provide further detail regarding GMO dealings. The Regulations also provide additional detail to assist the interpretation and operation of the provisions in the Act.

For example, the Regulations describe the types of dealings with GMOs that are exempt from the national regulatory scheme and those that are Notifiable Low Risk Dealings (NLRDs). For DIR applications, Regulations 9A and 10 detail matters which the Regulator must 'have regard to' and matters 'to be taken in to account' respectively.

### 3.3 Gene Technology (Recognition of Designated Areas) Principle 2003

The GTMC is empowered by subsection 21 (1) of the Act to issue policy principles. The Gene Technology (Recognition of Designated Areas) Principle 2003 specifies:

- areas (if any) that are designated under a State law for the purpose of preserving the identity of GM crops, non-GM crops, or both GM and non-GM crops, for marketing purposes, are recognised under the Act (Section 5);
- the issuing of the Principle does not require a State to make a law of the kind recognised under section 5 (Section 6); and
- the Principle does not affect the Regulator's obligations under sections 55 and 57 of the Act in relation to the issue of a GMO licence, or his or her duties to consider the matters under section 56 of the Act (Section 7).

The Principle commenced on 5 September 2003.

### 3.4 The Office of the Gene Technology Regulator

The Act stipulates the establishment of the Regulator, while the Department also established the *Office of the Gene Technology Regulator* (OGTR) to support the Regulator in administering the national gene technology system as set out in the Act.

According to the Parliamentary Secretary for Health's *Statement of expectations* (2009), the Regulator's primary concern is to protect the people and the environment from risks resulting from research and release into the environment of GMOs. The functions of the Regulator are specified in Section 27 of the Act. They are summarised in Box 3.2.

### 3.5 State and territory regulation of gene technology

The Commonwealth and all the States and Territories are parties to the Gene Technology Agreement (Commonwealth of Australia 2008), which sets out the roles and responsibilities of each of the Governments in the administration and enforcement of the regulatory scheme. Under this Agreement, all Commonwealth, State and Territory Governments have committed to maintaining a nationally consistent scheme. National recognition of approvals is given effect through the conferral of functions on the Regulator by the State and Territory corresponding legislation.

One of the reasons for this dual state/federal approach is that under the Australian Constitution, the Commonwealth Government's powers do not extend to sole traders who are not trading interstate, and may not extend to State/Territory-based organisations and some higher education institutions.

Box 3.2

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**THE REGULATOR'S FUNCTIONS**

The Regulator has the following functions:

- to perform functions in relation to GMO licences as set out in Part 5 (of the Act);
- to develop draft policy principles and policy guidelines, as requested by the Ministerial Council;
- to develop codes of practice;
- to issue technical and procedural guidelines in relation to GMOs;
- to provide information and advice to other regulatory agencies about GMOs and GM products;
- to provide information and advice to the public about the regulation of GMOs;
- to provide advice to the Ministerial Council about:
  - the operations of the Regulator and the Gene Technology Technical Advisory Committee; and
  - the effectiveness of the legislative framework for the regulation of GMOs, including in relation to possible amendments of relevant legislation;
- to undertake or commission research in relation to risk assessment and the biosafety of GMOs;
- to promote the harmonisation of risk assessments relating to GMOs and GM products by regulatory agencies;
- to monitor international practice in relation to the regulation of GMOs;
- to maintain links with international organisations that deal with the regulation of gene technology and with agencies that regulate GMOs in countries outside Australia;
- such other functions as are conferred on the Regulator by this Act, the regulations or any other law.

Source: Commonwealth of Australia 2010

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While the OGTR assesses and regulates issues relating to human safety and the environment, each state can introduce its own legislation addressing market and trade issues. For instance, when the Regulator issued licenses for the commercial release of GM canola lines in Australia, all states and territories except Queensland and the Northern Territory invoked the Recognition of Designated Areas Principle and enacted GM crop moratorium legislation to delay the commercial production of approved GM canola until market and trade considerations had been addressed. Two states, Queensland and Northern Territory, have had no moratoria on GM crops.

### **3.6 Complementary regulatory agencies**

In addition to the OGTR, other Commonwealth Government agencies also have responsibilities for the oversight of products and activities involving GMOs in a variety of areas such as medicine and food. In some cases approval of GMO dealings require approval by both the Regulator and another agency. These agencies are briefly described below.

- *Food Standards Australia and New Zealand (FSANZ)* — FSANZ is responsible for setting standards in the safety, content and labelling of food. All GM foods intended for sale in Australia and New Zealand have to go undergo a safety assessment by the FSANZ.
- *The Therapeutic Goods Administration (TGA)* — The TGA administers the Therapeutic Goods Act 1989. This Act provides a national framework for the regulation of medicines, medical devices, blood and tissues in Australia, including GM and GM-derived therapeutic products and ensures their quality, safety and efficacy.
- *The National Industrial Chemicals Notification and Assessment Scheme (NICNAS)* — New and some existing industrial chemicals, including those produced by GMOs, are assessed under NICNAS, which considered their effects on human health and environment.
- *The Australian Pesticides and Veterinary Medicines Authority (APVMA)* — APVMA is responsible for the evaluation, registration, regulation, quality assurance and compliance of pesticides and veterinary medicines up to the point of sale. This includes agricultural products containing or produced by GMOs.
- *Australian Quarantine and Inspection Service (AQIS)* — AQIS regulates the importation of all animal, plant and biological products that may pose a quarantine pest and/or disease risk.

## Chapter 4

# The previous review and its outcome

This Chapter discusses the Statutory Review of the Act and the Gene Technology Agreement completed in 2006. It examines the implementation of the findings of that Review.

### 4.1 Nature of the 2006 Statutory Review

As required by Section 194 of the Act, an independent Statutory Review was undertaken in 2006, on the fifth anniversary of the Act coming into force. The Gene Technology Ministerial Council appointed the independent panel and issued the Terms of Reference (TOR) in May 2005.

Some 280 submissions were received in response to the TOR. The 2006 Review also conducted stakeholder consultations, considered the experience of the first four years of operation of the Act, emerging trends and international developments in gene technology and consulted a range of reports and literature. Broadly, the Review report (Commonwealth of Australia 2006a) examined the following areas.

- *Scope of the Act* — whether the scope of the Act should be broadened or stay the same.
- *Act achieving its object* — whether the object of the Act is being achieved.
- *Operation of the Act* — this refers to the effectiveness of the Act's consultative structure and process.
- *Regulatory burden* — whether the regulatory burden was appropriate for the risk involved.
- *Interface with other systems* — the extent to which the Act overlapped with other legislation.
- *Changing circumstances* — the flexibility of the Act in terms of dealing with changing circumstances.
- *The inter-governmental agreement* — this refers to the degree to which State moratoria and the national framework are consistent with each other.

### 4.2 2006 Statutory Review recommendations

The terms of the 2006 Statutory Review were more extensive than those of the present Review. The 2006 Review recommended a number of changes to improve the operations of the Act. The 2006 Review's recommendations are summarised in Table 4.1.

Table 4.1

**2006 STATUTORY REVIEW CONCLUSIONS AND RECOMMENDATIONS**

Area	Recommendations
The scope of the Act	The Review recommended the scope and definitions of the Act remain unchanged, although some stakeholders had argued that the scope of the act should be broadened to include economic, social and marketing impacts.
The Act's objectives	The Review found that the Act was achieving its objectives, and that the regulatory system was transparent and appropriate, and applied effectively. However, the operational experience of the first four years highlighted the need for some amendments to the regulatory system.
The operation of the Act	The Review concluded that the consultative structure and process worked well, but that it could be improved by ensuring that GTTAC's membership includes members with primary expertise in health and environmental risk assessment. It also recommended that GTEC and GTCCC be combined, and that the NHMRC be no longer consulted on all dealings involving intentional release (DIR) applications. Some stakeholders called for a more rigorous application of the Regulator's enforcement powers, but the Review concluded that the powers were applied appropriately and proportionately.
Regulatory burden	<p>Many submissions from the research community indicated that the burden imposed by the Act was not commensurate with the risk posed by dealings with GMOs by researchers. Additionally, AQIS used different guidelines for laboratory certification, which caused practical problems. The Review recommended that the OGTR and AQIS work together on harmonising certification requirements and introducing a system of single audits.</p> <p>The Review recommended 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)</p>
Interface with other systems	Some stakeholders noted that there was some overlap with the OGTR and other regulatory agencies. The Review concluded that the agencies worked well together, to minimise duplication and to ensure consistency and coherence. The Review recommended that a forum should be established to formalise arrangements of the interaction between the OGTR and other regulatory agencies. It also recommended that the Regulator should take steps to align requirements with those of Standards Australia as far as practicable.
Changing circumstances	The Review recommended that the Act should be reviewed in 2011 to ensure that it is flexible enough to accommodate emerging trends. The Review also examined the technology regulatory framework in a number of countries, and concluded that the Australian system is one of the most rigorous, transparent and accessible.
Inter-governmental agreement	The Review noted that state moratoria on growing GM crops had undermined the nationally consistent framework, which the IGA was intended to support. Some stakeholders expressed concern that the moratoria created regulatory uncertainty stopping further investment in GM food crops and impeding domestic farmers in competing internationally. Other groups 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 the market for non-GM crops. The Review concluded that the moratoria were having negative impacts, and recommended that all jurisdictions should commit to a nationally consistent scheme.

Source: Allen Consulting Group summary of the Review report (Commonwealth of Australia 2006a)

### 4.3 Response of State, Territory and Commonwealth Governments

The State, Territory and Commonwealth Governments' response to the Statutory Review was developed in 2006. In most cases all governments agreed with the recommendations. However some recommendations were not fully agreed by all jurisdictions (see Table 4.2).

Table 4.2

**2006 REVIEW RECOMMENDATIONS NOT FULLY AGREED**

Recommendation	Outcome
5.8	The Review recommended that the statutory timeframe for commercial DIR licences be extended to 255 working days, consistent with other relevant regulatory systems, to ensure that the OGTR has adequate time for assessment and public discussion. All governments except Queensland agreed in principle.
5.9	The Review recommended that a 90 working day statutory time be applied to variations for licences and there be an explicit power to allow a licence-holder to apply for a variation. All governments except Queensland agreed in principle.
9.1	The Review recommended that the Commonwealth and States through the GTMC reconfirm their commitment to a nationally consistent scheme for gene technology and including a nationally consistent transparent approach to market considerations as soon as practicable. All governments reconfirmed their commitment to a nationally consistent scheme for gene technology but Queensland, Tasmania, Western Australia and South Australia did not agree to a nationally consistent transparent approach to market considerations. The GTMC agreed in April 2006 to refer the issue of market considerations to the Primary Industries Ministerial Council for consideration and advice by the end of 2007.
9.2	The Review recommended 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. All governments except Tasmania and Western Australia agreed. The GTMC agreed on 27 April 2006 to refer this issue to the Primary Industries Ministerial Council for consideration and advice, by the end of 2007, on a consistent and transparent framework for co-existence of both non-GM and GM crops which can be assessed for adoption by the States, who wish to do so, as each jurisdictions' moratorium ends or is reviewed.

Source: Based on The Governments' response to the recommendations of the Statutory Review, October 2006

The Governments' October 2006 response noted that the Commonwealth Government intended to introduce the Gene Technology Amendment Bill into the Australian Parliament as soon as possible and that the States and Territories would use their best endeavours to introduce corresponding amending legislation into their Parliaments before 31 December 2007. The Commonwealth legislation was amended in 2007 along the lines agreed by the GTMC.

#### **4.4 Outcome of the 2006 Statutory Review**

Following the 2006 Review all jurisdictions re-affirmed their commitment to a nationally consistent scheme for gene technology. However there are differences between jurisdictions in relation to 'market considerations', as well as issues with corresponding legislation. The Primary Industries Ministers Council and the GTMC discussed the issues raised in recommendations 9.1 and 9.2 but there was no progress towards a resolution of these matters.

"All states and territories, except Queensland and the Northern Territory, have moratoria on growing genetically modified crops based on marketing grounds. Most state moratoria are due to expire in 2008 and the Tasmanian moratorium has an expiry date of late 2009. New South Wales, Victoria, South Australia and Tasmania are currently reviewing the moratoria legislation."

State, Territory & Australian Governments' response to the recommendations of the Statutory Review, 2006b

#### 4.5 The current legislative situation

Current State and Territory legislation is summarised in Table 4.3.

Table 4.3

#### STATE AND TERRITORY GENE TECHNOLOGY LEGISLATION

State/Territory and title of Act	Corresponding status	Date declared corresponding (if applicable)	Last amended to reflect changes in Commonwealth legislation (1)	Current status
<b>NSW</b> Gene Technology (New South Wales) Act 2003	Declared corresponding	3 September 2008	The Commonwealth gene technology laws, as in force for the time being, apply as a law of this State.	'Lockstep' with Commonwealth legislation.
<b>Northern Territory</b> Gene Technology (Northern Territory) Act 2004	Declared corresponding	20 November 2008	The Commonwealth gene technology laws, as in force for the time being, apply as a law of this State.	'Lockstep' with Commonwealth legislation.
<b>ACT</b> Gene Technology Act 2003	Declared corresponding	27 June 2008	21 April 2008	Up-to-date.
<b>Queensland</b> Gene Technology Act 2001	Declared corresponding	21 July 2008	20 February 2008	Up-to-date and wind-back in place.
<b>South Australia</b> Gene Technology Act 2001	Declared corresponding	16 May 2002	29 July 2010	Up to date.
<b>Victoria</b> Gene Technology Act 2001	Declared corresponding	16 May 2002	1 January 2008	Up to date.
<b>Tasmania</b> Gene Technology Act 2001	Not declared corresponding	Not applicable	Amendments have not been made to reflect the 2007 amendments to the Commonwealth Act	Not yet up to date.
<b>Western Australia</b> Gene Technology Act 2006	Not declared corresponding	Not applicable	Amendments have not been made to reflect the 2007 amendments to the Commonwealth Act.	Not yet up to date.

Note: 1. Date that amended legislation came into effect.  
2. Details of State and Territory regulations can be found on the OGTR website  
Source: Allen Consulting Group based on information provided by OGTR.

State laws are declared corresponding in order to achieve consistent national coverage of GMO dealings. Having State laws that incorporate all Commonwealth Act amendments achieves consistency – the same provisions apply to all persons/organisations for the same GMO dealings within and between jurisdictions.

All jurisdictions with legislation declared 'corresponding State law' are currently up to date with all amendments to Commonwealth legislation. However this situation is expected to change on 1 September 2011 when new amendments to the Commonwealth Regulations come into force. However, unless revoked, declarations of correspondence continue and, surprisingly, there is no trigger to require a re-examination of the declaration of correspondence.

Having wind-back (see Chapter 5) achieves certainty of application of the laws (i.e. which law applies to organisations where Commonwealth reach is uncertain). This is particularly pertinent for the Regulator in a compliance/prosecution context.

For the national scheme to remain nationally consistent at any given time, all States and Territories must have laws declared ‘corresponding State laws’ which remain consistent by incorporating amendments (ideally contemporaneously) made to the Commonwealth legislation. For the national scheme to provide certainty of coverage and application all States and Territories must also have wind-back notice in place. The most efficient and certain way of ensuring consistency of provisions is for States to adopt the Commonwealth legislation by reference (‘lock-step’). This approach has been adopted by NSW and the Northern Territory.

Unless State and Territory laws are declared ‘corresponding’ (and the State/Territory confers functions on the Regulator) the State/Territory laws have the potential to create problems within jurisdictions and nationally.

#### **4.6 Conclusions**

As shown in this Chapter, there continue to be variations in the implementation of Australia’s regulation of gene technology. The efficiency and national consistency of the present arrangements are depended on timely legislative action in some States and Territories. The next Chapter discusses these issues in more detail and makes recommendations to improve this situation.

## Chapter 5

### Review

This chapter considers the key issues raised by stakeholders in their submissions to this Review. Those who made submissions to this Review were broadly divided into a number of categories. Many submissions indicated satisfaction with the way the gene technology legislation is being administered by the OGTR. Table 5.1 summarises points regarding the submissions from each stakeholder group, with further descriptions below.

Table 5.1

#### STAKEHOLDER GROUP SUMMARY

Stakeholder group	Key points
Industry organisations	<ul style="list-style-type: none"> <li>Broadly divided into those organisations representing gene technology related companies, and those representing organic approaches to farming.</li> </ul>
Companies	<ul style="list-style-type: none"> <li>Three submissions that addressed a range of issues.</li> </ul>
Government agencies	<ul style="list-style-type: none"> <li>Government agencies addressed aspects of gene technology that fall within their responsibilities. The Gene Technology Regulator provided significant input.</li> </ul>
Research organisations	<ul style="list-style-type: none"> <li>Addressed regulatory issues associated with research, including the role of IBCs.</li> </ul>
Non-government organisations	<ul style="list-style-type: none"> <li>NGOs were mostly critical of the use of gene technology in Australia.</li> </ul>
Individuals	<ul style="list-style-type: none"> <li>Over one third of the submissions came from individuals, who were mostly critical of the use of gene technology in Australia.</li> </ul>

Source: Allen Consulting Group

Industry organisations representing gene technology-related companies expressed considerable concern for the inconsistent nature of gene technology regulation in Australia, and the ensuing trade and market impacts. For example, one stakeholder said:

“The inconsistencies in legislation across the grain growing states is extremely prohibitive in attracting funding for research and development into traits specific to Australia and each unique region.”

Agforce Queensland submission

The major biotechnology industry organisation provided detailed comments on the TOR, summarised below:

“The Gene Technology Act 2000 remains relevant;

The Office of the Gene Technology Regulator (OGTR) is operating in an effective and efficient manner;

The OGTR continues to provide a transparent and consistent federal gene technology regulatory system;

Australia's science-based Federal regulatory system is rigorous and should remain focused on the assessment of human health, safety and the environment;

The OGTR continues to engage with stakeholders and communicates in both a transparent and timely manner to ensure the Australian community recognises of the existence and role of the OGTR in maintaining human health and environmental safety of Genetically Modified (GM) crops;

The Act was intended to establish a national, consistent and predictable gene technology regulatory system in Australia (which unfortunately has not been achieved);

Australia needs a nationally consistent gene technology scheme to provide a consistent path-to-market for approved GM traits and enabling technologies which can be applied to crops and pastures within Australia;

The Commonwealth and states, through the GTMC, needs to reconfirm its commitment and support for a nationally consistent scheme for gene technology regulation;

The Federal regulatory agencies responsible for gene technology (OGTR, Food Standards Australia and New Zealand (FSANZ) and the Australian Pesticides and Veterinary Medicines Authority (APVMA)) continue to focus on harmonising their operating procedures and assessment processes; ....”

AusBiotech submission

Organisations representing companies with an organic or non-GM approach to farming showed particular concern for those farmers inadvertently affected by GM crops and argued against the approval of GMOs and GM products. (e.g. Gene Ethics on behalf of the GM-Free Australia Alliance).

Some companies and organisations that are users of GMOs or of the outcomes of gene technology provided submissions that addressed issues in their particular areas of interest (e.g. Crop Life Australia and Bayer Crop Science).

Government agency responses addressed a range of issues, some concerned with barriers to the uptake of gene technology (e.g. the Department of Innovation, Industry, Science and Research). The Gene Technology Regulator provided a detailed submission that addressed the TOR of this Review. In addition, the Office of the Gene Technology Regulator provided information in response to requests from the Review team.

Research organisations addressed aspects of the regulation of research involving gene technologies, including the operations of Institutional Biosafety Committees (IBCs).

Over one third of the submissions were from individuals. Submissions from individuals were almost exclusively critical of the use of gene technology in Australia. These submissions included claims of inadvertent contamination of organic farms by GM crops. A number of the issues raised in these submissions lay outside the TOR of this Review. For example, examining decisions of the Regulator on individual DIR applications is not within the scope of this Review.

The remainder of this Chapter provides a detailed response to the Review's TOR.

## 5.1 Effectiveness and efficiency of regulatory arrangements

The effectiveness and efficiency of the regulatory scheme is a major focus of this Review, with particular attention to improvements to the national consistency of the national scheme, the overall efficiency and effectiveness of the national scheme, and the coordination of the national scheme. This Term of Reference also addresses emerging trends and international developments. It also examines definitions and other provisions of the Act that may need attention.

Some submissions claimed that Australian research and adoption of GMOs is significantly behind that of North America. For example:

“The amount of gene technology research in Australia to date has been limited; North America (Canada and the United States) has led the way in this area.”

Agforce submission

These submissions stated that there are new players in GM business in other countries that have less stringent regulatory requirements than Australia. The authors of some submissions believe that there is a risk of Australia importing products containing GM material that may not have been approved by the OGTR. Crop Life argued:

“New technology developers from other cultures/countries, may not be as rigorous about seeking regulatory approvals as Australian developers. It is feared that this will increase the risk that food imports will contain low levels of GM material not approved for sale in Australia, although they will have regulatory approval from a third country.”

Crop Life Australia submission

As noted in Chapter 3, to be fully effective, OGTR must work with other Commonwealth agencies such as AQIS and APVMA. Review team discussions with these other regulatory agencies show that there is very good cooperation with OGTR. This can be summed up in the comment of one agency:

“We are extremely happy with the relationship that we have with the OGTR.”

Senior officer, Commonwealth Government regulatory agency.

For example FSANZ has a Memorandum of Understanding with OGTR. They undertake collaborative activities and have agreed that one agency will not grant a GM-related approval in areas of common interest without consulting the other. FSANZ and OGTR also share horizon scanning.

Many submissions described the Act as effective and efficient. For example;

“... the Gene Technology Act 2000 (the Act) is an efficient and effective mechanism for regulating genetically modified organisms (GMOs) in Australia.”

Department of Innovation, Industry, Science and Research and CSIRO submission

Stakeholders have seen the OGTR gain experience in the implementation of the Act, concomitant with an improvement in the effectiveness and efficiency its administration. This reflects an appropriate regulatory environment that has coped well with the steady increase in use of gene technology in Australia.

The OGTR has reported that the diversity in the nature of licence applications has grown, and with this the risk analysis and approval activities, as well as monitoring and compliance programs. The quantitative deliverables and performance indicators for 2009-10 are shown in Table 5.2. In addition, all qualitative deliverables/indicators were met. Most importantly, 100 per cent of licence decisions were made within the statutory timeframe.

Table 5.2

**QUANTITATIVE DELIVERABLES**

Quantitative deliverables	2009-10 target	2009-10 actual	Deliverable/indicator met or substantially met
Number of risk assessment and risk management plans produced	25 plans	26 plans	✓
Number of licences issued for intentional release.	10 licences	8 licences	✓
Number of licences issued for contained dealings.	16 licences	18 licences	✓
Number of assessments of alleged breaches assessed within 10 working days and appropriate response initiated.	100%	100%	✓
Number of organisations accredited.	7 organisations	8 organisations	✓
Number of facilities certified.	215 facilities	182 facilities	✓
Percentage of field trial sites and higher-level containment facilities inspected.	20%	53% field trial sites and 22% containment facilities	✓
Number of variations to licences and other instruments processed.	329 variations processed	357 variations processed	✓

Note: The numbers of applications received are not within the control of the OGTR.

Source: adapted from OGTR 2010, *Operations of the Gene Technology Regulator Annual Report 2009-2010*.

In terms of the day-to-day operations of the OGTR, this Review has identified one area in which some efficiency gains could be made. The present Commonwealth legislation requires the responsible Minister to table quarterly reports in the Parliament. While this requirement was logical in the early years of the regulatory arrangements, there is now sufficient experience with their operation to form the view that these quarterly reports are no longer necessary.

The OGTR's annual report contains most of the information currently provided in the quarterly reports. In addition, the OGTR publishes extensive information about its regulatory activities on its website.

***Recommendation 1: The requirement for quarterly reporting to the Commonwealth Minister, to be tabled in Parliament, be discontinued.***

### ***The national scheme for gene technology regulation***

Both the 2006 Review and the current Review have been asked to examine the national consistency of the scheme. However, unlike the 2006 Review, the current Review finds more concern among stakeholders about the lack of national consistency of gene technology regulation in Australia. Stakeholders have identified a number of problems that arise from this lack of consistency. For example:

“Crop Life strongly urges the Federal Government and all Australian state government to recommit to a national approach to regulation. This recommendation was made during the last review of the gene technology Act but to date, has not been acted upon. This is a critical goal if Australia is to remain at the leading edge in modern agriculture.”

Crop Life Australia submission

“Despite the Inter-Government Agreement to establish a naturally consistent regulatory scheme in Australia, variation in State Government implementation of legislation related to market and trade access considerations has led to inconsistency and limited the commercial adoption of GM crops.”

Dairy Australia submission

“It seems likely that the inconsistencies between State Governments implementing legislation around market and trade or market access considerations for GM crops present greater difficulties and costs for industries than those that result from the Act and the work of the OGTR.”

National Farmers’ Federation submission

There are two main sources of problems. One arises from delays in some jurisdictions to the adoption of changes to the legislation that have been agreed by the Ministerial Council and passed by the Commonwealth Parliament. The other source is the declaration of GM-free areas and moratoria on some GM crops.

### ***Structural issues with the legislation***

Each State and Territory has its own legislation regulating gene technology dealings. In practice there can be some variations between jurisdictions. State and Territory actions following the 2006 Statutory Review highlight the complexity of the national gene technology regulatory environment, as the following discussion illustrates.

Amendments were made to the Commonwealth legislation in 2007 following the 2006 Review. Two jurisdictions (NSW and the Northern Territory) amended their respective legislation in ‘lockstep’ with the 2007 Commonwealth Act amendments. In these jurisdictions, Commonwealth gene technology regulations are adopted through an automatic procedure.

Other jurisdictions agreed to amend their legislation to correspond with the 2007 Commonwealth legislation. Four jurisdictions (ACT, Queensland, South Australia and Victoria) have done this. Tasmania and Western Australia have enacted legislation but not yet had it declared ‘corresponding’. As a result, the legislation in these two States does not yet form part of the nationally consistent scheme administered by the Regulator. In practice, the vast majority of organisations conducting dealings with GMOs are captured by the Commonwealth legislation.

For example, in some jurisdictions it is possible for two researchers employed by different organisations and working together in the same laboratory to be subject to different gene technology regulations. In this example, a CSIRO researcher is subject to Commonwealth legislation, while his colleague from a state government agency may be subject to different regulations as a result of different State or Territory requirements.

This has the potential to create confusion. It could also lead to a situation where the same dealings with GMOs could require different approvals, which could make compliance determinations particularly difficult. Unless jurisdictions amend their legislation (Acts and Regulations) contemporaneously, this situation can occur each time amendments are made to the Commonwealth legislation.

#### *Wind-back*

Wind-back is the term used to describe actions that can be taken under Section 14 of the Act. Where a wind-back notice has been issued, any uncertainties about jurisdiction with respect to dealings by State agencies and higher education institutions are resolved by this Section of the Act, which effectively provides for their regulation under State rather than Commonwealth legislation, irrespective of their constitutional status. This decreases uncertainty regarding the application of the law and promotes compliance.

For a wind-back notice to be issued, a corresponding State/Territory law must be in force and the notice applies regardless of whether the corresponding State/Territory legislation is corresponding ‘in fact’ or not. Queensland is the only jurisdiction to currently have wind-back in place.

***Recommendation 2: All jurisdictions reconfirm their commitment to a national regulatory scheme for gene technology.***

***Recommendation 3: Jurisdictions follow the example of NSW and the Northern Territory, automatically adopting changed gene technology regulation by reference to the Commonwealth legislation.***

***Recommendation 4: Where the Commonwealth Act has not been adopted by reference, jurisdictions commit to amending legislation at the same time as Commonwealth legislation is amended.***

#### *GM-free areas and moratoria*

In 2003 the Regulator approved GM canola for commercial release. However, all canola-growing states invoked the Recognition of Designated Areas Principle (see Section 3.3) and implemented moratoria on commercial cultivation of this crop.

Subsequently some jurisdictions have removed these moratoria to allow commercial production of GM canola. For example, following a review by committee chaired by Professor Nossal, the Victorian Government allowed its moratorium to lapse in February 2008. Some jurisdictions committed to review these moratoria, but it appears that none have occurred in recent years. Some stakeholders have argued that, after eight years of experience with GM canola, these moratoria are no longer justified. Several stakeholders consider that this is holding back progress in the adoption of gene technology in Australia.

The Commonwealth Department of Agriculture, Fisheries and Forestry stated in its submission:

“DAFF considers that the moratoria ... undermines the national legislation ... and creates a disincentive to invest in the development of GM varieties suited to Australian conditions.”

DAFF submission

Another stakeholder commented:

“One of the unfortunate consequences of the moratorium on the growing of GM crops in South Australia is the inability for the canola seed industry to transport canola sowing seed of GM varieties through South Australia. The moratorium prevents the movement of such canola sowing seed from Queensland/Victoria/NSW to Western Australia and from Western Australia to the Eastern States. Canola seed companies/producers in the Eastern states and Western Australia are now forced to ship GM canola seed by sea or move by road transport through Darwin, avoiding the natural transport route through South Australia. The consequences of rerouting canola planting seed due to this current scenario are:

- an increase in transportation costs,
- greater complexity in logistics,
- additional time to transport the seed to customers in the east or west, and
- increased risk of farmers losing yield potential due to having to delay planting as a result of delays in planting seed supply. (e.g. floods in 2011).”

Australian Seed Federation submission

In the case of South Australia, a review of the *Genetically Modified Crops Management Act 2004* was conducted during 2007. The South Australian Government considered the report of this review and other information and determined that “the benefits of maintaining a prohibition on the cultivation of GM food crops outweighed the benefits of allowing it to lapse” (PIRSA, 2011).

Under South Australian regulations, “any plant or plant material that forms part of a GM food crop grown outside South Australia, including seed for planting, harvested seed for cleaning, harvested grain for processing or export, or hay, is not permitted to enter South Australia” (PIRSA, 2011). This creates a number of problems, particularly for parties wanting to transfer GM crops between Western Australia and the eastern states. In the future it is likely to inhibit the development of GM-based biofuels.

The moratoria create uncertainty leading to:

- a poor path-to-market for GM products, which acts as a disincentive for private investment; and
- a potential to fall behind in developments and adoption of biotechnology innovations in its export competitor countries.

***Recommendation 5: Those jurisdictions with GM moratoria that have not been reviewed in the last three years commit to reviewing them by the end of 2014.***

### ***International developments in gene technology regulation***

Stakeholder submissions commented on the importance of the OGTR to keep abreast of international gene technology developments. Stakeholders that commented on OGTR performance in this area were positive, suggesting that the OGTR has followed international developments in gene technology well, which has been critical for the success of Australia’s gene technology regulatory environment. For example:

“The monitoring of international developments and assessment of GM products by the Office of the Gene Technology Regulator has been very effective and critical for Australian agriculture which exports to international markets.”

Dairy Australia submission

Much of the current regulation of gene technology, including that of Australia, is based on the work of the Organisation for Economic Development and Cooperation (OECD) since the 1980s. Since that time, the OECD has issued a series of consensus documents on the safety of novel foods and feeds (OECD, 2011) and continued its work on the harmonisation of regulatory oversight in biotechnology. The key developments in international regulation of gene technology are summarised in Table 5.3.

In addition, the European Commission has issued a number of regulations. These are summarised in Table 5.4, which also illustrates the frequency with which the European Commission has issued new Directives and Regulations.

Table 5.3

#### REGULATION OF GENE TECHNOLOGY

Year	Event	Significance
1986	OECD report <i>Recombinant DNA safety considerations</i> and OECD Council Recommendation	Developed over a period of two years by an expert group representing all OECD countries. Basic reference for much subsequent national legislation.
1986	USA coordinated framework for regulatory oversight of biotechnology	Required regulation to be handled within existing legislation and agencies.
1986	European Commission issues <i>A Community Framework for the Regulation of Biotechnology</i>	Starting point for subsequent EU biotechnology legislation.
1990	European Directives relating to the contained use of GM micro-organisms and field release of GMOs	Further development of European regulation.
1993	OECD report <i>Safety evaluation of foods derived from modern biotechnology: concepts and principles</i>	Widely cited report that provides a starting point for risk assessment of novel foods.
1999-2003	Codex Alimentarius Commission	Three documents relating to risk assessment and the safety of GM foods.
2000	United Nations' Cartagena Protocol on Biosafety	A multilateral environmental agreement.
2001	European Directive replacing 1990 Directive on field release of GMOs	Regulations on traceability and labelling of GM products.

Source: Allen Consulting Group based on OECD 2007

An OECD paper (OECD 2007) provides snapshots of national gene technology regulation in nineteen countries. In this report, Australia's regulation of gene technology appeared comparable with that of most other leading OECD countries.

There do not appear to have been any further authoritative international comparisons of gene technology legislation since 2007. However the Review has been advised by several Australian stakeholders that there is considerable overseas interest in Australia's approach, and we understand that OGTR has received a number of overseas visitors seeking first-hand information. In addition, staff of the OGTR have conducted risk assessment and risk management capacity building activities to assist other countries that are developing regulatory systems for gene technology.

***Recommendation 6: The OGTR continue to be active in OECD and other international fora to stay abreast of international developments in gene technology regulation.***

Table 5.4

**EUROPEAN DIRECTIVES & REGULATIONS RELEVANT TO GENE TECHNOLOGY UP TO 2007**

Directive/Regulation	Subject
D 90/219	Contained use of micro-organisms for research and industrial purposes (Amended by Directive 98/81)
D 90/220	Deliberate release into the environment of GMOs (Replaced by Directive 2001/18)
D 90/679	Safety of worker vis-à-vis biological agents (Replaced by Directive 2000/54)
R 258/97	Novel foods and food ingredients
D 98/44	Protection of biotechnological inventions
D 2001/18	Deliberate release into the environment of GMOs
R 1946/2003	Transboundary movements of GMOs
R 1829/2003	GM food and feed
R 1830/2003	Traceability and labelling of GMOs and food/feed products produced from GMOs
D 2004/35	Environmental liability
R 65/2004	System for the development and assignment of unique identifiers for GMOs
R 641/2004	Rules for implementation of R 1829/2003

Source: OECD 2007

***Issues regarding definitions and provisions within the Act***

Some submissions discussed emerging developments in gene technology, raising questions as to whether these new developments are covered by the existing legislation and whether the OGTR has mechanisms in place to address their potential impact on humans and the environment. For example:

“A new generation of GM plants is now being developed with slightly modified versions of endogenous genes, or similar genes from other plant species. Nuseed acknowledges the need for regulation of such products; we believe that the regulatory constraints need to reflect a potentially lower risk with these products especially if the novel genes or gene products are already present in the environment or in the human diet.”

Nuseed submission

In its submission, the OGTR noted that some new technologies continue to emerge and are challenging the definitional reach of the Act.

This raises two questions:

- Are the provisions of the Act adequate to cover recent developments?
- Is the Regulator able to implement changes to regulations in a timely manner in order to address these challenges?

### *Definitions*

The Act regulates ‘GMO dealings’. This does not cover the *use* of a GMO, unless the use occurs for the purposes of a dealing. The Explanatory Memorandum to the Gene Technology Bill (Commonwealth of Australia, 2000) describes the Act as a ‘gap filler’ to regulate dealings with GMOs and GM products not regulated by the existing regulators (FSANZ for food, TGA for therapeutic goods and APVMA for agricultural and veterinary chemicals). The Explanatory Memorandum provided examples of gaps and suggested that the legislation would have adequate coverage to address examples of existing regulatory gaps (e.g. the use of GMOs for bioremediation).

At the time that the Act was passed by the Parliament it was recognised that most gene technology regulatory gaps existed in relation to GMO dealings, while existing regulatory agencies already regulated most GM products. Despite the suggestion that such gaps could be adequately covered by the Act, the last ten years has revealed the emergence of a number of activities with GMOs that are potentially outside the coverage of the Act.

To date, the majority of applications, worldwide, involving environmental release have been for GM plants. GM plants are well covered by the current definition of dealings, including for situations of commercial or unrestricted release, but it is less clear for other types of GMOs. However there is ongoing development, in Australia and internationally, of GM microorganisms and GM animals (including insects, fish and mammals) with the ultimate goal of unrestricted environmental release.

Examples from overseas include: the recent experimental releases in the Cayman Islands and Malaysia of GM mosquitoes for biocontrol of mosquito populations to limit the transmission of dengue fever; and contained laboratory tests in Europe of GM *Pseudomonas fluorescens* bacteria for bioremediation of polychlorinated biphenyls (PCBs) in soil. Given the nature of the definition of ‘deal with’ in section 10 of the Act it is unclear whether the use of such GMOs in an unrestricted manner in the environment would be captured by the Act in the same way as GM plants.

While the Explanatory Memorandum referred to a gap filling role in relation to GMOs and GM products, the provisions of the Act arguably do not give the Regulator the capacity that was foreshadowed. As it is currently formulated, the definition of ‘dealings’ in Section 10 of the Act is not adequate to cover some of the matters described above and (in the case of bioremediation), mentioned in the Explanatory Memorandum as being covered by the Act. This makes it difficult for the Regulator to meet public expectations.

***Recommendation 7: The Ministerial Council review the definition of ‘dealings’ in the Act with a view to clarifying the scope of the regulatory scheme.***

Activities with GM *products* are not regulated directly under the Act. It is not an offence to deal with a GM product without a licence. However, the Regulator may condition a GM product that is derived from a GMO. The Regulator may:

“impose obligations in relation to GM products that are derived from a GMO in respect of which particular dealings are licensed.”

Section 62 (1) of the Act

There is no express legislative limit on the scope of conditions that can be placed on a GM product.

However, since the Act has no operation in respect of regulation of activities with a GMO other than in the course of one of the primary dealings, it is arguable that the range of permissible conditions placed on GM *products* would be similarly constrained. The Review considers that the scope of the Regulator's powers should be clarified where a GM product may not be regulated by another agency.

***Recommendation 8: The Ministerial Council review the conditioning of GM products in the Act with a view to clarifying the scope of the regulatory scheme.***

#### *Flexibility of the Act to address changing circumstances*

Some stakeholders are concerned that the definition of GMOs in the Act may not be adequate. For example, one organisation recommended:

“With the advent of new technologies the definition of GMOs captured within the Act should be reviewed and harmonized with its counter parts in affiliated regulatory agencies.”

Australian Seed Federation submission

“With the advent of new technologies whereby the incorporation of novel DNA to mimic natural processes, the definition of GMOs captured within the Act should be reviewed.”

Bayer CropScience submission

The Act already contemplates the emergence of new gene technologies by providing that the Regulator can, through Regulations:

- exclude a gene technology technique from regulation;
- declare a thing to be a GMO; and
- declare a thing not to be a GMO.

However, changes to Regulations can take up to eighteen months to implement and the process is complex (see Figure 5.1). The processes that the OGTR has to follow to amend its legislation are complicated by the combination of requirements of the Gene Technology Agreement and the *Legislative Instruments Act 2003*.

There are two significant problems with this situation:

- This process could limit the ability of the OGTR to move swiftly in relation to new technological developments or newly identified risks.
- Time delays of this sort result in uncertainty for researchers and users wanting to implement new technologies and this may also be a disincentive to investment in new technologies.

In addition, when an existing technology has been in use for some time and knowledge of its safety has been built through a large body of literature and experience, the Regulator may advise the GTMC that the level of regulation can be relaxed (e.g. safety features for technologies involving viral vectors). This could involve changing a classification of GMO dealings. The time delays in implementing such a change in Australia disadvantage our GM researchers and users *vis-à-vis* their international counterparts.

Stakeholder comment on these matters included:

“The inconsistencies in legislation across the grain growing states is extremely prohibitive in attracting funding for research and development into traits specific to Australia and each unique region.”

Agforce submission

“The intention of The Gene Technology Act 2000 to achieve a nationally consistent regulatory framework has not been achieved as indicated by the variety of legislations across the States. Therefore investors in GM technology have no clear path-to-market.

Such uncertainty added to the already costly regulatory system undermines the confidence and willingness of potential investors in R&D. Without such investment agricultural industries will struggle to keep our world-class researchers who provide innovative, productive, new technological options for Australian agriculture and will see a continuing downward trend of competitiveness in the world market.”

Producers Forum submission

“State legislation and moratoria in the Australian Capital, Territory, Tasmania and South Australia is hampering the innovation and growth of the agricultural, environmental and industrial biotechnology industries by restricting the path-to-market of OGTR-approved GM products.”

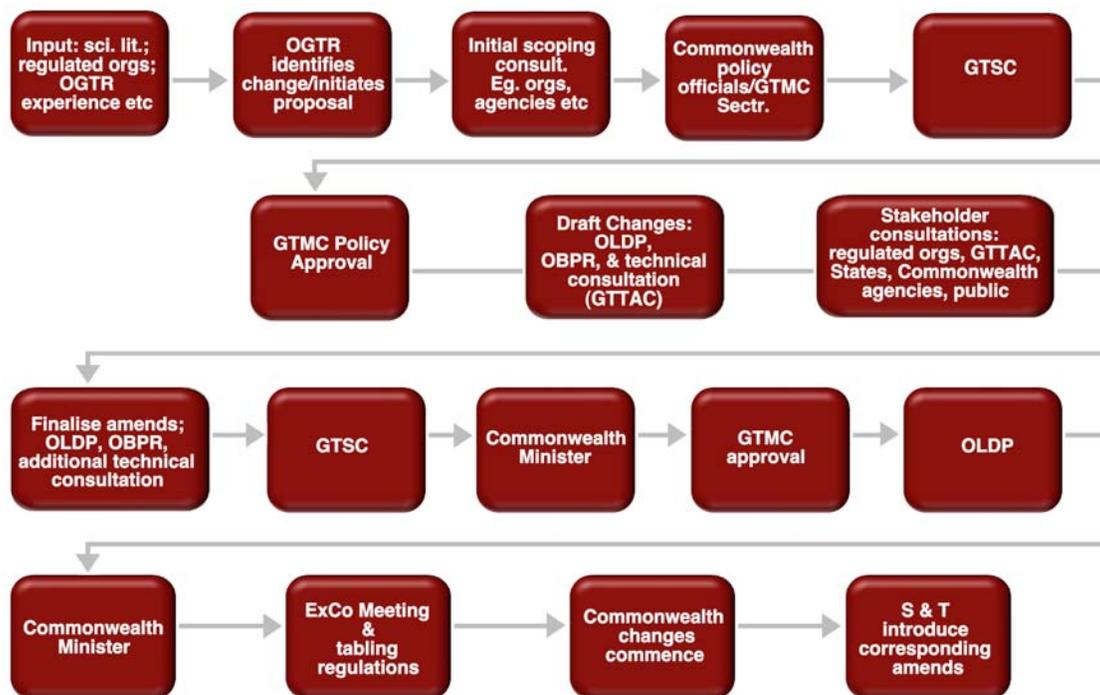
Ausbiotech submission

“The Gene Technology Act impacts on research because it imposes a regulatory burden which is greater than many overseas competitor countries. Within Australia other regulatory authorities also impact.”

Queensland Institute of Medical Research submission

Figure 5.1

**PROCESS FOR AMENDING THE GENE TECHNOLOGY LEGISLATION**



Notes: C/w = Commonwealth, S & T = States and Territories, OBPR = Office of Best Practice Regulation, OLDP = Office of Legislative Drafting and Publishing, ExCo = Executive Council

Source: Allen Consulting Group

One solution to this problem would be to amend the Act to permit the Regulator to regulate through the use of legal instruments capable of being amended in a timely manner at the discretion of the Regulator (acting with advice of the GTTAC). Such determinations would be subject to the Administrative Decisions (Judicial Review) Act 1977 and could be appealed.

***Recommendation 9: The Department of Health and Ageing explore with the Attorney General's Department and the Ministerial Council ways in which the process for amending the gene technology legislation could be streamlined.***

#### *Inadvertent dealings*

Following the 2006 Review, the Act was amended to provide for temporary licences for inadvertent dealings for the purposes of GMO disposal. The OGTR believes that this needs to be extended so that other dealings can be authorised that relate to disposal of inadvertently obtained GMOs. For instance, when a business believes that it may have inadvertently come in to the possession of a GMO, it may need to sample and perform tests to confirm this, store the GMO while tests are being undertaken, and even propagate or 'grow out' the GMO (in appropriate containment) to obtain material for testing.

Such dealings would be considered reasonable and part of the disposal process, but may not be permitted under the current provisions of the Act.

***Recommendation 10: The Act be amended so that the Regulator can authorise other appropriate dealings related to inadvertent dealings.***

#### *Institutional Biosafety Committees*

IBCs play an important role in the national regulatory framework. Some research stakeholders have expressed concerns that their IBCs are not functioning as efficiently and effectively as they should. However some of these concerns appear to relate to functions outside IBC responsibilities under the Act.

One submission suggested that there is a need to review and clarify the role of IBCs that supervise the licenced dealings at 'multi-user' facilities:

"It is not clear how the IBC of an organisation overseeing a multiuser site should operate. As multi-disciplinary research becomes more common there is a need for clarity in supervision of this research."

WA Department of Agriculture and Food

There may be some over-regulation of low-risk GM rodents. Some researchers have suggested that the costs and benefits of IBCs need to be examined. These matters appear to lie outside the TOR of this Review. However they suggest that there is a need to ensure that IBCs more clearly distinguish their work in relation to compliance with the Act from other tasks that they undertake.

***Recommendation 11: The OGTR continue to provide information to IBCs to assist them in understanding their responsibilities under the Act. IBCs should differentiate this aspect of their work from other activities for which they may also be responsible.***

## 5.2 Achievements of the objective of the Act

As noted in Chapter 3, the object of the 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.

While many stakeholders feel that the Act's objectives are being achieved, there were a number of submissions alleging failures of the Act in achieving its objectives. Some of these submissions raised matters that are outside the TOR of this Review such as the impact of herbicides on human health. For example, one alleged that pollen from GM plants expressing the *Bacillus thuringiensis* (Bt) toxin has sub-lethal effects on bees.

Some submissions questioned the capacity of the Act to protect traditional and organic farmers from neighbouring GM crops. For example, it was claimed that an organic farmer had GM canola seeds blown on to his property, costing him his organic certification. Some stakeholders argued for a liability regime to be imposed on farmers growing GM crops, to protect organic farmers while others felt that the coexistence of GM and traditional crops is impossible. The previous Review considered such matters and concluded that it is appropriate that they remain outside the scope of the Act.

### *Effectiveness of the regulatory framework of the Act*

Box 5.1 presents the regulatory framework of the Act, as described in Section 4 of the Act.

Box 5.1

#### REGULATORY FRAMEWORK OF THE ACT

##### **Part 1, Section 4 of the Gene Technology Act 2000**

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 (such as those that regulate food, agricultural and veterinary chemicals, industrial chemical and therapeutic goods).

Source: *The Gene Technology Act 2000*

### *The Precautionary Principle<sup>2</sup>*

The regulatory framework provides for a precautionary approach to gene technology regulation to protect against environmental damage. Submissions argued both for and against this approach.

<sup>2</sup> The Precautionary Principle can be stated as: If an action or policy has a suspected risk of causing harm to the public or to the environment, in the absence of scientific consensus that the action or policy is harmful, the burden of proof that it is not harmful should fall on those taking the action.

Those for a precautionary approach agreed that concern for the environment should reflect potential risks from the release of GMOs and GM products. For example:

“The OGTR appears to consistently ignore the precautionary principle which should be fully integrated into the GT Act, as it is in the Environment Protection and Biodiversity Conservation Act.”

Consumers for GM Free Food submission

Those against the precautionary principle felt that such an approach hampered the role for market forces to determine the acceptability of products. For example:

“The precautionary principle should not be incorporated into any regulatory regime. Application of the precautionary principle will destroy our ability to advance in agricultural development and use.”

Western Graingrowers submission

Opponents to the precautionary approach wanted to see a distinction between the role of government in protecting the health and safety of people and the environment, and the role of the market in determining acceptable products derived from GMOs and GM products.

Scientific evidence underpins a precautionary approach to gene technology regulation. Many submissions affirmed a desire for the science-based approach to regulation not to be compromised. A science-based approach relies on evidence to inform decisions and regulation. The OECD (OECD 2007) has discussed the precautionary approach. It finds that this approach has generally worked successfully. However it expresses concern that, while biotechnology has now enjoyed an excellent safety record over an extended period, this is not reflected in the action of some countries that have introduced ever more stringent regulation.

***Recommendation 12: Governments in Australia maintain a science-based precautionary approach to the regulation of gene technology.***

### **5.3 Powers of the Act to enforce compliance**

Few submissions commented on the power of the Act to enforce compliance. Some commented positively on the appropriateness and effectiveness of the current powers of the Act, with one describing the compliance process (between the OGTR and stakeholders) as now a proactive and consultative process rather than a punitive approach. Until the legislation has been the subject of litigation, it will be difficult to form a definitive view of the powers of the Act. The present approach of the OGTR is to achieve compliance through consultation with a view to achieving cooperative compliance.

OGTR’s active monitoring and inspection program includes audits and practice reviews. To date there has been no need for prosecutions since the regulated community has shown a willingness to meet the requirements of the gene technology legislation. Potential non-compliance would undergo a risk assessment and be addressed immediately with the cooperation of the licence holder.

#### 5.4 Consultation provisions of the Act

This Review has examined the effectiveness of the consultation provisions of the Act (including methods to communicate, the costs and benefits of the consultation provisions, and the transparency of the consultation provisions), the roles of the statutory advisory committees (the Gene Technology Technical Advisory Committee (GTTAC) and the Gene Technology Ethics and Community Consultative Committee (GTECCC)), and issues relating to the stakeholders consulted with during the application process<sup>3</sup>.

##### *Effectiveness of consultation arrangements*

The Review has examined the effectiveness of the consultation provisions with respect to changes in communication modes, any costs and benefits, and the transparency and accountability that they provide.

Stakeholder submissions commented on the OGTR's general consultation and communication processes. For example:

“AFAA believes that communication has been both transparent and timely, and has improved considerably since the last Gene Technology Act review conducted in 2006, including advertising, electronic notifications, media, participation in events and face-to-face dialogues with stakeholders.”

Agrifood Awareness Australia submission

One stakeholder described the OGTR as able to facilitate good two-way communication, while another described the consultation provisions of the Act as world class:

“After extensive consultation with all stakeholders, the Gene Technology Act 2000 gave Australia a gene technology system that is considered as possibly the best and most rigorous, transparent and effective in the world. The Statutory Review of 2006 confirmed this view.”

National Farmers Federation submission

OGTR makes good use of its website and communicates with a large database of persons and organisations which have indicated an interest in OGTR's work. The website appears to be well maintained and up-to-date. Many submissions commended the OGTR's communication modes, including the significant improvement in use of electronic notifications, media, event participation and face-to-face dialogue with stakeholders.

However, there are still some concerns that the community remains confused about GMOs and GM crops, in particular about their safety and impact on the environment.

There are also considerable sections of the community who remain unaware that there is a regulatory framework in place. One submission (Department of Innovation, industry, Science and Research) reported a survey that showed a very low awareness of OGTR.

Some stakeholders have commented that OGTR could be much stronger and more pro-active in its communications activities. For example:

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<sup>3</sup> For this final point, the 'applications' has been interpreted to mean the processes of applying for dealings approval or dealings licence.

“Not with-standing the increased and improved communications from the OGTR and others over the life of the act, in general, there remains confusion in the community about GM crops and foods and their safety for humans and the environment. Indeed, it appears that there are still considerable sections of the community who remain unaware that there is a regulatory framework in place.”

National Farmers’ Federation submission

“ASF recommends that the OGTR continues to engage with stakeholders in this same manner and where possible enhance its communication so as to ensure that the Australian community (including the seed industry) recognises the existence and strategic role of the OGTR in assessing and adjudicating.”

Australian Seed Federation

It was felt that there is a need for more public confidence in OGTR’s processes, which could be achieved if the OGTR directly addressed misinformation about the regulatory processes by opponents of gene technology. While OGTR is expected to take a neutral position on the technology itself, these stakeholders would like the OGTR to be clearer about the extensive review and testing required before GMOs are released.

***Recommendation 13: The OGTR increase its communications to the general public to raise its profile and build confidence in Australia’s regulation of gene technology.***

#### *Consultations on individual proposals*

The communication strategy followed by the OGTR in relation to individual proposals exceeds that required by the Act. For instance, in addition to the requirement to publish notifications in the Gazette, in newspapers and on the OGTR website, the Regulator engages in direct communication techniques (such as emails and letters). The OGTR currently has a list of approximately 700 people and organisations (covering the entire spectrum of views on gene technology) that receive every OGTR notification by email.

The Act’s consultation provisions for DIR applications (Section 52) requires publishing notices in the *Commonwealth Gazette* and in a newspaper circulating generally in all states. Gazette notices have minimal impact, but provide a low costs permanent public record. Advertising in state and national high-circulation newspapers is significantly more expensive, but provides greater exposure. While some advertising should remain, it is apparent that most interest generated from the public consultation process arises from OGTR contacting and advising those on their circulation email list (of 700 people and organisations).

A number of submissions were concerned about the requirements to consult local councils about specific licence applications in their region. For example:

“The requirement to consult with local government seems inefficient, redundant and costly in time and money.”

Bayer CropScience submission

“Some stakeholders that the regulator must consult with (e.g. local councils) during the application/approval process are unlikely to have expertise in gene technology ...”

Producers Forum Submission

Concerns were raised that councils do not have the appropriate background and expertise to comment on details of a particular licence. This process represents a cost to OGTR that is not providing net benefits. This Review doubts that bringing local councils into consultations is necessary or useful.

Questions were raised about the public availability of licence application information presented by applicants. Two issues have been raised in this regard. One is the large volume of material provided with some applications. This makes it difficult for OGTR to provide information electronically. The second problem is the issue of the confidential commercial information (CCI) exemption from some scientific data.

Some stakeholders consider that this exemption compromises the transparency of the regulatory system. For example:

“The ‘confidential commercial information’ exemption from disclosure of key scientific data needed for assessment and scrutiny of licence applications must be modified to allow access to construct and preliminary stability and gene number and gene location data, for examples, to those interested in commenting on a proposed release.”

Ian Turnbull submission

There are no simple solutions to these issues. In some cases it may be possible for OGTR to arrange for the applicant to provide non-confidential summaries of large documents and CCI information that can be made available to interested stakeholders.

***Recommendation 14: For many DIR applications, advertising in local or state newspapers in the region where the DIR is to occur is sufficient (given OGTR’s established electronic communications channels with interested parties). For issues/licences of national importance it should be sufficient for OGTR to place advertisements in one national newspaper. The OGTR could experiment with using social media to communicate with stakeholders in appropriate situations.***

### **Functions and roles of the advisory committees**

Most discussion surrounding the advisory committees concerned the GTECCC (recently formed by the amalgamation of the GTEC and the GTCCC). The Gene Technology Technical Advisory Committee (GTTAC) appears to be working well.

Comments were made regarding the value of the GTECCC. Many supported the amalgamation and formation of the new GTECCC, while some still questioned its role and purpose. One stakeholder felt that the advisory committees offered a suitable platform for discussing value-based issues, while another felt value-based judgements would weaken the OGTR’s science-based focus. Yet another stakeholder stated that such value-based issues should be discussed outside the Act.

Questions were raised about the membership of the GTECCC. One submission spoke of the vested interest of current participants, while another stated that committee membership should not include anyone involved in public campaigns against GM technology. Yet another submission suggested that the government advisory bodies should be represented at least 50:50 in terms of proponents and opponents of gene technology. Some expertise in gene technology is clearly necessary for members of GTTAC.

The Review has discussed advisory arrangements with the chairs of the two committees and considers that the present advisory arrangements are satisfactory.

### 5.5 Interaction with other regulation

Some submissions also raised concerns regarding interaction between the Act and other relevant Acts and schemes, such as:

- the lack of harmonisation between OGTR and AQIS legislative requirements;
- a claim that the OGTR does not have to consider safety issues that are dealt with by the TGA and FSANZ;
- suggestions that there may be some duplication between APVMA and OGTR; and
- the differences in the GMO definition between the Act and that used by agencies such as FSANZ and APVMA.

The consideration of Bt cotton<sup>4</sup> provides a useful example. The OGTR was responsible for assessing the health and environmental implications. APVMA was required to take into account health, environmental, efficacy and trade issues. The two agencies should continue working together in such cases, with a view of reaching a common position on the health and environmental issues.

Following passage of the *Gene Technology Consequential Amendments Act*, the Gene Technology Act, APVMA, FSANZ, the TGA and NICNAS all now use the same definitions of GMOs and GM products. The Review has seen no evidence to suggest that there are real problems in relation to the other issues. However the OGTR needs to be more effective in communicating to stakeholders how it works with other regulatory agencies.

#### *The GMO Record*

The Regulator is obliged to maintain the GMO Record under Section 138 of the Act. The Record includes authorisations of GMO dealings made under the Act. However it is also required to include GM product approvals of APVMA, TGA, FSANZ and NICNAS. Maintaining GM *products* approved by these other agencies on the GMO Record duplicates the record keeping of these other agencies and is administratively inefficient. The requirement to include GM products in the GMO record could be removed from the Act.

***Recommendation 15: The requirement to include GM products approved by APVMA, TGA, FSANZ and NICNAS in the GMO Record be removed.***

### 5.6 Regulatory burden of the legislation

Almost all regulations have the potential to impact on productivity. It is therefore essential for regulations (concerning any industry or sector) to be effective and efficient. In the case of gene technology regulation, the regulatory burden should be commensurate with risk so that the safety and health of people and the environment are maintained, while industries and organisations that involve gene technology are able to be productive.

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<sup>4</sup> Bt cotton is cotton that has been modified by inserting the gene coding for the Bacillus thuringiensis toxin – a natural insecticide.

Regulatory duplication and inconsistencies lead to uncertainty, planning delays and increased compliance costs for organisations working in gene technology.

Quite a number of submissions believe gene technology regulatory requirements and compliance costs to be reasonable and commended the OGTR's performance in regulating gene technology in Australia.

“The current costs of the processes associated with a stakeholder operating within the Act are reasonable based on the current classes of approval and the compliance approach undertaken by the OGTR within the Act.”

Australian Seed Federation submission

The Review was informed that a number of overseas visitors familiar with gene technology regulation have commented favourably on the Australian regulatory framework for GMOs, including classification and consultations arrangements.

The different approaches taken by various States and Territories in relation to 'marketing issues' result in additional compliance costs. These relate to difficulties and costs in managing cross-border operations and the forgone opportunities from accessing technologies that might assist their farm operations.

Another area where compliance costs and effort are seen as burdensome related to those dealings that have seen a reduction in risk with improved technology, but have not yet seen a commensurate benefit in reduced compliance costs.

Research institutes and universities spoke of the regulatory burden for IBCs. One example related to NRLDs. The process of varying or modifying a NRLD — necessary when there are changes in the people, the facilities or the class of genes — requires researchers to submit details to their IBC. This can create some additional work for IBCs.

Another issue for IBCs is the time that IBC members must spend reading and assessing applications. One institute calculated that for larger institutes, this can be a commitment of 2-3 days a month throughout most of the year. This suggests that some IBCs may need more members and subcommittees to spread the workload.

## **5.7 Proposed amendments to the Act**

Proposals for changes to the Act that have been discussed in preceding sections of this report are summarised in Table 5.5.

Table 5.5

**PROPOSED AMENDMENTS TO THE GENE TECHNOLOGY ACT**

Issue	Change proposed
Quarterly reports	The requirement for quarterly reporting to the Commonwealth Minister, to be tabled in Parliament, should be discontinued.
Definition of dealings & conditions on GM products	The definition of 'dealings' and the conditioning of GM products should be reviewed by the Ministerial Council with a view to bringing these fully into line with the Explanatory Memorandum.
Processes for amending the Act	The Department of Health and Ageing should explore with the Attorney General's Department and the Ministerial Council ways in which the process for amending the gene technology legislation could be streamlined.
Inadvertent dealings	The Act should be amended to so that the Regulator can authorise other actions related to inadvertent dealings
Advertising in relation to DIRs	The Act should be amended to relax the requirements for OGTR to advertise DIRs in newspapers.
GM products and the GMO Record	The requirement to include GM products approved by APVMA, TGA, FSANZ and NICNAS in the GMO Record should be removed.

**Technical amendments**

The following technical amendments in Table 5.6 have been identified as requiring attention. These amendments are essentially 'housekeeping'.

Table 5.6

**TECHNICAL AMENDMENTS TO THE GENE TECHNOLOGY ACT**

Issue	Change proposed
Section 30	The current language suggests that the issue of the <i>application</i> for a licence is the subject of consideration rather than the licence itself. More appropriate wording might be "whether GMO licence is issued or refused in relation to a particular application."
Section 71 (2B)	This subsection was inserted when the Act was amended following the 2006 Statutory Review. In its present form, this provision precludes regard being had to risk assessment for licences other than the one to be varied. In reality, the same or similar GMOs and dealings may be subject to more than one application and assessment. The requirement to confine the new risk assessment to the previously assessed risk should be removed.
Section 74	The current formulation of Section 10 sets out a list of matters that must be considered before dealings can be declared to be NLRDs. However experience has shown that these considerations are not necessarily relevant to all types of GMOs (particularly to dealings considered to be low risk. A more effective approach could be to consider whether the risk profile of particular dealings necessitates assessment and regulation on a case by case basis and therefore under licence, or whether it can be safely undertaken pursuant to a set of generic requirements stipulated in the regulations.
Section 138	Subsection (1) refers to GM Product dealings. A GM product is not a GMO, and only dealings with GMOs are the subject of dealings under the Act.

Some submissions to the Review called for amendment to Section 10 of the Act, to delete all of the words in 10 (d) after "a human being". The Review understands that the definitional text relating to human beings was intended in the original drafting of the Bill noted in the Explanatory Memorandum (page 48) and is unrelated to the Prohibition of Human Cloning for Reproduction Act 2002.

The proposed deletion could have the unintended consequence that germ cell line modification of humans would not be covered by the Act. The Review has therefore not included this suggestion in Table 5.6.

***Recommendation 16: Technical amendments, as described in this report, be made to Sections 30, 71, 74 and 138 of the Act.***

## 5.8 Summary response to the Review's Terms of Reference

This Review has found that the Act is working well, although there are aspects of its implementation at State and Territory level that need attention. The OGTR is operating in an effective and efficient manner. The Review considers that current consultation processes in relation to applications under the Act are working well and that the OGTR is providing a rigorous, highly transparent regulatory system.

Table 5.7 provides a summary of the Review's response to its TOR. Recommendations relating to each term of reference are shown in Table 5.7 and listed in Table 5.8 for ease of reference.

Table 5.7

### SUMMARY REVIEW RESPONSE TO TOR

TOR	Finding/comment	Recommendations
1	The national scheme for gene technology regulation in Australia is effective and efficient. However there is scope to improve national consistency in order to fully achieve the aims of the Gene technology Agreement. Emerging trends and international developments are closely monitored by the Regulator. At this time, there is sufficient flexibility to address new developments in the technology, although the processes that may be needed to implement changes are slow. Some areas of the Act that need to be reconsidered in the light of experience have been identified.	R1, R6, R15
2	The objective of the Act is being achieved and the regulatory framework set out in Section 4 of the Act is operating effectively.	R2, R9, R10, R12
3	To date, the powers of enforcement in the Act have been adequate.	
4	The consultation provisions of the Act are generally working well. The Regulator is making good use of the Internet and email to communicate with stakeholders. The statutory committees are working satisfactorily.	R13, R14
5	The interface between the Act and other related legislation has received a great deal of attention from the Regulator. Other regulatory agencies consulted as part of this review were very positive about cooperation with the Regulator.	R11,
6	The regulatory burden and compliance costs appear justifiable compared with the benefits achieved. The Regulator can reduce regulatory requirements when the risks are considered to have declined although the processes involved are slow.	
7	Recommendations for amendments to the Act and related State and Territory legislation to improve timeliness, efficiency and effectiveness have been proposed (see below).	R3, R4, R5, R7, R8, R16

Source: Allen Consulting Group

Table 5.8

**REVIEW RECOMMENDATIONS**

No.	Recommendation
R1	The requirement for quarterly reporting to the Commonwealth Minister, to be tabled in Parliament, be discontinued.
R2	All jurisdictions reconfirm their commitment to a national regulatory scheme for gene technology.
R3	Jurisdictions follow the example of NSW and the Northern Territory, automatically adopting changed gene technology regulation by reference to the Commonwealth legislation.
R4	Where the Commonwealth Act has not been adopted by reference, jurisdictions commit to amending legislation at the same time as Commonwealth legislation is amended.
R5	Those jurisdictions with GM moratoria that have not been reviewed in the last three years commit to reviewing them by the end of 2014.
R6	The OGTR continue to be active in OECD and other international fora to stay abreast of international developments in gene technology regulation.
R7	The Ministerial Council review the definition of 'dealings' in the Act with a view to clarifying the scope of the regulatory scheme.
R8	The Ministerial Council review the conditioning of GM products in the Act with a view to clarifying the scope of the regulatory scheme.
R9	The Department of Health and Ageing explore with the Attorney General's Department and the Ministerial Council ways in which the process for amending the gene technology legislation could be streamlined.
R10	The Act be amended so that the Regulator can authorise other appropriate dealings related to inadvertent dealings.
R11	The OGTR continue to provide information to IBCs to assist them in understanding their responsibilities under the Act. IBCs should differentiate this aspect of their work from other activities for which they may also be responsible.
R12	Governments in Australia maintain a science-based precautionary approach to the regulation of gene technology.
R13	The OGTR increase its communications to the general public to raise its profile and build confidence in Australia's regulation of gene technology.
R14	For many DIR applications, advertising in local or state newspapers in the region where the DIR is to occur should be sufficient (given OGTR's established electronic communications channels with interested parties). For issues/licences of national importance it should be sufficient for OGTR to place advertisements in one national newspaper. The OGTR could experiment with using social media to communicate with stakeholders in appropriate situations.
R15	The requirement to include GM products approved by APVMA, TGA, FSANZ and NICNAS in the GMO Record be removed.
R16	Technical amendments, as described in this report, be made to Sections 30, 71, 74 and 138 of the Act.

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## Appendix A

### Submissions received

The Table below lists organisations and individuals who presented written public submissions. Submissions are listed in order of receipt.

Sub. No	Organisation or Individual
1	Ian Turnbull, Melbourne, VIC
2	Anne Goddard, Maroubra, NSW
3	Dr. L.S. Manning, Research Centre, Royal Perth Hospital IBC, WA
4	Hon Bryan Green MP, Deputy Premier Tasmania
5	Paula Fitzgerald, Agrifood Awareness Australia Limited, Kingston ACT
6	Sally Wylie, Consumers for GM Free Food, Margaret River, WA
7	Guy Izzett
8	Bruce Piper, Council of Grain Grower Organisations Ltd (COGGO), Como, WA
9	Bridgett Leggett and Anne Barr, WA
10	Elizabeth Beggs, Laboratory and Biosafety Committee, Deakin University, Burwood, VIC
11	Graham Wearne, Woodanilling, WA
12	Tracy Skippings, Margaret River, WA
13	Kim Hack, National Association for Sustainable Agriculture Australia WA Inc (NASAA WA Inc), Margaret River, WA
14	Anne Goddard, Maroubra, NSW
15	Dr. Monica Leggett
16	Mary Gardner, Byron Bay, NSW
17	Matt Linnegar, National Farmers' Federation, Kingston, ACT
18	Dr. Mark Sweetingham and Dr. Rosalie McCauley, Government of Western Australia, Department of Agriculture and Food, WA
19	Dr Helen Leonard, Queensland Institute of Medical Research, QLD
20	Heather Baldock, Producers Forum, Kimba, SA
21	Kim Hack and Penny Massop, York, WA
22	Dr Anna Lavelle, Ausbiotech, Malvern, VIC
23	Alan Hales, Research Services University of Newcastle, Callaghan, NSW
24	Matthew Cossey, Crop Life Australia, Canberra ACT
25	Nina Murray, AgForce, QLD
26	Dr Joe Smith, Office of the Gene Technology Regulator (OGTR), Department of Health and Ageing, Canberra, ACT
27	Peter Olson, Goonengerry, NSW
28	Professor John Rasko, Associate Professor Bing Yu and Dr Gabrielle O'Sullivan, Royal Prince Alfred Hospital Institutional Biosafety Committee, Camperdown, NSW
29	Michael Leader, Monsanto, St Kilda Central, VIC

Sub. No	Organisation or Individual
30	Robin Condron, Dairy Industry, Southbank, VIC
31	David Harris, Nuseed, Laverton VIC
32	Phil Aitken, WA
33	Alan Hill, The Western Australian Farmers Federation (Inc.) (WAFarmers), East Perth, WA
34	Sherry Thomas, Organic & Biodynamic Meats WA Co-operative Ltd, WA
35	James Holden, Pioneer Hi-Bred Australia, Toowoomba, QLD
36	Janet Thompson, Western Graingrowers, Pastoralists and Graziers Association of WA (Inc), Belmont WA
37	Bill Fuller, Australian Seed Federation, Manuka, ACT
38	Dr Nina McCormick, Bayer CropScience Pty Ltd, East Hawthorn, VIC
39	Confidential
40	Trixie Whitmore, Sydney, NSW
41	Beatrix Ludwig, Bondi, NSW
42	Mark Walter, Slater & Gordon Lawyers on behalf of The Safe Food Institute, Melbourne, VIC
43	Elizabeth Hamilton, Sydney, NSW
44	Shirley Collins, Shenton Park, WA
45	Dr Zoltan Lukacs, Grains Research and Development Corporation (GDRC), Kingston, ACT
46	Bob Phelps, Gene Ethics on behalf of the GM-Free Australia Alliance, Carlton VIC
47	Department of Innovation, Industry, Science and Research, Canberra, ACT
48	Department of Agriculture, Fisheries and Forestry, Canberra ACT

*Appendix B***Regulation of GMOs in other countries****REGULATION OF GMOS IN OTHER COUNTRIES**

Country	Regulatory framework for GMO or biotechnology products
New Zealand	In New Zealand, the Environmental Risk Management Authority (now the EPA) has similar functions to the Office of the Gene Technology Regulator in Australia. ERMA operates under the Hazardous Substances and New Organisms (HSNO) Act, with goals of protecting the environment and the health and safety of people by preventing and managing adverse effects of hazardous substances and new organisms. If the GM organism will be used to produce goods, FSANSZ has a role in ensuring its safety for human consumption.
Denmark	The Danish Environmental Protection Agency is responsible for gene technology. Applications for the use of GMOs have to be processed by the Danish EPA, and have to be approved according to the Environment and Gene Technology Act. The Danish EPA also supervises compliance with the terms of approvals. It has responsibility for general provisions, requirements and compliance of the Environment and Gene Technology Act.
Sweden	In Sweden, several authorities oversee gene technology activities under the Swedish Environmental Code. Under this Code, a permit is required for all activities involving GMOs. A risk assessment must be carried out before any release of GMOs. Consent is granted only if the activity is 'ethically justifiable'.
United Kingdom	In the United Kingdom, the Department for Environment, Food and Rural Affairs (DEFRA) is the lead government agency on the environmental safety of GMO releases. It also deals with issues in relation to the use of GM crop technology. The Food Standards Agency leads on the safety of GM food and feed, and on applications to market GM food and feed products. To release a GMO or market a GM product, the applicant is required to obtain authorisation either at the EU level or the national level (by DEFRA for proposed releases in England, or by the relevant authorities in Wales, Scotland or Northern Ireland). Applications for marketing product are assessed at the EU level, while applications for releasing a GMO for research and development purposes are assessed at the national level.
United States	The United States has a risk-based system to ensure new biotechnology products are safe for the environment and human and animal health. Established as a formal policy in 1986, the Coordinated Framework for Regulation of Biotechnology describes the Federal system for evaluating products developed using modern biotechnology. New regulations and policies are introduced as new products are developed. Various government agencies are responsible for oversight of products involving agricultural biotechnology. They are: the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (USDA-APHIS), the U.S. Environmental Protection Agency (EPA), and the Department of Health and Human Services' Food and Drug Administration (FDA).
Canada	Health Canada, which engages in research, information distribution and other activities to provide better health outcomes to Canadians, is responsible for assessing the safety of all GM foods. Companies are required to submit scientific data for review and approval by Health Canada before such foods can be sold. Health Canada has to conduct a safety assessment of all biotechnology-derived foods to demonstrate that a novel food is safe and nutritious before it is allowed in the Canadian marketplace.

Source: The Allen Consulting Group