Australian Government and state and territory governments' response to the recommendations of the 2011 Review of the Gene Technology Act (2000)

Review summary

The Australian Government and state and territory government's (all Governments) recognise the need for a nationally consistent gene technology regulatory scheme. 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.

The Review of the *Gene Technology Act 2000* (the Act) (the Review) was commissioned by the then Department of Health and Ageing (DoHA) on behalf of the then Ministerial Council (hereafter referred to as the Legislative and Governance Forum on Gene Technology (GT Forum)). It follows the 2006 *Statutory Review of the Act and the Intergovernmental Gene Technology Agreement* (2006 review), which recommended the Act be reviewed again in 2011 to ensure it continues to be current and to reflect and accommodate emerging trends.

The review investigated:

- the 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).

Governments generally support the overall findings of the 'Review of the Gene Technology Act 2000 – Final Report' (the Report) that:

- the Act is working well, although there are aspects of its implementation by the states and territories that need attention;
- the Office of the Gene Technology Regulator (OGTR) is operating in an effective and efficient manner;
- the current consultation processes in relation to applications under the Act are working well;
- the OGTR is working well with other regulatory agencies and is providing a rigorous, highly transparent regulatory system;
- the scope of the regulatory scheme be clarified through further review by the GT Forum;
- ways to streamline the process for the amendment in response to technology developments be investigated; and
- a number of minor amendments should be made to improve the efficiency of the operation of the Act.

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

The all Governments response addresses the 16 recommendations that were in the Report.

It is noted for any legislative change, the Commonwealth will have regard to the Regulatory Impact Analysis requirements and will seek advice from the Office of Best Practice Regulation. Also where there are legislative changes, these will be handled in a coordinated way with other legislative amendments.

Introduction

The Act is the Commonwealth's component of the nationally consistent regulatory scheme for gene technology in Australia. Its object is to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with genetically modified organisms.

The Intergovernmental Gene Technology Agreement 2001 (GTA) sets out the understanding between Commonwealth, State and Territory Governments regarding the establishment of a nationally consistent regulatory system for gene technology. The GTA requires an independent review of the Act every five years. The first review was completed in 2006.

The 2006 review found that the Act and the national regulatory scheme worked well over the previous five years (2000-2005), and no major changes were required. The review panel recommended a number of changes intended to improve the operation of the Act. In particular, the 2006 review recommended that the Act be reviewed in five years (2011) to ensure that it continues to accommodate emerging trends.

The Terms of Reference (ToR) for the 2011 Review were announced by the GT Forum. The 2011 review was limited to issues within the scope of the object of the Act (ie. health and safety of people and the environment). The review also considered the findings from the 2006 review.

The Allen Consulting Group was commissioned to undertake the Review. This review drew upon 48 submissions received from industry, government agencies, researchers, non-government organisations and individuals following stakeholder consultation. The Allen Consulting Group also met with individuals from related regulatory agencies and consulted the two advisory committees that operate under the Act (The Gene Technology Technical Advisory Committee (GTTAC) and The Gene Technology Ethics and Community Consultative Committee (GTECCC)).

On the 26 August 2011, The Allen Consulting Group presented the Report which was submitted to the GT Forum. The report was published on the web in December 2011.

The ToRs, written submissions and the report are available at:
http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-techact-review

Acknowledgements

The response to the recommendations of the Review has been collaboratively prepared by the Australian Government and state and territory governments.

The Australian and state and territory governments acknowledge the Gene Technology Standing Committee (GTSC) and the *Gene Technology Act 2000* Review Working Group (Working Group) in providing input and shaping the drafting of the all Governments' response.

AUSTRALIAN, STATE AND TERRITORY GOVERNMENTS' RESPONSE

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

Governments' response:
All Governments (except Queensland) support in principle recommendation 1. Queensland reserves its position until further consideration by the Queensland Government.

Proposed Action
The GT Forum will request the Commonwealth Minister to consider amendments to the legislation to give effect to this recommendation.

Comment
The present Commonwealth legislation requires the responsible Commonwealth Minister to table quarterly reports in the Commonwealth Parliament. While this requirement was important in the early years of the regulatory arrangements, there is now sufficient experience with the operation of the OGTR that 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. The removal of the requirement for quarterly reporting would represent an efficiency gain with no impact on transparency.

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

Governments' response:
All governments (except Queensland) support in principle recommendation two in relation to human health and safety and the environment. Queensland reserves its position until further consideration by the Queensland Government.

Proposed Action
No action required.

Comment
The operation of the nationally consistent scheme for regulating gene technology relies on corresponding state and territory legislation which incorporates amendments to Commonwealth legislation. Amendments were made to the Commonwealth legislation in 2007 following the 2006 Review. Two jurisdictions, New South Wales (NSW) and the Northern Territory (NT) amended their respective legislation in 'lockstep' with the 2007 Commonwealth Act amendments.

As a part of the national scheme, the states and territories can pass laws on matters other than health and safety of people and the environment. These are laws that can regulate genetically modified organisms (GMO's) for economics and marketing.

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

Governments' response:
All governments (except Queensland) recognise the administrative and efficiency gains proposed by this legislation (eg "lock-step"), however, implementation is a matter to be decided by individual jurisdictions. Queensland reserves its position until further consideration by the Queensland Government.

Proposed Action
States and territories will review their current legislative arrangements and determine an approach that best meets their requirements and circumstances

Comment
The nationally consistent legislative scheme for regulating gene technology is comprised of the Commonwealth *Gene Technology Act 2000* and the Gene Technology Regulations 2001, and corresponding State and Territory legislation. The most efficient way of maintaining consistent legislation between the Commonwealth and corresponding state and territory legislation is by adoption by reference.

NSW and the NT amended their respective legislation in 'lockstep' with the 2007 Commonwealth Act amendments. In these jurisdictions, Commonwealth gene technology legislation is adopted through an automatic procedure. Other jurisdictions, the Australian Capital Territory (ACT), Queensland (QLD), South Australia (SA), Victoria (VIC) and Tasmania (TAS), have amended their legislation to correspond with the 2007 Commonwealth legislation. Western Australia (WA) have enacted legislation but has not been declared 'corresponding'. As a result, the legislation in WA does not yet form part of the nationally consistent scheme administered by the Gene Technology Regulator (Regulator). In practice, the vast majority of organisations conducting dealings with GMOs are captured by the Commonwealth legislation. However, if the Commonwealth and state legislation is different because the state legislation is not up to date then organisations doing exactly the same work with GMOs would be subject to different requirements.

In practice, there may be some variations between jurisdictions due to delays in the adoption of changes to the legislation that have been agreed by the GT Forum and passed by the Commonwealth. This creates additional complexity in the national gene technology regulatory environment.

This has the potential to create confusion for regulated organisations and individuals and the Regulator's compliance activities.

Unless jurisdictions either amend their legislation (Acts and Regulations) contemporaneously, or adopt by reference, this situation can occur each time amendments are made 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.

Governments' response:
All governments (except Queensland) support in principle recommendation 4. Queensland reserves its position until further consideration by the Queensland Government.

Proposed Action
No further action required.

Comment
While all governments support in principle, it is on the understanding that each state and territory will use its best endeavours as defined under the GTA. As discussed above for recommendation 3, not all jurisdictions have state legislation which is up to date with the Commonwealth legislation. For the national scheme to remain consistent, states and territories must keep legislation up to date with changes to the Commonwealth legislation.

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.

Governments' response:
All governments (except Queensland) believe this recommendation is beyond the scope of the Review. Queensland reserves its position until further consideration by the Queensland Government.

Proposed Action
No action proposed.

Comment
None.

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

Governments' response:
All governments (except Queensland) support recommendation 6. Queensland reserves its position until further consideration by the Queensland Government.

Proposed Action
The OGTR will continue participation in the OECD and other international fora.

Comment
Governments note that the Regulator will continue informing the GT Forum of international developments as an important strategy for ensuring Australia's gene

technology regulatory scheme continues to both reflect and contribute to international best practice.

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

Governments' response:
All governments (except Queensland) support in principle recommendation 7. Queensland reserves its position until further consideration by the Queensland Government.

Proposed Action
The GT Forum will request the Commonwealth Government Minister to consider amendments to the legislation to give effect to this recommendation.

Comment
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 (Food Standards Australia New Zealand for food, Therapeutic Goods Administration for therapeutic goods and Australian Pesticides and Veterinary Medicines Authority 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 Commonwealth 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.

The Governments note that a review of the definitions in the Act would serve to clarify the scope of operational capture of the legislative scheme and the intersection of legislative provisions of other regulators.

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.

Governments' response:
All governments (except Queensland) support recommendation 8. Queensland reserves its position until further consideration by the Queensland Government.

Proposed Action
The GT Forum in consultation with the Regulator will review the conditioning of GM products in the Act with a view to clarifying the scope of the regulatory scheme.

Comment
Activities with GM products are not regulated directly under the Act. However, the Regulator may impose conditions on a GM product that is derived from a GMO. The Regulator may, pursuant to s62(1) of the Act, "impose obligations in relation to GM products that are derived from a GMO in respect of which particular dealings are licensed."

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 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.

Governments' response:
All governments (except Queensland) support recommendation 9. Queensland reserves its position until further consideration by the Queensland Government.

Proposed Action
The Regulator, in conjunction with the Department of Health, will undertake further analysis and consultation with relevant stakeholders and report in the first instance to the GTSC for advice to the GT Forum.

Comment
The Review considered whether the provisions of the Act are adequate to cover recent developments and whether the Regulator is able to implement changes to regulations in a timely manner in order to keep pace with rapid and continuing advances in gene technology.

The Review found that changes to Regulations can take up to eighteen months to implement. The processes that have been followed to amend the legislation are complicated by the combination of requirements of the GTA and the *Legislative Instruments Act 2003*.

All Governments noted the need for legislation to keep up with and allow for expeditious responses to technological advances. The discussion behind this recommendation raised two issues:

- whether current definitions of what is or is not a GMO under the Act are sufficient to provide clarity around the intended scope of regulatory coverage in light of ongoing technological advances;
- that the process for introducing legislative amendment to clarify what is and is not regulated under the Act is complex.

All Governments also agreed that the issue of regulatory scope should be further investigated in order to reduce ambiguity. To progress this issue may require consideration of the intent and the capacity of the Act to currently capture or exclude emerging technologies.

All Governments note that the Department of Health, in consultation with the Regulator, proposes to explore ways to ensure that legislation both keeps up with and allows for expeditious responses to technological advances.

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

Governments' response:
All Governments (except Queensland) support in principle recommendation 10. Queensland reserves its position until further consideration by the Queensland Government.

Proposed Action
The GT Forum will request the Commonwealth Minister to consider amendments to the legislation to give effect to this recommendation.

Comment
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 such as storing and testing can be authorised (that relate to disposal of inadvertently obtained GMOs). Such dealings would be considered reasonable and part of the disposal process, but may not be permitted under the current provisions of the Act.

All Governments noted that the Act relates only to 'disposal' and needs to be amended to authorise other dealings necessary to determine the fate of a suspected unintended presence of a GMO.

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.

Governments' response:
All Governments (except Queensland) support recommendation 11. Queensland reserves its position until further consideration by the Queensland Government.

Proposed Action
The Regulator will continue to provide advice and support to IBCs and regulated organisations and will report to the GT Forum.

Comment
The Review noted that Institutional Biosafety Committees (IBCs) play an important role in the national regulatory framework but that there was some stakeholder concern

around their effectiveness and efficiency. However some of these concerns appear to relate to functions outside IBC responsibilities under the Act.

IBCs are an integral part of the regulatory system, providing regulated organisations with independent quality assurance and advice. While IBCs are not intended to be responsible for the conduct of the organisations that they assist, they play an important role in promoting compliance with the Act. Some organisations also confer an internal governance role on IBCs to monitor and ensure compliance with the gene technology legislation, as well as other legislation and requirements, for example, for biosecurity and laboratory safety.

The Review noted that the OGTR was actively engaged with IBCs and that this important relationship would continue.

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

Governments' response:
All Governments (except Queensland) support recommendation 12. Queensland reserves its position until further consideration by the Queensland Government.

Proposed Action
No further action required.

Comment
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.

The regulatory framework described in section 4(aa) of the Act provides for a precautionary approach to gene technology regulation to protect against environmental damage. Precaution is an inherent element of risk analysis. The Regulator's assessment of GMOs follows a science-based approach and he must not issue a licence unless satisfied that risks to human health and safety and the environment can be managed.

The application of the precautionary approach was also considered by the 2006 Review of the Act. It concluded that the Regulator applied a cautionary approach to licence decisions and that the articulation of the precautionary approach in the Act is still appropriate.

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.

Governments' response:
All Governments (except Queensland) support in principle recommendation 13. Queensland reserves its position until further consideration by the Queensland Government.

Proposed Action
The Regulator will continue to develop his communication activities and will continue to report to the GT Forum on communication activities.

Comment
The Review found that the OGTR makes good use of its website and communicates with a large number of people and organisations which have indicated an interest in OGTR's work. However, there are some concerns that the community remains confused about GMOs and GM crops, in particular about their safety and impact on the environment and that there are considerable sections of the community who remain unaware that there is a regulatory framework in place.

The Review also found that there is a need for more public awareness of 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, some stakeholders would like the OGTR to be clearer about the extensive review and testing required before GMOs are released.

All Governments agreed the need for a balanced approach and for the OGTR to remain independent and objective in its public communications.

Recommendation 14:
For many 'dealings involving intentional release' (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.

Governments' response:
All Governments (except Queensland) support in principle recommendation 14. Queensland reserves its position until further consideration by the Queensland Government.

Proposed Action
The GT Forum will request the Commonwealth Minister to consider amendments to the legislation to give effect to this recommendation.

Comment
All Governments noted that the OGTR consulted widely when seeking comment on applications, exceeding the requirements of the Act. However, there is not always value in engaging in all of the modes of communication prescribed in the Act. The OGTR needs flexibility to choose the most appropriate form of consultation and media activities including new social media.

Recommendation 15:
The requirement to include GM products approved by

APVMA, TGA, FSANZ and NICNAS in the GMO Record be removed.

Governments' response:
All Governments (except Queensland) support in principle recommendation 15. Queensland reserves its position until further consideration by the Queensland Government.

Proposed Action
The GT Forum will request the Commonwealth Minister to consider amendments to the legislation to give effect to this recommendation.

Comment
The Regulator is obliged to maintain the Record of GMOs and GM Product Dealings 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 the Australian Pesticides and Veterinary Medicines Authority (APVMA), Therapeutic Goods Administration (TGA), Food Standards Australia and New Zealand (FSANZ) and National Industrial Chemicals Notification and Assessment Scheme (NICNAS) on the GMO Record. Maintaining GM products approved by these other agencies on the GMO Record duplicates the record keeping of these other agencies and is administratively inefficient.

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

Governments' response:
All governments (except Queensland) support in principle recommendation 16. Queensland reserves its position until further consideration by the Queensland Government.

Proposed Action
The GT Forum will request the Commonwealth Minister to consider amendments to the legislation to give effect to this recommendation.

Comment
The Review suggests that the technical amendments detailed in this recommendation will result in decreased regulatory burden.

Section 30 Proposed Change: The current language suggests that the issuing or refusing the application for a licence is the subject of consideration rather than issuing or refusing the licence itself. More appropriate wording might be "whether GMO licence is issued or refused in relation to a particular application".

Section 71 (2B) Proposed Change: 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, so that in considering variations to GMO licences, the Regulator's assessment of the risks posed by a proposed variation may also take into account not just the application under review, but previous risk assessments of the same or similar GMOs.

Section 74 Proposed Change: The current formulation of s74 sets out a list of matters that must be considered before dealings can be declared to be Notifiable Low Risk Dealings. 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 Proposed Change: 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.

List of Acronyms and Abbreviations

2006 review	Statutory Review of the *Gene Technology Act 2000* and the Intergovernmental Gene Technology Agreement
Act	*Gene Technology Act 2000*
APVMA	Australian Pesticides and Veterinary Medicines Authority
DIR	Dealings involving intentional release
DoHA	Department of Health and Ageing
FSANZ	Food Standards Australia and New Zealand
GM	Genetically modified
GMO(s)	Genetically Modified Organism(s)
Governments	Australian, State and Territory Governments'
GT Forum	Legislative and Governance Forum on Gene Technology (formerly known as the Gene Technology Ministerial Council)
GTA	Intergovernmental Gene Technology Agreement 2001
GTSC	Gene Technology Standing Committee
GTTAC	Gene Technology Technical Advisory Committee
GTTEC	Gene Technology Ethics and Community Consultative Committee
IBC(s)	Institutional Biosafety Committee(s)
Ministerial Council	Gene Technology Ministerial Council (now known as the Legislative and Governance Forum on Gene Technology)
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
OECD	Organisation for Economic Co-operation and Development
OGTR	Office of the Gene Technology Regulator
Report	Review of the *Gene Technology Act 2000* – Final Report
Regulations	*Gene Technology Regulations 2001*
Regulator	Gene Technology Regulator
Review	2011 Review of the Gene Technology Act 2000
TGA	Therapeutic Goods Administration
ToR	Terms of Reference
Working Group	*Gene Technology Act 2000* Review Working Group