

Queensland Government response to the recommendations of the Review of the *Gene Technology Act 2001* (Queensland)

April 2014

Introduction

The object of the Commonwealth, States and Territories gene technology legislation, which gives effect to the gene technology regulatory scheme for Australia, is to protect the health and safety of people and to protect the environment from any risks posed by, or as a result of, gene technology, by identifying those risks and managing them through regulation of certain dealings with genetically modified organisms (GMOs).

The *Gene Technology Act 2001*¹ (the Queensland Act) is Queensland's component of the regulatory scheme.

State legislation was developed to ensure full regulatory coverage given the constitutional limitations of Commonwealth powers, for example, in relation to State Government agencies and higher education institutions.

Section 194 of the Queensland Act requires a review of the operation of the Queensland Act whenever a review of the *Gene Technology Act 2000* (the Commonwealth Act) is undertaken. The review of the Queensland Act must be undertaken either as part of the review of the Commonwealth Act or after the review of the Commonwealth Act.

As Minister responsible for gene technology, the Minister for Science, Information Technology, Innovation and the Arts caused a review² of the operation of the Queensland Act in April 2013.

The Review of the Queensland Act (the Queensland Review) was commissioned by the Department of Science, Information Technology, Innovation and the Arts and was conducted by an independent review team between July and November 2013.

The purpose of the Queensland Review was to investigate whether the Queensland Act is operating as an efficient and effective component of the regulatory scheme.

The findings of the Queensland Review were as follows:

- Queensland's co-existence framework for GM and non-GM crops was developed in 2005 and may reference documents that are no longer valid. The framework should be updated to ensure that it remains current.
- The science-based precautionary approach to the regulation of gene technology pertaining to risks of the technology to the health and safety of people and protection of the environment is 'fit for purpose'. This needs to be communicated more effectively to stakeholders and the broader Australian public and that the administrative oversight of the OGTR is also effective and efficient.
- Structural issues identified in the 2011 Commonwealth Review in relation to the Commonwealth / State legislative framework are relevant to Queensland. 'Periods of inconsistency' exist in regard to present arrangements in Queensland and these are of concern particularly to IBCs across the State. The resultant uncertainty has the potential for negative impact for Queensland particularly since new and emerging technologies will require rapid regulatory responsiveness if Queensland is not to be disadvantaged.

¹ The Queensland Act can be viewed at www.legislation.qld.gov.au.

² The first review of the Queensland Act occurred in 2006.

- There is overall strong support amongst researchers and industry to adopt a 'lock-step' approach similar to that adopted by New South Wales and Northern Territory which automatically and immediately adopt any changed gene technology regulation by the Commonwealth.
- There continues to be scope for improvements to be made to gene technology regulation in Australia. In particular, new and emerging developments in gene technology are challenging existing legislation and whether the OGTR has mechanisms in place to address their potential impact on humans and the environment. The recommendation of the 2011 Commonwealth Review that "The Ministerial Council review the definition of 'dealings' in the Act with a view to clarifying the scope of the regulatory scheme" is timely and well founded.
- This Review of the Queensland Act occasioned by the 2011 Review of the Commonwealth Act and informed by public submissions to both reviews, has identified that the Queensland Act is operating as an effective and efficient component of the nationally consistent gene technology regulatory scheme.
- There is considerable concern amongst researchers and industry that the fee for service / cost recovery proposal being tested by the OGTR will have a negative impact on investment in gene technology research and development in Queensland.
- For the Queensland Government, moving to lock-step with the Commonwealth gene technology legislation should only proceed if there are legislated provisions accompanying the change to lock-step which provide adequate safeguards for Queensland.
- Moving to lock-step with the Commonwealth would avoid the need to prepare new Queensland gene technology legislation and have it considered by the Queensland Parliament every time there is a change to the Commonwealth gene technology legislation and would result in a reduction of the regulatory burden for Queensland.

Background on the regulatory scheme and the Commonwealth Act and Review

The gene technology regulatory scheme for Australia consists of three components: gene technology legislation, the intergovernmental *Gene Technology Agreement 2001* (GTA) and the Council of Australian Governments' Legislative and Governance Forum on Gene Technology (LGFGT). The legislative component of the regulatory scheme includes a framework to assess the risks to human health and the environment associated with the various dealings of genetically modified organisms (GMOs). The GTA reflects agreement between the Commonwealth, States and Territories that there is a need for a cooperative legislative scheme that is nationally consistent; based on a scientific assessment of risks and ensures the regulatory burden is consistent with the risks. The LGFGT oversees implementation of the regulatory scheme and provides policy guidance for the operation of the *Gene Technology Act 2000* (the Commonwealth Act).

Section 194 of the Commonwealth Act stipulates that the operation of the Commonwealth Act, including the structure of the Office of the Gene Technology Regulator (OGTR), should be reviewed independently as soon as possible after the fourth anniversary of the commencement of the Act. The first review of the Commonwealth Act (the Commonwealth Review) was completed in 2006. Clause 44 of the GTA states that further reviews will be conducted at intervals of no more than five years.

The second Commonwealth Review was undertaken in 2011³ and investigated emerging trends and international developments in biotechnology and its regulation, the efficiency and effectiveness of the operation of the Commonwealth Act consistently across the national scheme for gene technology regulation in Australia and the interface between the Commonwealth Act and other regulations.

The Commonwealth Review concluded that although the Commonwealth Act is working well, some aspects of implementation at a state and territory level need attention. The Commonwealth Review proposed 16 recommendations to improve the effectiveness and efficiency of the operation of gene technology regulation in Australia.

An Australian, State and Territory Governments' (all governments') response⁴ to the Commonwealth Review recommendations has been prepared and was considered by the LGFGT in April 2013. Queensland reserved its position on the response to the review of the Commonwealth Act, pending further consideration by the Queensland Government and given the upcoming required review of the Queensland Act.

Terms of Reference of the Queensland Review

The Terms of Reference of the Queensland Review were as follows:

Using the submissions from the Commonwealth Review and its final report as a basis, investigate:

- *the outcomes / findings of the Commonwealth Review as they apply to Queensland*
- *whether the object of the Queensland Act is being achieved and if there is a more effective and efficient way of achieving it:*
 - *in particular, propose options on how implementation of the 'lock-step' approach could be achieved*
- *mechanisms to reduce the regulatory burden given the Queensland Government's commitment to red tape reduction.*

Five written submissions were received, with a range of additional information and comments provided to the independent review team by way of personal interview and teleconference discussions.

A report was prepared and submitted to the Department of Science, Information Technology, Innovation and the Arts, to be conveyed to the Minister for Science, Information Technology, Innovation and the Arts.

³ The Commonwealth Review report and submissions are available at <http://www.health.gov.au/internet/main/publishing.nsf/Content/Gene%20Technology-2>.

⁴ The all governments' response is available at <http://www.health.gov.au/internet/main/publishing.nsf/Content/Gene%20Technology-2>.

Queensland Review recommendations and government response

Queensland Government departments generally support the findings of the Queensland Review. Departments recognise that there is room to improve Australia's arrangements to regulate gene technology and that this would improve the efficiency and effectiveness of the Queensland Act.

The Queensland Review made seven recommendations. The Queensland Government response to each recommendation is as follows:

Recommendation 1: That Queensland continues to confirm its commitment to a national regulatory scheme for gene technology.

Government's response:

The Queensland Government agrees to recommendation 1 provided that there is continued alignment with the *Queensland Government principles for intergovernmental activities*.

Comment

The regulatory scheme is underpinned by the intergovernmental *Gene Technology Agreement 2001* (GTA) which is signed by all Australian jurisdictions. It sets out the understanding between governments of the nationally consistent regulatory scheme and commits the States and Territories to pass corresponding laws.

It reflects agreement between the Commonwealth, States and Territories that there is a need for a cooperative legislative scheme that is nationally consistent; based on a scientific assessment of risks and ensures the regulatory burden is consistent with the risks.

The *Queensland Government principles for intergovernmental activities* identify, protect and advance Queensland's intergovernmental interests. They are underpinned by a desire to improve the well-being of Queenslanders, preserve Queensland's constitutional roles and responsibilities, and through its intergovernmental activities support the government's desire to work with the private and not-for-profit sectors to deliver better service delivery outcomes.

Recommendation 2: That Queensland gives consideration to following the example of New South Wales and the Northern Territory, automatically adopting changed gene technology regulation by reference to the Commonwealth legislation (that is, in lock-step with the Commonwealth gene technology legislation).

Government's response:

The Queensland Government supports a lock-step approach as per recommendation 3.

Comment

The Commonwealth Review proposed that jurisdictions follow the example of New South Wales and the Northern Territory, automatically adopting changed gene technology regulation by reference to the Commonwealth legislation in order to achieve further administrative and efficiency gains. This recommendation is an efficiency measure aimed at reducing administration of separate legislation in States and Territories and associated costs. Jurisdictions that are not in “lock-step” with the Commonwealth legislation currently experience a period of inconsistency during which the existing State legislation continues to operate until amendments can be passed by the respective legislatures.

Currently, Queensland has retained its capacity to exercise regulatory influence over its State agencies and universities through the Queensland Act which corresponds with the Commonwealth legislation.

Moving to lock-step with legislated provisions to provide adequate safeguards for Queensland's autonomy is in alignment with the *Queensland Government principles for intergovernmental activities*.

Recommendation 3: That, alternatively, Queensland proceeds to move to investigate and adopt another approach with which there are legislated provisions accompanying the change to 'lock-step' which provide adequate safeguards for Queensland's autonomy.

Government's response:

The Queensland Government agrees in-principle to recommendation 3. Legislative amendments are required to implement this recommendation.

Comment

An approach that balances the administrative efficiencies resulting from lock-step and provides adequate safeguards for Queensland's autonomy is important.

Consistent with the *Queensland Government principles for intergovernmental activities*, it is important that any proposed changes to Queensland legislation are carefully considered in terms of the extent to which they align with the Queensland Government's policy priorities and the extent to which they are of benefit to businesses and the community in Queensland.

Recommendation 4: That, in view of the challenges to existing legislation by new and emerging developments in gene technology, Queensland supports moves by the Council of Australian Governments' Legislative and Governance Forum on Gene Technology (formerly the Gene Technology Ministerial Council) in relation to the recommendation of the 2011 Commonwealth Review that "The Ministerial Council review the definition of 'dealings' in the Act with a view to clarifying the scope of the regulatory scheme."

Government's response:

The Queensland Government agrees to recommendation 4.

Comment

The Commonwealth Review noted that new and emerging developments in gene technology are causing questions to be asked as to whether the existing legislation adequately defines and covers them, and whether the OGTR has mechanisms in place to address their potential impact on humans and the environment. The continued maintenance and support of a science-based precautionary approach to the regulation of gene technology is critical.

Recommendation 5: That Queensland supports more effective communication to its stakeholders highlighting the effectiveness of the science-based precautionary approach to regulation of gene technology and the effective and efficient administrative oversight of the Office of the Gene Technology Regulator, while acknowledging the broader role of the Commonwealth to more effectively communicate a similar message to the Australian public.

Government's response:

The Queensland Government agrees to recommendation 5.

Comment

Effective communication with stakeholders regarding regulatory frameworks is a key component in enabling compliance and reducing the regulatory burden on business and the community.

There are existing mechanisms that could potentially be utilised to assist the Queensland Government in communicating with its stakeholders.

Communications to the general public by the OGTR need to increase to raise its profile and build confidence and trust in Australia's regulation of gene technology. With this trust comes increased acceptance by consumers of products produced by GMOs and supports adoption of the technology.

Recommendation 6: That Queensland ensures that the co-existence framework for GM and non-GM crops remains current and is able to deal with the co-existence of GM and non-GM crops in Queensland in the foreseeable future.

Government's response:

The Queensland Government agrees to recommendation 6.

Comment

A policy principle issued under the Commonwealth Act allows States and Territories the right to manage market and trade issues related to GM crops separately and distinctly from health and environmental safety issues which are jointly managed under the Commonwealth and State and Territory legislation.

In 2005, Queensland developed a framework for co-existence of GM and non-GM crops to address the issue of market considerations (unlike other States which have established separate GM crops legislation). The framework is a set of principles that guide cropping industries and supply chains to actively prepare for segregation issues associated with any new commercial release of GM crops. The framework enables strategies to be developed to facilitate participants along the supply chain to competitively meet the requirements of their chosen market, and give consumers the ability and freedom to select products according to their preference.

Recommendation 7: That the Australian Government be made aware of the concern amongst researchers and industry that the fee for service / cost recovery proposal being tested by the Office of the Gene Technology Regulator will have a negative impact on investment in gene technology research and development in Queensland.

Government's response:

The Queensland Government notes that this recommendation is outside the Terms of Reference for the Queensland Review.

Comment

When the regulatory scheme was introduced in 2001, the intention to recover costs was foreshadowed, with section 127 of the Commonwealth Act making provision for the Regulator to charge for services. An underlying principle of cost recovery policy is that agencies should set charges to recover all the costs of products or services, where it is efficient and effective to do so. In light of the developing maturity of the sector, the former Commonwealth Government considered that it was appropriate to assess possible options for the cost recovery that might provide a sustainable basis for funding OGTR operations into the future.

Stakeholder feedback suggests that cost recovery could impact on gene technology research, with the potential for research to cease, regulator backlash, reduced compliance and redirection of research dollars (potentially offshore due to the 'mobile nature' of the technology). It may also reduce the long term benefits of research to the community and hinder the development of GMOs for the public good which lack commercial attractiveness.

Glossary

GM	genetically modified
GMO(s)	genetically modified organism(s)
GTA	<i>Gene Technology Agreement 2001</i>
IBC(s)	Institutional Biosafety Committee(s)
LGFGT	Council of Australian Governments' Legislative and Governance Forum on Gene Technology (formerly known as Ministerial Council)
OGTR	Office of the Gene Technology Regulator