



Gene Technology (Queensland) Bill 2016

Report No. 20, 55th Parliament

**Education, Tourism, Innovation and Small Business Committee
September 2016**

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Abbreviations and glossary

'deal with' a GMO	see definition on page 3 of this report
department	Department of Science, Information Technology and Innovation
Gene Technology Standing Committee	A committee of senior officials from each jurisdiction, which advises the Ministerial Council (see below). The Director-General of the Department of Science, Information Technology and Innovation represents Queensland on the Standing Committee
GMO	Genetically modified organism
GTA	Gene Technology Agreement – the inter-governmental agreement made in 2001 between the Commonwealth and all States and Territories
Minister	Minister for Innovation, Science and the Digital Economy and Minister for Small Business (Qld)
OGTR	Office of the Gene Technology Regulator
proposed Act	<i>Gene Technology Act 2016</i> [if the Bill is passed]
SLC	Scrutiny of Legislation Committee
the Commonwealth Act	<i>the Gene Technology Act 2000</i>
the Commonwealth regulation	<i>the Gene Technology Regulations 2001</i>
the forum	<i>the Legislative and Governance Forum on Gene Technology (or Ministerial Council), consisting of Ministers from all jurisdictions</i>
the Queensland Act	<i>Gene Technology Act 2001</i>
the Queensland Regulation	<i>Gene Technology Regulation 2002</i>
the Regulator	the Gene Technology Regulator, appointed under the Commonwealth Act
the Western Australian Act	<i>Gene Technology Act 2006</i>

Chair's foreword

On behalf of the Education, Tourism, Innovation and Small Business Committee of the 55th Parliament of Queensland, I present this report on the committee's inquiry into the Gene Technology (Queensland) Bill 2016.

The Bill was introduced into the Legislative Assembly by the Minister for Innovation, Science and the Digital Economy and Minister for Small Business on 16 August 2016. The committee was required to report to the Legislative Assembly by 4 October 2016.

In considering the Bill, the committee's task was to consider the policy to be given effect by the Bill, and whether the Bill has sufficient regard to the fundamental legislative principles in the *Legislative Standards Act 1992*. The fundamental legislative principles include whether legislation has sufficient regard to the rights and liberties of individuals and to the institution of Parliament.

On behalf of the committee, I thank those who made written submissions about the issues in this inquiry, and the departmental officials who briefed the committee.

I commend the report to the House.



Scott Stewart MP
Chair

Recommendations

Recommendation 1:

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The committee recommends that the Gene Technology (Queensland) Bill 2016 be passed.

1 Introduction

1.1 Role of the committee

The Education, Tourism, Innovation and Small Business Committee (the committee) was established as a portfolio committee by resolution of the Legislative Assembly on 27 March 2015. The committee consists of three government and three non-government members.

The committee's areas of portfolio responsibility are:

- education
- tourism and major events
- innovation
- science, and
- the digital economy and small business.¹

The *Parliament of Queensland Act 2001* sets out the role of portfolio committees, which includes consideration of Appropriation Bills, other Bills and subordinate legislation, public accounts and public works issues, and issues referred to it by the Legislative Assembly.

1.2 Referral of the Bill

The Gene Technology (Queensland) Bill 2016 (the Bill) was referred to the committee on 16 August 2016, and the committee was required to report to the Legislative Assembly by 4 October 2016.

1.3 Committee inquiry process

Officials from the Department of Science, Information Technology and Innovation briefed the committee on the Bill on 29 August 2016. Transcripts of the briefings are published on the committee's webpage.

The committee invited submissions from interested stakeholders by advertising on its website. A call for submissions was also emailed to over 900 committee subscribers, and email invitations were sent to 18 stakeholders.

The committee received five submissions on the Bill (see list at Appendix A).

Submissions received and accepted by the committee are also published on the webpage at:

<http://www.parliament.qld.gov.au/work-of-committees/committees/ETISBC/inquiries/current-inquiries/10GeneTech>

1.4 Should the Bill be passed?

Standing Order 132(1) requires the committee to recommend whether the Bill should be passed. The committee considered the Bill, information provided by the department and the information and views expressed in submissions, and recommends that the Bill be passed.

Recommendation 1:

The committee recommends that the Gene Technology (Queensland) Bill 2016 be passed.

¹ Schedule 6 of the *Standing Rules and Orders of the Legislative Assembly*, effective from 31 August 2004.

2 Background to the Bill

2.1 Gene technology

Gene technology is the term given to molecular techniques that alter the genetic material of a living organism (plant, animal, bacteria or virus).² These techniques involve the insertion or removal of one or more genes³ in order for an organism to either change, gain or lose a particular characteristic or set of characteristics.⁴ Organisms that have been modified or created using these techniques are referred to as genetically modified organisms (GMOs).⁵ Gene technology does not include sexual reproduction, homologous recombination or any other technique specified as not gene technology in the Commonwealth *Gene Technology Regulations (2001)* (the Commonwealth Regulation).⁶ The Commonwealth *Gene Technology Act 2000* (the Commonwealth Act) states that GMOs do not include human beings, or organisms declared by regulation not to be GMOs.⁷

Gene technology has a range of applications which include:

- research - for example, in biology and medicine with GM microorganisms, animals and plants
- agriculture - incorporating resistance to pests or diseases, herbicide tolerance, altering the timing and duration of flower production, or improving nutrition
- therapeutic goods - modifying microorganisms to produce therapeutic products such as insulin and vaccines
- medicine - diagnosing and treating disease
- industrial uses - enzyme production for food processing, paper pulp production and biological leaching of minerals, and
- bioremediation – decomposition of toxic substances or site clean-up by microorganisms.⁸

Practical examples in Australia include research undertaken by the CSIRO to improve crop and animal productivity and sustainability. Specifically, genetic technology was used to expedite the conventional breeding of black tiger prawns and to help cotton to resist the *Helicoverpa* larvae.⁹

2.2 Gene technology regulation in Australia

Scientific advances through gene technology can benefit the community, business, industry and the environment however there is broad recognition that the risks and benefits have to be carefully examined and appropriately managed.

The Australian government regulates gene technology activities through a national legislative scheme. The Commonwealth Act and the Commonwealth regulation, together with State and Territory laws, provide a nationally consistent system that aims to ensure all entities and individuals in Australia are similarly covered.¹⁰

² An organism is any biological entity that is viable; or capable of reproduction; or capable of transferring genetic material. *Gene Technology Act 2000*, s 10.

³ A gene is a sequence of DNA that is located on a chromosome. Department of State Development, Queensland Biotechnology Code of Ethics, 2006, p 13.

⁴ Office of the Gene Technology Regulator, Fact sheet: What is Biotechnology? What is Gene Technology?, January 2014, p 1

⁵ Organisms that are not genetically modified organisms are listed in more detail in Appendix E.

⁶ *Gene Technology Act 2000*, s 10. Techniques that are not gene technology are listed in more detail in Appendix D.

⁷ *Gene Technology Act 2000*, s 10.

⁸ Office of the Gene Technology Regulator, <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/fact-biotechnology-htm>. (All web references in this report were accessed on 19 September 2016.)

⁹ CSIRO, <http://www.csiro.au/en/Research/Farming-food/Innovation-and-technology-for-the-future/Gene-technology/Overview>

¹⁰ Michael Taylor AO et al, Review of the *Gene Technology Act 2001 (Queensland)*, Foursight Associates Pty Ltd, November 2013, p 5.

There are three components to the gene technology regulatory scheme:

- gene technology legislation which provides a framework to assess the risks to human health and the environment associated with GMOs – includes the Commonwealth Act, the Commonwealth regulations; and corresponding State and Territory legislation
- the intergovernmental Gene Technology Agreement (GTA) – the 2001 agreement between the Commonwealth, States and Territories to maintain a nationally consistent regulatory scheme, and
- Legislative and Governance Forum on Gene Technology (the Forum) – made up of Commonwealth, State and Territory Ministers who oversee the implementation of the national scheme, and provide policy guidance to the Gene Technology Regulator (the Regulator) for the operation of the Commonwealth Act.¹¹

The objective of the Commonwealth 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.’¹² The Commonwealth Act defines what it means to ‘deal with’ a GMO as:

*...to conduct experiments with the GMO; to make, develop, produce or manufacture the GMO; breed the GMO; propagate the GMO; use the GMO in the course of manufacture of a thing that is not the GMO; grow, raise or culture the GMO; import the GMO; transport the GMO; dispose of the GMO; and includes the possession, supply or use of the GMO for the purposes of, or in the course of, a dealing.*¹³

The Gene Technology Regulator, appointed by the Governor-General, is an independent statutory office holder responsible for administering and enforcing the national gene technology regulatory system.¹⁴ Section 118 of the Commonwealth Act establishes the role of the Regulator and Part 3 sets out the Regulator’s functions and powers. The Gene Technology Regulator is supported by the Office of the Gene Technology Regulator (OGTR).

The Regulator is responsible for identifying the risks posed by gene technology, and is required to manage those risks by regulating certain dealings with GMOs. All dealings with live and viable GMOs are illegal unless authorised under the Commonwealth Act.¹⁵

A number of other regulatory agencies, prescribed in the Commonwealth Regulations, have a role in the regulation of gene technology. They include the Therapeutic Goods Administration, Food Standards Australia New Zealand, Australian Pesticides and Veterinary Medicines Authority, the National Industrial Chemicals Notification and Assessment Scheme, and currently the Australian Government’s Department of Agriculture, Fisheries and Forestry Biosecurity.¹⁶ The Regulator must consult with the agencies prescribed in the Commonwealth regulations on licence applications and likewise agencies are required to consult with and/or notify the Regulator about applications for the registration of GM products or GM products that contain GMOs.¹⁷

Queensland companies that have dealings with GMOs and are currently accredited by the Regulator are listed in Appendix F. A diagrammatic representation of the national gene technology regulatory scheme is in Appendix G.

¹¹ Michael Taylor AO et al, Review of the *Gene Technology Act 2001* (Queensland), p 11; Queensland Government response to the recommendation of the Review of the *Gene Technology Act 2001* (Queensland), p 3; Office of the Gene Technology Regulator, <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/governance-1>.

¹² *Gene Technology Act 2000* (Cwlth), s 3.

¹³ *Gene Technology Act 2000* (Cwlth), s 10.

¹⁴ Office of the Gene Technology Regulator, <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/about-regulator-1>.

¹⁵ *Gene Technology Act 2000* (Cwlth), s 31; and Office of the Gene Technology Regulator, <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/import-regs-1>

¹⁶ See *Gene Technology Regulations 2001*, regulation 9.

¹⁷ Office of the Gene Technology Regulator, <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/governance-1>

2.3 Other jurisdictions

The Commonwealth and all States and Territories committed to a nationally consistent regulatory system for gene technology under the inter-governmental GTA in 2001. Most organisations that have dealings with GMOs are covered by Commonwealth legislation because they are constituted under corporations law or they are federal bodies.¹⁸ However Commonwealth legislation does not cover sole traders who are not trading interstate, and may not extend to State and Territory agencies, and higher education institutions.¹⁹ Therefore both Commonwealth and State legislation is required to ensure full regulatory coverage of gene technology in Australia.

While each jurisdiction has committed to a nationally consistent scheme there are variations in the implementation of gene technology legislation. New South Wales has adopted a 'lock-step' approach with no 'opt out' provision whereby the Commonwealth Gene Technology laws are automatically applied as laws of New South Wales. The Northern Territory and Tasmania adopted a 'lock-step, opt out' approach which is similar to New South Wales but with safeguards to enable the State or Territory to 'opt out' of any Commonwealth amendments. Queensland, Victoria and South Australia currently have mirror schemes where State legislation reflects the original Commonwealth legislation. This means that State needs amendment every time Commonwealth gene technology legislation is amended to ensure consistency with Commonwealth legislation.

Western Australia is the only jurisdiction that does not have corresponding gene technology legislation.²⁰ This means that the Regulator does not currently administer the Western Australian *Gene Technology Act 2006* (the Western Australian Act).²¹ A review of the Western Australian Act found that 'all appropriate legislative and administrative steps need to be taken to ensure that the State has gene technology laws that are a corresponding State law for the purposes of the scheme.' The review also noted that applying the Commonwealth gene technology laws as laws of Western Australia would enable the State to meet its obligations under the intergovernmental GTA.²² According to the Explanatory Notes the Legislative Council of Western Australia is currently considering a Bill that proposes a 'lock-step opt out' approach.²³

2.4 Queensland's gene technology legislation

The *Gene Technology Act 2001* (the Queensland Act) and the *Gene Technology Regulation 2002* (the Queensland Regulation) are Queensland's components of the national scheme. The legislation provides coverage under the scheme for State government agencies, higher education institutions and sole traders. Queensland's legislation has been declared as corresponding legislation under the Commonwealth Act which provides the Regulator with complete regulatory oversight.²⁴

The department advised that the primary functions of the Queensland Act are:

*to prohibit anyone from dealing with a GMO unless certain regulatory conditions are met; to establish a process to assess risk to human health and the environment associated with various dealing with GMOs; including opportunity for public input; and to provide extensive powers to allow monitoring and enforcement of the legislation.*²⁵

The Queensland legislation mirrors the Commonwealth legislation, and any amendments to the Commonwealth gene technology legislation must be reflected by amendments to Queensland's

¹⁸ Explanatory Notes, p 1.

¹⁹ The Allen Consulting Group, Final Report: Review of the *Gene Technology Act 2000*, p 10.

²⁰ Explanatory Notes, 7.

²¹ Department of Science, Information Technology and Innovation, Clarifying Statement, 29 August 2016, p 1.

²² Greg Calcutt AM SC, Review of the *Gene Technology Act 2006 (WA)*, June 2012, p 30.

²³ Explanatory Notes, p 7.

²⁴ Explanatory Notes, p 1.

²⁵ Public briefing transcript, Brisbane, 29 August 2016, p 2.

corresponding legislation. According to the Explanatory Notes it may take at least six months before these amendments are placed before the Queensland Parliament.²⁶

2.5 Legislative reviews of gene technology legislation

Legislative reviews of gene technology at both national and State levels have recommended that Queensland move to an applied law scheme. The 2011 review of the Commonwealth Act found that while the Commonwealth Act was 'working well' improvements were needed at the State and Territory level to improve national consistency. The review recommended that jurisdictions automatically adopt changed gene technology regulation by reference to the Commonwealth legislation.²⁷

In 2013 Queensland's then Department of Science, Information Technology, Innovation and the Arts commissioned an independent review of the Queensland Act (the Review). The purpose of the Review was to:

*...investigate whether the Queensland Act is operating as an efficient and effective component of the nationally consistent gene technology regulatory scheme and to investigate particular aspects as specified in the Terms of Reference.*²⁸

While the Review found that the Queensland Act was achieving its objectives it concluded that potential efficiencies could be achieved by adopting a lock-step approach to the Commonwealth legislation. However the review recommended that 'this should only proceed if there are legislated provisions accompanying the change to lock-step which provide adequate safeguards for Queensland...'.²⁹

The Queensland government's response to the Review was publically released in 2014 and outlined in-principle agreement to the Review's Recommendation 3 – 'that Queensland invest and adopt a lock-step approach that provides adequate safeguards for Queensland's autonomy.'³⁰ By 2015 the Queensland Government authorised the drafting of the Bill, which was introduced in August 2016.³¹

²⁶ Explanatory Notes, p 2.

²⁷ The Allen Consulting Group, Final Report: Review of the *Gene Technology Act 2000*, p vi, vii.

²⁸ Michael Taylor AO et al, Review of the *Gene Technology Act 2001* (Queensland), p 5.

²⁹ Michael Taylor AO et al, Review of the *Gene Technology Act 2001* (Queensland), p 2.

³⁰ Queensland Government response to the recommendations of the Review of the *Gene Technology Act 2001* (Queensland), p 6.

³¹ Explanatory Notes, p 2.

3 Examination of the Bill

3.1 Gene Technology (Queensland) Bill 2016.

3.1.1 Purpose

The purpose of the proposed Act is the same as the Commonwealth Act. Clause 3(1) of the Bill states:

The purpose of this Act is to -

- (a) 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*
- (b) manage those risks through regulating certain dealings with genetically modified organisms.*

3.1.2 Policy objectives of the Bill

The Bill's policy objectives are to:

- meet the Queensland Government's commitment to a nationally consistent scheme for gene technology regulation under the intergovernmental GTA, and to
- provide certainty and consistency for Queensland state government agencies, higher education institutions and sole traders in regard to the gene technology regulatory scheme and clarity around regulatory compliance.

3.2 Consultation on the Bill

Consultation on the Bill was undertaken by the Department of Science, Information Technology and Innovation with the Office of the Gene Technology Regulator, the Gene Technology Secretariat in the Commonwealth Department of Health, and the Commonwealth Director of Public Prosecutions.³² The department released a draft of the Bill for public consultation in April this year.³³ The department received three submissions which the committee has considered.

3.3 Applying the Commonwealth laws as laws of Queensland

To meet the Queensland Government's commitment under the GTA to a nationally consistent scheme for gene technology regulation, clause 6 of the Bill applies the Commonwealth gene technology laws (including any amendments) as laws of Queensland and clause 23 repeals the *Gene Technology Act 2001*. The Explanatory Notes state that the Bill is national scheme legislation.³⁴

Clause 6 of the Bill applies the Commonwealth gene technology laws, which are the *Commonwealth Gene Technology Act 2000*; the *Gene Technology (Licence Charges) Act 2000*; and all regulations, guidelines, principles, standards and codes of practice in force under those two Acts. The applied laws (and any modifications to them under section 7) are the 'applied provisions' in the Bill.

The Explanatory Notes state that automatically applying Commonwealth gene technology laws (including amendments) as laws of Queensland will reduce future legislative costs; improve administrative efficiencies; and create clarity, consistency and certainty for State agencies, higher education institutions and sole traders who have dealings with GMOs.³⁵

The 'lock-step' approach proposed in the Bill will remove the need to prepare new Queensland legislation every time Commonwealth gene technology legislation is amended.³⁶

³² Department of Science, Information Technology and Innovation, Public briefing transcript, Brisbane, 29 August 2016, p 2.

³³ Explanatory Notes, p 7.

³⁴ Explanatory Notes, p 3.

³⁵ Explanatory Notes, pp 1-3.

³⁶ Explanatory Notes, p 3.

Queensland's current gene technology legislation has been amended four times since 2007. The department advised:

This manual amendment process is cumbersome and usually results in a period of misalignment between the Queensland and Commonwealth legislation. The Queensland and Commonwealth legislation are currently out of alignment as a result of a small number of minor and technical amendments to the Commonwealth legislation coming into force on 11 March 2016.³⁷

The Explanatory Notes describe the implications of misalignment for the gene technology sector in Queensland:

When the Queensland legislation is out of alignment with the Commonwealth legislation, a period of uncertainty and inconsistency exists for Queensland state government agencies, higher education institutions and sole traders who will need to adhere to existing, potentially outdated legislation compared to researchers working for private companies or Federal bodies who will be covered under amended, updated Commonwealth legislation.³⁸

The Minister for Innovation, Science and the Digital Economy and Minister for Small Business outlined the disadvantages of the misalignment for Queensland entities covered by State legislation:

When GMO risk assessments are updated and tightened to require more stringent safety procedures, Queensland researchers who continue operating under earlier, unamended legislation may be put at unnecessary risk. Conversely, when regulatory requirements are reduced in response to knowledge and experience gained over long periods of safe use of a GMO, Queensland research programs and organisations that continue operating under unamended, more stringent legislation may be disadvantaged and viewed as a less appealing investment.³⁹

Clause 21 of the Bill requires the Minister for Innovation, Science and the Digital Economy to table a copy of amendments to the Commonwealth legislation within 10 sitting days of its commencement. The Explanatory Notes state that this provision will 'ameliorate to some extent' the lack of parliamentary scrutiny of applied national scheme legislation.⁴⁰

Submitter's views

Friends of the Earth Australia does not support the 'lock-step opt out' approach of the Bill and raised concerns about limitations on parliamentary scrutiny of the legislation:

Our primary concern is that the Bill will result in a virtually complete bypassing of Parliamentary oversight and debate for legislation that will affect Queensland. We dispute the claim in the Explanatory Memorandum that the effect of not subjecting legislative changes to Parliamentary debate will be 'ameliorated' by tabling. Merely informing Parliament of steps taken in Ministerial Council is not democratic nor does it satisfy any of the proper roles of Parliament.⁴¹

Gene Ethics submitted that automatically amending Queensland legislation when Commonwealth legislation is amended will provide 'minimal opportunity for the Queensland Minister or parliament to review or debate legislation what would affect Queensland agriculture.' Gene Ethics concurred with Friends of the Earth that tabling Commonwealth amendments would not 'ameliorate' the loss of parliamentary scrutiny.

³⁷ Public briefing transcript, Brisbane, 29 August 2016, p 2.

³⁸ Explanatory notes, p 2.

³⁹ Queensland Parliament, Record of Proceedings, 16 August 2016, p 2764.

⁴⁰ Explanatory Notes, p 4.

⁴¹ Submission 3, p 1.

The Explanatory Memorandum to the Bill asserts that merely tabling proposed legislative changes would ameliorate the loss of Parliamentary debate. But only informing Parliament of changes that a Ministerial Council has already agreed to subverts Parliament's role and undermines its democratic processes.⁴²

The Gene Technology Regulator supported the Bill and stated that the 'lock-step' approach proposed in the Bill would provide stakeholders with legislative consistency and clarity:

The Gene Technology (Queensland) Bill 2016 would avoid this inconsistency and avoid the confusion and uncertainty for regulated organisations as to which provisions apply. Legislative consistency also avoids potential compliance issues for organisations and the Regulator, and avoids situations which could potentially undermine risk management.⁴³

According to Ausbiotech, a biotechnology industry organisation, the 'lock-step' approach will give Queensland companies greater certainty in developing and implementing new gene technologies.

The adoption of the Draft Gene Technology (Queensland) Bill 2016 will provide predictability for companies working in this rapidly changing industry, reducing red tape and streamlining the adoption of available gene-based technologies.⁴⁴

3.4 Provisions to opt out

The Bill adopts a 'lock-step opt out' approach by providing Queensland the ability to 'opt out' of Commonwealth amendments by regulation if the amendments are not in 'Queensland's interests'.⁴⁵ Clause 7 allows for the modification of Commonwealth gene technology laws by a regulation enabling Queensland to apply the Commonwealth legislation as if the amendment had not taken effect. The Explanatory Notes state that a regulation under clause 7 can be made to specify that an amendment to Commonwealth gene technology laws will not come into force in Queensland.⁴⁶

Both clauses 7 and 22 provide the power to make regulations under the new Act. Any regulation made to 'opt out' of a Commonwealth amendment would be subject to the possibility of disallowance by the Legislative Assembly under section 50 of the *Statutory Instruments Act 1992*.⁴⁷

A clause that provides for amendment of an Act by regulation is called a 'Henry VIII clause' and discussed further in chapter 4 of the report.

The Explanatory Notes state that the 'opt out' provision in the Bill is a safeguard for Queensland but one that would be used rarely.⁴⁸ Advice from the department illustrates their confidence in the consultation and approval process for any proposed changes to Commonwealth gene technology legislation.⁴⁹ According to the Explanatory Notes there is 'considerable opportunity for a jurisdiction to raise issues and seek to resolve any matters of concern'.⁵⁰

Currently proposed amendments to the Commonwealth gene technology legislation are placed before the Gene Technology Standing Committee for consideration before they are submitted to the Legislative and Governance Forum on Gene Technology (the Forum), formally the Ministerial Council.⁵¹ The GTA requires that amendments are submitted to the Forum one month prior to their introduction. Importantly, the GTA stipulates that any proposed changes to the Commonwealth legislation must be approved by special majority of the Forum before they are introduced.⁵²

⁴² Submission 4, p 1.

⁴³ Submission 2, p 2.

⁴⁴ Submission 1, p 2.

⁴⁵ Explanatory Notes, pp 2, 6 and 7.

⁴⁶ Explanatory Notes, p 8.

⁴⁷ Explanatory Notes, p 9.

⁴⁸ Explanatory Notes, p 3.

⁴⁹ Public briefing transcript, Brisbane, 29 August 2016, p 3.

⁵⁰ Explanatory Notes, p 4.

⁵¹ Department of Science, Information Technology and Innovation, Public briefing transcript, Brisbane, 29 August 2016, p 3.

⁵² Gene Technology Agreement 2001, Clause 40.

The department advised that the Queensland Government has to date agreed to all amendments to Commonwealth gene technology legislation. This does not preclude potential issues arising in the future:

*A purely hypothetical example could be where an amendment is proposed that may not have a certain level of scientific rigour behind it... That might be an opportunity that Queensland could look to opt out in terms of making sure that researchers and research organisation are appropriately protected for their health and safety.*⁵³

Stakeholder's and submitter's views

CropLife Australia, a peak industry organisation representing the agricultural chemical and biotechnology sector, raised concerns with the department about the 'opt out' provision during the government's consultation on the draft Bill. While it supported the majority of the draft Bill CropLife Australia stated that it:

*...does not support those parts of the Bill that provide provisions to 'opt out' of particular amendments by regulation in instances where 'it is not in Queensland's interests' ...Vague inferences, such as 'not in Queensland's interests' could lead to unnecessary uncertainty. This may result in a failure to meet the intended outcomes of this Bill, namely, to provide efficiency, certainty, consistency and confidence to the Queensland biotechnology industry and the state's farming sector.*⁵⁴

CropLife did not make a submission to the committee. During the committee's briefing on the Bill the department advised that gene technology research often involved work across State boundaries and CropLife:

*Essentially, ... [does] not want the Queensland government to have the option of saying, 'No, we don't believe that should be happening in Queensland.' They would prefer to have a consistent approach across states so they can have the same laws apply whenever they are doing their collaborative work.*⁵⁵

The Commonwealth Department of Health submitted that the 'lock-step' approach in the Bill provided greater certainty to regulated organisations under the scheme and commented on the 'opt out' provisions in the Bill:

*I acknowledge the 'opt out' provisions within this Bill and support the principle as noted in the Bill's explanatory notes that these provisions only be used rarely and as a last resort. It is the intention of the Commonwealth for the rigorous process in place within the IGA [GTA] to ameliorate concerns prior to legislation being enacted...*⁵⁶

3.5 National uniformity and transitional arrangements

3.5.1 Officer functions and powers under applied provisions

To ensure national uniformity, clause 9 of the Bill provides that the Regulator and other authorities and officers have the same functions and powers under the applied provisions as they do under Commonwealth gene technology legislation. Clause 10 provides that delegations made by the Regulator under the Commonwealth Act would have effect in Queensland.

3.5.2 Application of other Commonwealth laws to the Act

Clause 8 of the Bill applies the *Acts Interpretation Act 1901* (Cwth) to interpret the applied provisions in the proposed Act and excludes the *Queensland Acts Interpretation Act 1954* and *Statutory Instruments Act 1992*.

⁵³ Public briefing transcript, Brisbane, 29 August 2016, p 3.

⁵⁴ CropLife Australia, Correspondence to the Department of Science, Information Technology and Innovation, 9 May 2016

⁵⁵ Public briefing transcript, Brisbane, 29 August 2016, p 5.

⁵⁶ Submission 5, p 2.

The Bill adopts relevant Commonwealth criminal laws and applies them to offences against the applied provisions.⁵⁷ These include the *Crimes Act 1914*; the *Criminal Code Act 1995*; the *Director of Public Prosecutions Act 1983*; and the *Judiciary Act 1903*.⁵⁸ An offence against the applied provisions in the Act will be treated as an offence against Commonwealth laws and offenders would be prosecuted by the Commonwealth Director of Public Prosecutions.⁵⁹

Clause 15(1) of the Bill adopts Commonwealth administrative laws, for example the *Administrative Appeals Tribunal Act 1975* and the *Freedom of Information Act 1982*, as laws of Queensland in relation to any matters arising from the applied provisions. Clause 15(2) provides that Commonwealth provisions that confer jurisdiction on the Federal Court will not be applied as Queensland law.⁶⁰ According to the Explanatory Notes 'a person affected by a decision under the applied provisions may apply to the Administrative Appeals Tribunal in the same way they would if the decision had been made under the Commonwealth legislation.'⁶¹

Clause 16 provides that certain 'jurisdiction specific legislation', for example, the *Auditor-General Act 2009* and *Public Service Act 2008* would not apply to the Regulator. If a State entity exercised functions under the applied provisions, the relevant Queensland laws would continue to apply to the State entity.⁶²

3.5.3 Transitional arrangements

Part 8 of the Bill (clauses 24 to 51) contains transitional provisions. Except for clause 43, the effect of transitional arrangements is that decisions or actions that are pending at the commencement of the proposed Act will be dealt with under the repealed legislation, and decisions or actions occurring after commencement would be dealt with under the applied provisions.⁶³ Transitional clauses include those dealing with offences, licences, certification, accreditation, enforcement, inspections, review of decisions, and to confidential commercial information. The only issue submitters raised about transitional provisions, relate to licence variations.

3.5.3.1 Applications to vary GMO licences

The Bill reflects amendments to Commonwealth gene technology laws in March this year about applications to vary a licence. Clause 31 provides that undecided applications to vary existing GMO licences made under the current Act will be dealt with under section 71 of the repealed Act but would exclude section 71(2B). Section 71(2B) provides that the Regulator must not vary a licence if the original application for the licence does not cover the risks posed by the new dealings raised by the variation.⁶⁴ The Explanatory Notes state that by excluding section 71(2B) the Regulator will be able to approve licence variations by taking into account the risk assessment and risk management plans already prepared for licence applications (for which licences have been issued) other than the original licence.⁶⁵

The department advised the committee that the most common requests made to the Regulator to vary licences include: variation of field trial licences when poor weather conditions impact on research and trial sites; extension of time when further funding has been received; addition of local government areas to locate enough growers for plant trials; and changing the configuration and number of trial sites if experimental plans have changed. Requests to vary licences for contained laboratories include: adding or removing facilities; extending the period of a licence; and adding new organisms, genes or

⁵⁷ Clause 11 lists examples of these offences.

⁵⁸ Clause 12.

⁵⁹ Clause 9, Explanatory Notes p 11.

⁶⁰ Explanatory Notes, p 10.

⁶¹ Explanatory Notes, p 10.

⁶² Explanatory Notes, p 5 and 10.

⁶³ Explanatory Notes, p 7.

⁶⁴ *Gene Technology Act 2001(Queensland)*, s 71 (2B).

⁶⁵ Explanatory Notes, p 12.

vectors to the licence (but only when proposed dealings have been assessed in the Risk Assessment and Risk Management Plans for that licence or another licence).⁶⁶

Submitter's views

Gene Ethics and Friends of the Earth do not support the policy approach in clause 31. In particular, Gene Ethics cautioned against using the risk assessment from another licence for new genetically modified organisms.

*Clause 31 would allow the federal Regulator, OGTR, to make a judgement that an application was substantially equivalent to an existing licence to expedite a: 'risk assessment and risk management plan in respect of an application for another licence.' Such comparisons are not based on the rigorous scientific methods we expect of our regulators, so this proposal should not be allowed to predetermine the risk assessment for new genetically manipulated organisms. Each GM event is unique and that is why the national uniform system was made case-by-case.*⁶⁷

The lack of scientific rigour behind licence variations was also raised by Friends of the Earth. 'Risk assessment by analogy, which is what this provision permits, is not a scientific approach to risk assessment.'⁶⁸

The department advised the committee that the Commonwealth amendments [as applied in clause 31] were about providing the Regulator with the ability to take into account a broader range of information when dealing with licence variations:

*Specifically, those amendments were around removing a restriction on licence variations to broaden the circumstances in which the Gene Technology Regulator can vary licences rather than requiring a new licence application to be submitted, basically taking into account a broader range of information and not having to get an organisation to reapply if information already exists that can be used by the regulator.*⁶⁹

⁶⁶ Department of Science, Information Technology and Innovation, Correspondence, 31 August 2016, attachment 1, p 1.

⁶⁷ Submission 4, p 1.

⁶⁸ Submission 3, p 1.

⁶⁹ Public hearing transcript, Brisbane, 29 August 2016, p 6.

4 Compliance with Legislative Standards Act

4.1 Fundamental legislative principles and other issues

4.1.1 Introduction

Section 4 of the *Legislative Standards Act 1992* states that ‘fundamental legislative principles’ are the ‘principles relating to legislation that underlie a parliamentary democracy based on the rule of law’.

The principles include that legislation has sufficient regard to:

- the rights and liberties of individuals
- the institution of Parliament.

The committee has examined the application of the fundamental legislative principles to the Bill and brings the following potential FLP issues to the attention of the Legislative Assembly.

4.1.2 Rights and liberties of individuals:

Clauses 8, 12, 15 and 16 of the Bill allow for the application of Commonwealth laws over State laws.

The introduction of Commonwealth laws at the expense of State laws potentially breaches the rights and liberties of individuals pursuant to section 4(1) of the *Legislative Standards Act 1992*. It may be the case that a particular issue addressed under the provision(s) of a Queensland law is dealt with differently by a Commonwealth law, thereby removing the rights and expectations a person may have for how their matter would be dealt with under Queensland law.

The consequence of adopting a national approach to gene technology is that it may be more appropriate for Commonwealth laws to apply and interact with the provisions contained in the Bill.

The committee notes clause 15 where a person affected by a decision under the applied provisions still has the option of appealing to the Administrative Appeals Tribunal. In light of this review function and the further justifications provided in the Explanatory Notes the committee considers the clauses appropriate in these circumstances.

4.1.3 National scheme legislation:

Clauses 6, 7, 21, and 22 together provide for the application of a ‘lock-step opt out’ approach to gene technology legislation in Queensland.

As previously discussed the Bill incorporates national scheme legislation. The former Scrutiny of Legislation Committee (SLC) was generally wary of national scheme legislation as it believed that when the legislation was introduced or tabled in Parliament following national agreement on the laws under administrative arrangements, there was little real capacity of the Parliament to amend, refuse to pass, or disallow the law.

The Explanatory Notes acknowledge those concerns and state that clauses 7 (the ability to opt out of amendments by regulation) and 21 (a requirement for the Minister to table Commonwealth amendments within 10 days of commencement) seek to address the concern in relation to national scheme legislation.

It may be argued that clause 7 breaches section 4(4)(c) of the *Legislative Standards Act 1992*, which provides that a Bill should allow or authorise the amendment of an Act by another Act only and not a regulation.

A Bill should only authorise the amendment of an Act by another Act.⁷⁰ A clause in an Act, which enables the Act to be expressly or impliedly amended by subordinate legislation or executive action is defined as a Henry VIII clause. The SLC’s approach to Henry VIII clauses was that if an Act purported to be amended by a statutory instrument (other than an Act) in circumstances that were not justified,

⁷⁰ *Legislative Standards Act 1992*, s 4(4)(c).

the SLC would voice its opposition by requesting that Parliament disallow the part of the instrument that breached the FLP requiring legislation to have sufficient regard for the institution of Parliament.⁷¹

The SLC considered the possible use of Henry VIII clauses in the following limited circumstances, to facilitate:

- immediate executive action
- the effective application of innovative legislation
- transitional arrangements, and
- the application of national scheme legislation.⁷²

The committee notes that the SLC considered the use of Henry VIII clauses as appropriate to facilitate the application of national scheme legislation.

In relation to clause 22 (providing the Governor in Council with the power to make a regulation) the Explanatory Notes state that a regulation will be used 'to opt out of particular amendments of the Commonwealth law in instances where it is not in Queensland's interests'.⁷³

The Bill has sought to address concerns about the application of national scheme legislation through the provisions contained in clauses 7 and 21. Clause 7 allows for Commonwealth laws that have been applied to Queensland, to be amended by regulation, while clause 21 requires tabling in the Queensland Legislative Assembly of amendments to Commonwealth laws and regulations involving gene technology listed at clause 21(1)(a)-(c). The committee notes the Explanatory Notes state that the use of regulations under clause 22 will only be used in instances where the Commonwealth law is not in Queensland's best interests.

Further, the committee considers the use of regulations contained in clauses 7 and 22 as appropriate in this instance, given that any regulation would come before the committee for consideration and be subject to disallowance.

In view of the justifications provided in the Explanatory Notes the committee considers that sufficient regard has been given to the institution of Parliament in relation to clauses 7, 21 and 22.

4.2 Explanatory notes

Part 4 of the *Legislative Standards Act 1992* relates to Explanatory Notes. It requires that an Explanatory Note be circulated when a Bill is introduced into the Legislative Assembly, and sets out the information an Explanatory Note should contain.

Explanatory Notes were tabled with the introduction of the Bill. The Notes are fairly detailed and contain the information required by Part 4 and a reasonable level of background information and commentary to facilitate understanding of the Bill's aims and origins.

⁷¹ Office of the Queensland Parliamentary Counsel, *Fundamental Legislative Principles: The OQPC Notebook*, p 159.

⁷² Office of the Queensland Parliamentary Counsel, *Fundamental Legislative Principles: The OQPC Notebook*, p 159.

⁷³ Explanatory Notes, p 5.

Appendices

Appendix A: List of submissions

Sub No.	Submitter
001	AusBiotech
002	Gene Technology Regulator
003	Friends of the Earth Australia
004	Gene Ethics
005	Department of Health (Cwlth)

Appendix B: Officials at the public briefing

Public briefing –29 August 2016
Department of Science, Information Technology and Innovation
Lea Diffey, Executive Director, Science Development
Mark Jacobs, Acting Assistant Director-General
Grant Woollett, Acting Director, Science Policy and Evaluation Services
Sarah Bloxsom, Principal Project Officer, Science Policy and Evaluation Services

Appendix D: Techniques that are not gene technology

Schedule 1A Techniques that are not gene technology (regulation 4)

Item	Description of technique
1	Somatic cell nuclear transfer, if the transfer does not involve genetically modified material.
2	Electromagnetic radiation-induced mutagenesis.
3	Particle radiation-induced mutagenesis.
4	Chemical-induced mutagenesis.
5	Fusion of animal cells, or human cells, if the fused cells are unable to form a viable whole animal or human.
6	Protoplast fusion, including fusion of plant protoplasts.
7	Embryo rescue.
8	In vitro fertilisation.
9	Zygote implantation.
10	A natural process, if the process does not involve genetically modified material. Examples of natural processes include conjugation, transduction, transformation and transposon mutagenesis.

Source: *Gene Technology Regulations 2001* (Cwlth) (including amendments 2011).

Appendix E: Organisms that are not genetically modified organisms

Schedule 1: Organisms that are not genetically modified organisms (regulation 5)

Item	Description of organism
1	A mutant organism in which the mutational event did not involve the introduction of any foreign nucleic acid (that is, non-homologous DNA, usually from another species).
2	A whole animal, or a human being, modified by the introduction of naked recombinant nucleic acid (such as a DNA vaccine) into its somatic cells, if the introduced nucleic acid is incapable of giving rise to infectious agents.
3	Naked plasmid DNA that is incapable of giving rise to infectious agents when introduced into a host cell.
6	An organism that results from an exchange of DNA if: (a) the donor species is also the host species; and (b) the vector DNA does not contain any heterologous DNA.
7	An organism that results from an exchange of DNA between the donor species and the host species if: (a) such exchange can occur by naturally occurring processes; and (b) the donor species and the host species are micro-organisms that: (i) satisfy the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 1; and (ii) are known to exchange nucleic acid by a natural physiological process; and (c) the vector used in the exchange does not contain heterologous DNA from any organism other than an organism that is involved in the exchange.

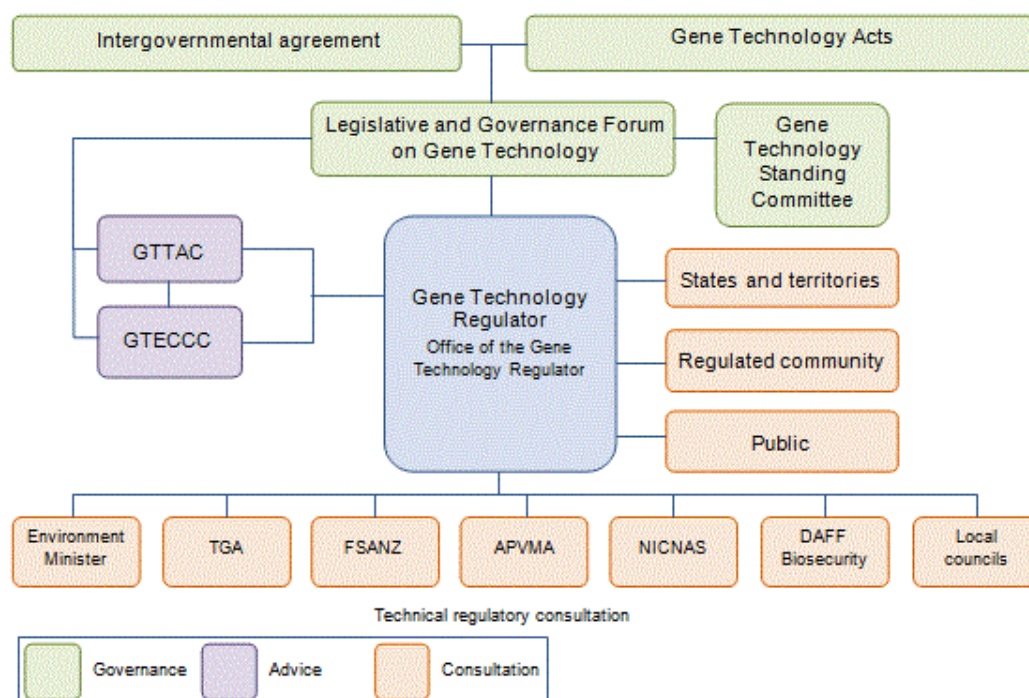
Source: *Gene Technology Regulations 2001* (Cwlth) (including amendments 2011).

Appendix F: Queensland companies currently accredited by the Regulator

Advanta Seeds Pty Ltd
Australian Army Malaria Institute
Australian Genome Research Facility
Australian Institute of Marine Science
Central Queensland University
Children's Health Queensland Hospital and Health Service
Clinical Network Services Pty Ltd
Department of Agriculture and Fisheries
Ethanol Technologies Limited
Griffith University
James Cook University
Mater Medical Research Institute
PaxVax Aus Pty Ltd
PharmaSynth Pty Ltd
Pioneer Hi-Bred Australia Pty Ltd
QIMR Berghofer Medical Research Institute
Queensland Clinical Trials Network Inc
Queensland Health Forensic and Scientific Services
Queensland University of Technology
Royal Brisbane and Women's Hospital
SGS Australia Pty Ltd
Sugar Research Australia Limited
The Prince Charles Hospital, Metro North Health Service District
The University of Queensland
Translational Research Institute Pty Ltd
University of Southern Queensland
University of the Sunshine Coast

Source: Office of the Gene Technology Regulator,
<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/accredorg-1>

Appendix G: Australia’s regulatory system for gene technology



Key:

- TGA Therapeutic Goods Administration
- FSANZ Food Standards Australia New Zealand
- APVMA Australian Pesticides and Veterinary Medicines Authority
- NICNAS The National Industrial Chemicals Notification and Assessment Scheme
- DAFF Department of Agriculture, Fisheries and Forestry Biosecurity (Cwlth)
- GTTAC Gene Technology Technical Advisory Committee
- GTECCC Gene Technology Ethics and Community Consultation Committee

Source: Office of the Gene Technology Regulator,
[http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/AD8BEE0631173F20CA257D41001895C7/\\$File/Australia%E2%80%99s%20regulatory%20system%20for%20gene%20technology%20chart.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/AD8BEE0631173F20CA257D41001895C7/$File/Australia%E2%80%99s%20regulatory%20system%20for%20gene%20technology%20chart.pdf)

