Queensland

Gene Technology Act 2001

REVIEW OF THE GENE TECHNOLOGY ACT 2001 (QUEENSLAND)

Mr Michael Taylor AO
Dr Graham Mitchell AO
Dr Robert Sward

November 2013

FOURSIGHT

15 November 2013

Mr Andrew Garner

Director General, Department of Science, Information Technology, Innovation and the Arts

Dear Director General,

We are pleased to present to you a report on the *Review of the Gene Technology Act 2001 (Queensland),* undertaken in accordance with Section 194 of the Queensland Act, for you to convey to the Hon. Ian Walker MP, Minister for Science, Information Technology, Innovation and the Arts.

In summary, our Review found that the object of the Queensland Act is being achieved and that it continues to operate as an effective part of the national gene technology regulatory scheme.

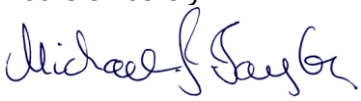
In addressing the Terms of Reference we have concluded there are potential efficiencies to be gained from automatically adopting changed gene technology regulation by reference to the Commonwealth legislation (that is, having Queensland's gene technology legislation in 'lock-step' with the Commonwealth gene technology legislation).

However, it is our recommendation that this should only proceed if there are legislated provisions accompanying the change to lock-step which provide adequate safeguards for Queensland. An alternative to adopting a lock-step approach could be for Queensland to amend its gene technology legislation contemporaneously with changes to the Commonwealth gene technology legislation. We have provided four alternative options, that to varying extents, would potentially reduce regulatory burden.

We would like to thank all parties who have been involved with the Review and in particular we wish to acknowledge the excellent support provided by the Science Policy and Evaluation Services unit within the Innovation and Science Development division of the Department of Science, Information Technology, Innovation and the Arts.

We commend this report to you.

Yours sincerely



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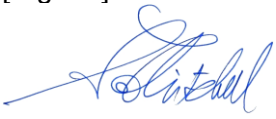
Mr Michael Taylor AO



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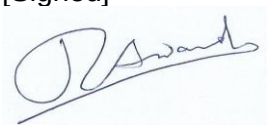
Dr Graham Mitchell AO



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Dr Robert Sward

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PREFACE

This report was commissioned in mid July 2013, with most of the background work being completed during July, August and September 2013.

The Reviewers are immensely grateful to the extraordinary support from all the parties who have been involved with the Review.

Parties external to the Department gave freely of their time and advice and were at all times very helpful. Within the Department, insight and advice was always open and freely given with a view to assisting the reviewers in every way.

Undertaking this Review involved gathering together an extensive range of materials, considering and organising a wide range of submissions, inputs, reviewer requests, documenting material and interviews. The assistance provided by Ms Karen Thompson and Ms Sarah Bloxsom to facilitate these activities for the Review was exceptional and without it the preparation of this report would not have been possible.

We wish to thank Mrs Lorraine Ryan for her invaluable support in the Foursight Associates office.

Finally Dr Mark Jacobs' commitment and insight to the project and his focus on how best matters can be organised to facilitate the long-term objectives of the Review, along with his deep understanding of the associated policy, administrative, financial and governance issues assisted the Reviewers immensely.

Michael Taylor AO
Graham Mitchell AO
Robert Sward

OVERVIEW

The *Gene Technology Act 2001 (*the Queensland Act) is the Queensland Government's component of the nationally consistent regulatory scheme for gene technology in Australia.

The object of the Commonwealth and States and Territories gene technology legislation, which gives effect to the nationally consistent scheme, 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) (see Chapters 2 and 3 for more detail).

The need for consistent legislation between the Commonwealth and the States and Territories is to ensure that all individuals and entities in Australia are covered in the same way by the scheme.

Section 194 of the Queensland Act requires a review of the operation of the 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. The first review of the Queensland Act was conducted by an independent reviewer, Ms Kathryn Adams, in 2006[1].

As the second review of the Commonwealth Act was completed in August 2011 (the Commonwealth Review), the second review of the Queensland Act is required to be undertaken. The purpose of the Queensland Review is 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 (TOR).

TERMS OF REFERENCE FOR THE QUEENSLAND REVIEW

Using the submissions from the Commonwealth Review and its Report as a basis, the Review will investigate:

1. the outcomes/findings of the Commonwealth Review as they apply to Queensland [TOR 1]
2. whether the object of the Queensland Act is being achieved and if there is a more effective and efficient way of achieving it [TOR 2]
    a. in particular, propose options on how implementation of the 'lock-step' approach could be achieved [TOR 3]
3. mechanisms to reduce the regulatory burden given the Queensland Government's commitment to red tape reduction [TOR 4]

[1] The *Gene Technology Act 2001* (Queensland). Statutory Review. October 2006

EXECUTIVE SUMMARY

This Review of the Queensland *Gene Technology Act 2001* occasioned by the 2011 Review of the Commonwealth *Gene Technology Act 2000* and informed by public submissions to both reviews, has identified that the Queensland Act is operating as an efficient and effective component of the nationally consistent gene technology regulatory scheme. This is an important conclusion and indicates there is no sense of current or imminent problems of consequence.

Clearly, 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". Indeed, this needs to be communicated more effectively to the Australian public and that the administrative oversight of the Office of the Gene Technology Regulator is also effective and efficient. Nevertheless, efforts to improve harmonisation of Australia's arrangements to regulate gene technology, is an important ongoing endeavour.

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 Institutional Biosafety Committees 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.

There is overall strong support amongst researchers and industry to move to 'lock-step' akin to New South Wales and the Northern Territory which automatically and immediately adopt any changed gene technology regulation by the Commonwealth. For the Queensland Government and bureaucracy, and despite inbuilt safeguards against unilateral Commonwealth actions, matters for consideration pertain to the current system working well, a perceived loss of autonomy and determination by the State of Queensland, and the fact that not all States have signed up to lock-step. Moving to lock-step should only proceed if there are legislated provisions accompanying the change to lock-step which provide adequate safeguards for Queensland.

We propose five options in relation to consideration of a lock-step approach in Queensland:

(A) Maintain *status quo* by keeping Queensland's gene technology legislation declared as corresponding with wind-back in place (but noting that it may take at least six months to have legislative amendments placed before the Queensland Parliament following changes to the Commonwealth legislation);

(B) Follow 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);

(C) Follow in a similar way to the example set by Tasmania, automatically adopting changed gene technology regulation by reference to the Commonwealth legislation (that is, in lock-step with the Commonwealth gene technology legislation), but with an added provision which requires that any amendments to the Commonwealth Act and Regulations be tabled in the Queensland Parliament within a specified period (for example 10 sitting-days) from the date on which the Commonwealth amendment commences;

(D) Investigate an approach similar to option (C) above, subject to Queensland's Parliamentary Counsel's advice, which allows the Queensland Government and/or Parliament to decline or 'opt-out' of lock-step within, for example, a 30-day deadline if Queensland does not agree with the change to the Commonwealth legislation; or

(E) Investigate in consultation with Queensland's Parliamentary Counsel an option that allows the Queensland Government and/or Parliament to contemporaneously 'opt-in' to a lock-step approach if Queensland agrees to a change in the Commonwealth legislation.

with the latter four options having the effect, to varying extents, of reducing the regulatory burden for Queensland.

RECOMMENDATIONS

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

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).

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.

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."

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.

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.

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.

CHAPTER 1 ABOUT THE REVIEW

1.1 Background

The Queensland Act is part of the nationally consistent legislative scheme for regulating gene technology. The scheme aims to protect the health and safety of people and the environment by identifying risks posed by or resulting from gene technology. The risks are managed through the regulation of dealings with GMOs. State and Territory 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.

A statutory review of the Queensland Act is required whenever a review of the Commonwealth Act is undertaken. The Queensland Act was first reviewed in 2006 following the first review of the Commonwealth Act. The Commonwealth Act was reviewed for the second time in 2011.

The purpose of the second review of the Queensland Act is to investigate whether the Queensland Act is operating as an efficient and effective component of the nationally consistent gene technology regulatory scheme.

This Review of the Queensland Act is intended to be read in conjunction with the Final Report of the "Review of the *Gene Technology Act 2000*" by the Allen Consulting Group dated August 2011[2].

1.2 The Reviewers

This Review has been undertaken by Mr Michael Taylor AO and Dr Graham Mitchell AO of Foursight Associates, joined by Dr Robert Sward of BioBotanicals Consulting (see Appendix 1).

1.3 The Review process

The Reviewers were engaged to undertake the Review in mid July 2013 and commenced the examination of a range of reference documents, including the Final Report of the review of the Commonwealth Act undertaken by the Allen Consulting Group and submitted to the Department of Health and Ageing in August 2011.

[2] Allen Consulting Group 2011, Review of the Gene Technology Act 2000, undertaken for the Department of Health and Ageing, Canberra, August 2011

A notice announcing the Review and calling for submissions was published on the Queensland Government's Get involved consultation website as well as the website of the Department of Science, Information Technology, Innovation and the Arts (DSITIA) on 5 August 2013 (see Appendix 3).

Submissions relating to the Review were also sought through the use of social media and by way of Public Advertisement in five Queensland newspapers on 10 August 2013. Information was also sent directly to all key stakeholders (e.g. Queensland Institutional Biosafety Committees (IBCs) and relevant bodies). Submissions were requested to be lodged by close of business on 30 August 2013 (see Appendix 6 for list of written submissions received).

The submissions to the 2011 Commonwealth Review were analysed and all key points of relevance to the Queensland Act were drawn out and summarised (see Appendix 5).

The Queensland Act was analysed and the various mechanisms relating to its mode of operation examined and reported on. Particular attention was paid to Recommendation 3 of the Commonwealth Review, which proposes that jurisdictions follow the example of New South Wales and the Northern Territory and automatically adopt changed gene technology regulation by reference to the Commonwealth legislation[3] (that is, having Queensland's gene technology legislation in 'lock-step' with the Commonwealth gene technology legislation) in order to achieve further administrative and efficiency gains.

At the present time, Queensland has retained its capacity to exercise regulatory influence over its State agencies and universities through the Queensland legislation which corresponds with the Commonwealth legislation, however consistent with the terms of reference, the advantages and disadvantages of 'lock-step' have been examined and reported on (see Chapter 5).

Each of the submissions provided to the Queensland Review was examined. In addition, a range of consultations were conducted, as determined from these submissions and from information drawn from the Commonwealth Review and other general insights, into the operation of the Queensland Act. Consultations were held with the Gene Technology Regulator, as well as officers of Departments with an interest in the Queensland Act and officers of relevant IBCs and other relevant parties.

Based on the information gathered by the above methods, a report was prepared and subsequently provided to the Director General of the Department of Science, Information Technology, Innovation and the Arts, to be conveyed to the Minister for Science, Information Technology, Innovation and the Arts by 15 November 2013 as stipulated in the review contract.

[3] Note that where the term 'legislation' is used, it refers to both the Act and the Regulations, unless otherwise specified; for example, where quoting directly from another document.

Chapter 2 GENE TECHNOLOGY AND ITS REGULATION

This chapter considers the issue of gene technology, describes the national gene technology regulatory scheme and aspects of the application of gene technology in Queensland.

2.1 Gene technology and the regulation of gene technology in Australia

Gene technology, in its broader sense, is the term given to a range of activities concerned with understanding how genes function and interact. More specifically, gene technology may involve identifying, isolating or modifying the genes or other genetic material of microorganisms, plants and animals.

Genetic material may be modified by the direct incorporation, deletion or alteration of one or more genes or genetic sequences and transferred to different host organisms to change existing traits or introduce new traits. The modified organisms, which result, are known as genetically modified organisms or GMOs.

In Australia in the late 1990s, a cooperative process was put in place by the Australian Government and State and Territory Governments to develop a uniform approach to the regulation of gene technology in Australia. In exploring the development of a uniform approach, Australian governments sought to balance potential benefits to society against community concerns over possible risks related to the deployment of the technology.

The *Gene Technology Act 2000* and the *Gene Technology Regulations 2001* came into effect in Australia in June 2001. 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."

The national gene technology regulatory scheme 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[4]).

The intergovernmental GTA reflects agreement between the Commonwealth and States and Territories that there is a need for a cooperative national 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 national regulatory scheme for gene technology and provides policy guidance for the operation of the gene technology legislation.

[4] The LGFGT was formerly the Gene Technology Ministerial Council (GTMC)

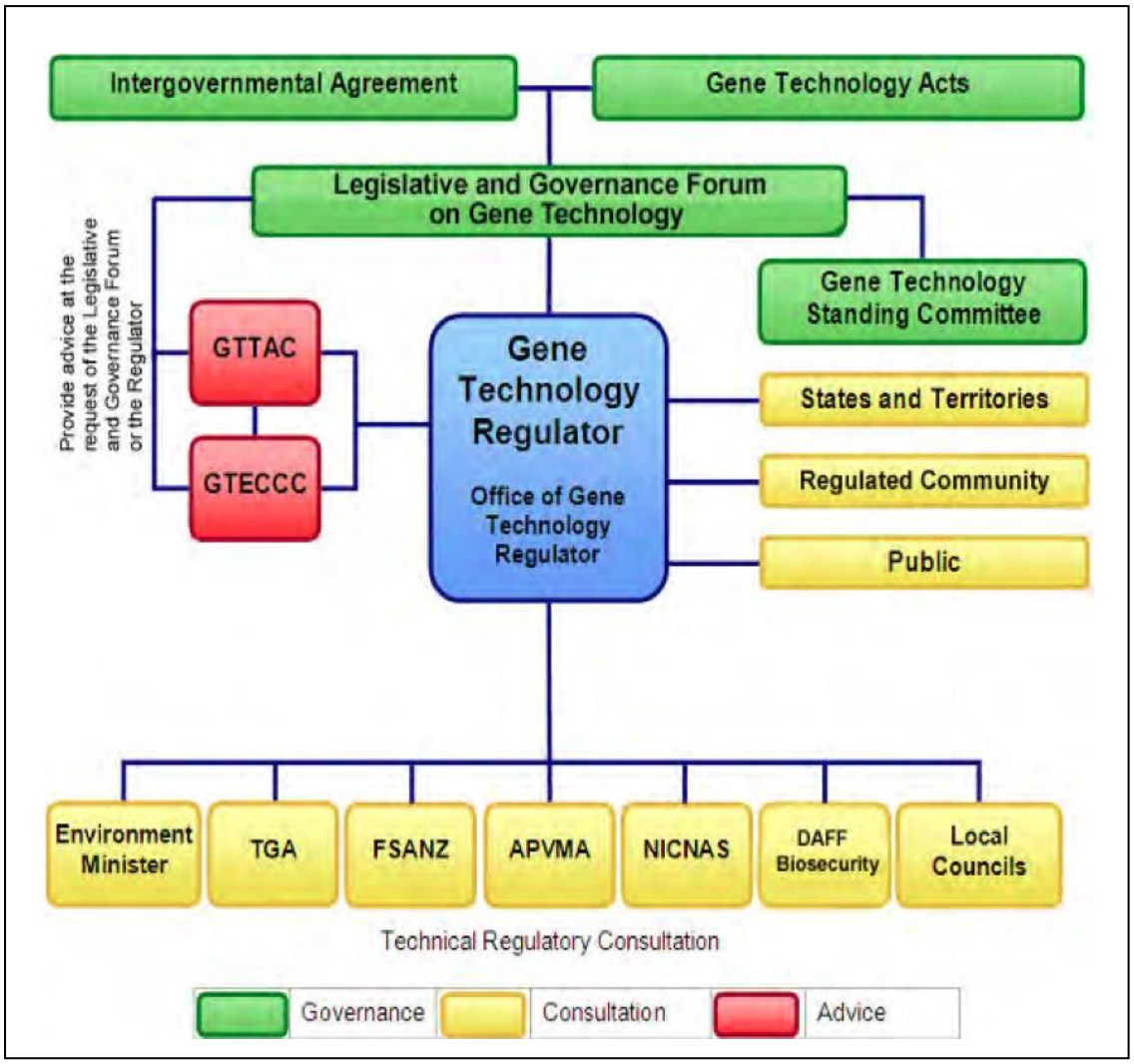
The Commonwealth Act establishes the role of the Gene Technology Regulator (the Regulator) who is responsible for assessing risks to human health and safety and risks to the environment from GMOs proposed for release in Australia. The Office of the Gene Technology Regulator (OGTR) supports the Regulator in his/her role.

The Regulator is the primary regulator for any dealings or processes involving a GMO, in assessing the risks of GMOs proposed for release in Australia, but must operate in conjunction with, and take into account the views of complementary Commonwealth and State regulatory schemes relevant to GMOs and GM products, including:

- Food Standards Australia and New Zealand (FSANZ)
- The Therapeutic Goods Administration (TGA)
- The National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
- The Australian Pesticides and Veterinary Medicines Authority (APVMA)
- Australian Quarantine and Inspection Service (AQIS) and the Australian Government Department of Agriculture, Fisheries and Forestry Biosecurity.

Box 1 provides a visual representation of the National Gene Technology Regulatory System in Australia.

Box 1. The National Gene Technology Regulatory System flow chart[5]



See **Appendix 4** for more detailed information about gene technology and the national gene technology regulatory scheme.

2.2 Gene technology in Queensland

The *Gene Technology Act 2001* (the Queensland Act)[6] commenced on 1 November 2001 and is part of the national scheme established by the States, Territories and Commonwealth legislation to protect the health and safety of people and to protect the environment from risks associated with gene technology.

[5] Taken from the website of the OGTR:
http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/about-index-1#flowchart
[6] https://www.legislation.qld.gov.au/LEGISLTN/CURRENT/G/GeneTechA01.pdf

As the State and Territory laws do not create any of their own administrative entities they can only have operational effect if they are able to confer functions, powers and duties relating to State / Territory matters on the Regulator and other Commonwealth authorities and officers.

Thus, the Queensland Act confers responsibility on the Regulator for assessing risks to human health and the environment from GMOs in Queensland. The Queensland gene technology legislation was developed to ensure full regulatory coverage given the constitutional limitations of Commonwealth powers, for example, in relation to GMO research and development conducted by State Government agencies and higher education organisations.

The 2006 Review of the Queensland Act[7] noted that the Queensland Act is generally consistent with the Commonwealth Act and while there are some differences in various sections of the Act, the important differences come under 5 main areas:

a) minor wording changes to reflect jurisdictional drafting preferences

b) giving authority for the Regulator to operate under State jurisdiction

c) creating the Office of the Gene Technology Regulator under the Commonwealth Act only

d) Penalties and strict liability in relation to penalties (reflects different jurisdictional approach to penalties)

e) Conditions of entry by an inspector (s152)

The Commonwealth Act provides for the LGFGT to issue a policy principle "recognising areas, if any, designated under a law of the State for the purpose of preserving the identity of one or both GM or non-GM crops for marketing purposes". It is this separate 'GM crops' legislation which provides the powers to the States and Territories and enabled the implementation of the various GM crops moratoria that were, or are current in most States and Territories.

Queensland, unlike most other jurisdictions, has not acted under this policy principle to introduce separate GM crops legislation. Rather than establish separate GM crops legislation, Queensland developed a co-existence framework for GM and non-GM crops[8]. The co-existence framework is described as a set of principles that are applied by Industry and Government to develop specific plans for segregating GM crops from non-GM crops.

[7] The *Gene Technology Act 2001* (Queensland). Statutory Review. October 2006

[8] Queensland Government (2005) "Developing strategies for GM and non-GM crops in Queensland. A framework for co-existence", Department of Primary Industries and Fisheries. October 2005

Finding 1
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.

In Queensland, gene technology is being applied across a number of areas, including human health and medicine, animal health, agriculture and food production and environmental management. An example is provided in Box 2.

Box 2. GM bananas: from nutrition to disease resistance

Professor James Dale and his team at the Queensland University of Technology (QUT) have come far since gaining support from the Bill and Melinda Gates Foundation (BMGF) in 2005. Initially focused on vitamin-rich genetically modified (GM) bananas for growers in Uganda, work has extended to India with disease resistance thrown into the mix, while Dale mentions the possibility of collaboration with Nigerian and Indonesian scientists in the future.

Nutrition for the developing world:

Dale's work received a boost in 2004 when the BMGF put out a call for expressions of interest around grand challenges in global health. "Most of those global challenges were new vaccines, antibiotics and the control of insect vectors of human diseases; there was one, grand challenge nine, which was to develop staple crops with a complete set of micronutrients.

"We'd already started to work with the National Agricultural Research Organization in Uganda so I suggested we make an expression of interest. "In Uganda their staple food is bananas, and in that whole region there's very high banana consumption, very high levels of Vitamin A deficiency, and very high levels of iron deficiency; anemia."

QUT received the funding to collaborate with their Ugandan counterparts, and Dale says "remarkable" progress has been made since then. "So we've now got bananas with more than double our target levels that we wanted for provitamin A." He says bananas already have pro-vitamin A through beta-carotene and alpha-carotene, but genetic modification has allowed the scientists to augment the level. "We were able to take the genes from one of them [beta-carotene] that makes very large amounts and put that banana gene into East African Highland Bananas and into Cavendish.

"The whole issue of vitamin deficiency is really complex – micronutrient deficiencies particularly. There is still this very poor population that don't buy food and don't access health clinics, and that can be anywhere between 30-50% of the population in developing countries.

The first field trial for Vitamin A was from 2009 to 2013 [*south of Innisfail in North Queensland*], with a plan of developing the technology in Australia and then transferring that technology but not the plants to Uganda. "Now that project is moving into the development phase where we can go and develop an elite line that we'll take all the way through to farmer release in Uganda, and that will be available to other countries in the region if they want it. He adds the next part of the Ugandan project is to increase iron levels, which is "much harder". "But we're getting there. We've got a 50% increase but we actually want a 400% increase. We've got our next field trial in Australia already happening."

On the back of the Ugandan collaboration's success, QUT was approached by the Indian government to work on a similar project with its Department of Biotechnology. "They wanted disease resistance as well, which we put in – they want resistance to bunchy top and Panama wilt."

Source: Fresh Fruit Portal – October 2013. www.freshfruitportal.com/2013/08/23/gm-bananas-from-nutrition-to-disease-resistance/?country=others.

See also: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/DIR109

Chapter 3 ANALYSIS OF THE 2011 REVIEW OF THE COMMONWEALTH ACT

This Chapter addresses the Queensland Review's Term of Reference 1 and investigates the outcomes and findings of the Review of the *Gene Technology Act 2000* (the Commonwealth Act) as they apply to Queensland.

TOR - 1
Using the submissions from the Commonwealth Review and its Report as a basis, investigate the outcomes/findings of the Commonwealth Review of the *Gene Technology Act 2000* (the Commonwealth Act) as they apply to Queensland.

3.1 Background to the 2011 Review of the Commonwealth Act - The Commonwealth Review

The second review of the Commonwealth Act commenced in May 2011 and was undertaken by the Allen Consulting Group.

The review 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.

Forty-eight public submissions were received from industry, researchers, non-government organisations and individuals. The Commonwealth Review Report was presented to the (then) Department of Health and Ageing in September 2011 and is available on the website of the Australian Government Department of Health[9].

The Commonwealth Review concluded that although the Commonwealth Act is working well, some aspects of implementation at a State and Territory level need attention. In particular, improved harmonisation of Australia's arrangements to regulate gene technology would lead to economic benefits and improved efficiency and effectiveness.

An Australian, State and Territory Governments' (all governments') response to the Commonwealth Review recommendations has been prepared and was considered by the LGFGT in April 2013 and is also available on the website of the Australian Government Department of Health.

Queensland has reserved its position on the response to the review of the Commonwealth Act, pending further consideration by the Queensland Government.

See **Appendix 5** for details of the Commonwealth Review and submissions of relevance to the Queensland Review.

[9] http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-techact-review

3.2 Summary of key outcomes and findings of the Commonwealth Review relevant to Queensland

There were a number of outcomes/findings of the Commonwealth Review of the *Gene Technology Act 2000* which apply to Queensland:

1. The Commonwealth Act is generally regarded as an effective and efficient mechanism for regulating GMOs in Australia, although there is scope for some improvement.
2. The OGTR is viewed as having gained experience in the implementation of the Commonwealth Act, concomitant with an improvement in the effectiveness and efficiency of its administration.
3. Some concerns were raised about new players in GM related business in other countries that have less stringent regulatory requirements than Australia which may exacerbate any risk of Australia importing products containing GM material that may not have been approved by the OGTR. In response, the Commonwealth Review noted that to be fully effective, the OGTR must work with other Commonwealth agencies such as FSANZ, AQIS, TGA and APVMA.
4. The Commonwealth Review commented on structural issues with the legislation and the impact of delays in some jurisdictions to the adoption of changes to the legislation that have been agreed by the (former) Ministerial Council and passed by the Commonwealth Parliament following earlier reviews. In relation to these structural issues, the Commonwealth Review made three recommendations:
    i. All jurisdictions reconfirm their commitment to a national regulatory scheme for gene technology;
    ii. Jurisdictions follow the example of NSW and the Northern Territory, automatically adopting changed gene technology regulation by reference to the Commonwealth legislation; and
    iii. Where the Commonwealth Act has not been adopted by reference, jurisdictions commit to amending legislation at the same time as Commonwealth legislation is amended.
5. The Commonwealth Review recommended that: “The OGTR continue to be active in OECD and other international fora to stay abreast of international developments in gene technology regulation.”
6. 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. On this basis, the Commonwealth Review recommended that: “The Ministerial Council review the definition of ‘dealings’ in the Act with a view to clarifying the scope of the regulatory scheme.”

7. It was noted that activities with GM products are not regulated directly under the Commonwealth Act, although the Regulator may condition a GM product that is derived from a GMO and there is no express legislative limit on the scope of conditions that can be placed on a GM product. The Commonwealth Review considered that the scope of the Regulator's powers should be clarified where a GM product may not be regulated by another agency and made a recommendation that "The Ministerial Council review the conditioning of GM products in the Act with a view to clarifying the scope of the regulatory scheme."

8. The Commonwealth Review recommended that the Department of Health and Ageing explore with the Attorney General's Department and the Ministerial Council (now LGFGT) ways in which the process for amending the gene technology legislation could be streamlined, noting that changes to Commonwealth Regulations can be slow and may take up to eighteen months to implement. It was noted that delays could limit the ability of the OGTR to move swiftly in relation to new technological developments or newly identified risks, which may result in uncertainty for researchers and users wanting to implement new technologies and a disincentive to investment in new technologies.

9. The Commonwealth Review noted that, following the 2006 Review the Commonwealth Act was amended to provide for temporary licences for inadvertent dealings for the purposes of GMO disposal. The Commonwealth Review recommended that the Commonwealth Act be again amended so that the Regulator can authorise other appropriate dealings related to inadvertent dealings.

10. The Commonwealth Review recommended that the OGTR continue to provide information to IBCs to assist them in understanding their responsibilities under the Act, and that IBCs should differentiate this aspect of their work from other activities for which they may also be responsible.

11. The Commonwealth Review suggested that some IBCs may need more members and subcommittees to spread the workload in response to the concerns expressed by research institutes and universities about the regulatory burden for IBCs and that IBC members must spend excessive time reading and assessing applications.

12. The Commonwealth Review recommended that Governments in Australia maintain a science-based precautionary approach to the regulation of gene technology.

13. The Commonwealth Review recommended that the OGTR increase its communications to the general public to raise its profile and build confidence in Australia's regulation of gene technology.

14. The Commonwealth Review recommended that for many DIR applications, advertising in local or state newspapers in the region where the DIR is to occur is sufficient. For issues/licences of national importance it should be sufficient for the OGTR to place advertisements in one national newspaper; and the OGTR could experiment with using social media to communicate with stakeholders in appropriate situations.

Finding 2
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.

As noted in point 4 above, the Commonwealth Review specifically commented on structural issues with the legislation and the impact of delays in some jurisdictions to the adoption of changes to the legislation that have been agreed by the (former) Ministerial Council and passed by the Commonwealth Parliament following earlier reviews.

The structural issues identified have arisen as a consequence of the nature of the interface between the Commonwealth and State / Territory legislation and relate to the limits of the constitutional reach of the Commonwealth gene technology legislation. See Box 3 below for further elaboration of this point.

Box 3. Notes on constitutional reach of the Commonwealth gene technology legislation

- Constitutional corporations are clearly covered under Commonwealth gene technology legislation, whereas sole traders are not.
- However, it can remain unclear if universities and state government agencies are covered under Commonwealth gene technology legislation even when the State/Territory Acts are declared corresponding.
- It is only when State/Territory legislation is declared corresponding and when wind-back is in place that it becomes clear that universities and state government agencies, along with sole traders, are all covered by the State/Territory Act.

It should be noted that while Queensland's gene technology legislation is declared corresponding and wind-back is in place (and Queensland has been historically judicious in making changes to its State legislation to keep up with changes to the Commonwealth legislation) it has not moved to amend its legislation in 'lock-step' with the Commonwealth Act amendments.

The following discussion provides further insights into the structural issues, which also arise as a consequence of each State and Territory having its own legislation regulating gene technology dealings and that in practice, there can be some variations between jurisdictions.

The 2011 Commonwealth Review pointed out that State and Territory actions following the 2006 Commonwealth Statutory Review highlighted the complexity of the national gene technology regulatory environment and provided the following example, valid at the time of the 2011 Commonwealth Review:

- Amendments were made to the Commonwealth legislation in 2007 following the 2006 Review.
- Two jurisdictions (NSW and the Northern Territory) amended their respective legislation in 'lock-step' with the 2007 Commonwealth Act amendments; and in these jurisdictions, Commonwealth gene technology regulations are adopted through an automatic procedure.
- Other jurisdictions agreed to amend their legislation to correspond with the 2007 Commonwealth legislation. Four jurisdictions (ACT, Queensland, South Australia and Victoria) had done this, whereas Tasmania and Western Australia had enacted legislation but had not yet had it declared 'corresponding'. As a result, the legislation in those two States did not, at that time, form part of the nationally consistent scheme administered by the Regulator.
- In practice, the vast majority of organisations conducting dealings with GMOs are captured by the Commonwealth legislation, however, in some jurisdictions it is possible for two researchers employed by different organisations and working together in the same laboratory to be subject to different gene technology regulations. For example, a CSIRO researcher is subject to Commonwealth legislation, while a colleague from a state government agency may be subject to different regulations as a result of different State or Territory requirements.
- This has the potential to create confusion. It could also lead to a situation where the same dealings with GMOs could require different approvals, which could make compliance determinations particularly difficult. Clearly these circumstances lead to a "situation of uncertainty".
- Unless jurisdictions amend their legislation (Acts and Regulations) contemporaneously, this "situation of uncertainty" can occur each time amendments are made to the Commonwealth legislation.

The majority of changes recommended to the Commonwealth Act by the 2011 Commonwealth Review are aimed at decreasing the regulatory burden for certain licences and assessments. It could therefore be argued that in Queensland any lag in amending the State legislation would disadvantage State Government and university researchers compared to researchers working in constitutional corporations in Queensland and research colleagues in other States where legislation is amended contemporaneously (in 'lock-step').

In addition, if new information comes to light regarding for example, the impact of a particular GMO on human health, then the Commonwealth may make changes to the risk status of that GMO. If the Queensland Act is not changed at the same time as the Commonwealth Act, it could result in a situation where researchers who come under the Queensland Act and are working with the GMO in question could be subject to unnecessary risk.

An in-depth discussion of the lock-step approach is provided in Chapter 5.

Chapter 4 GENE TECHNOLOGY ACT 2001 (QUEENSLAND)

This Chapter addresses the Queensland Review's Term of Reference 2 and investigates whether the object of the Queensland Act is being achieved and if there is a more effective and efficient way of achieving it.

4.1 Submissions made to the Queensland Review

There were five written submissions received - see list at **Appendix 6**.

A range of information and comments was provided to the Reviewers by way of personal interview and teleconference discussions.

A summary of issues raised in submissions is provided at **Appendix 7**.

The majority of submissions as well as individuals consulted generally indicated satisfaction with the way the gene technology legislation is being administered by the OGTR. Most parties strongly supported a finding of the 2011 Commonwealth Review which noted that, while the object of the Commonwealth Act is being met, improved harmonisation of Australia's arrangements to regulate gene technology would lead to improved efficiency and effectiveness.

Most submissions supported Recommendation 3 of the Commonwealth Review proposing that jurisdictions (for example Queensland) follow the example of New South Wales and the Northern Territory (and subsequently Tasmania), automatically adopting changed gene technology regulation by reference to the Commonwealth legislation in order to achieve further administrative and efficiency gains.

It was clear that most of those responding to the Review felt that Queensland should move to 'lock-step' with Commonwealth gene technology legislation in order to avoid periods of inconsistency and uncertainty.

Finding 3
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.

Finding 4
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.

4.2 Whether the object of the Queensland Act is being achieved

TOR - 2
Investigate whether the object of the Queensland Act is being achieved and if there is a more effective and efficient way of achieving it

A number of the findings of the 2011 Commonwealth Review can be regarded as applicable to the Queensland Review and indicative of whether the object[10] of the Queensland Act is being achieved.

Specifically, the relevant findings are:

i. The object of the Act is being achieved and although the Act is generally regarded as an effective and efficient mechanism for regulating GMOs in Australia, there is scope for some improvement.

ii. The OGTR is viewed as having gained experience in the implementation of the Act, concomitant with an improvement in the effectiveness and efficiency of its administration. Nevertheless, it was recommended that: "the OGTR continue to be active in OECD and other international fora to stay abreast of international developments in gene technology regulation."

iii. There are structural issues with the legislation and concern about the impact of delays in some jurisdictions to the adoption of changes to the legislation that have been agreed by the (former) Ministerial Council and passed by the Commonwealth Parliament following earlier reviews. In relation to these structural issues, the Commonwealth Review made three recommendations:
   a. All jurisdictions reconfirm their commitment to a national regulatory scheme for gene technology;
   b. Jurisdictions follow the example of New South Wales and the Northern Territory, automatically adopting changed gene technology regulation by reference to the Commonwealth legislation; and
   c. Where the Commonwealth Act has not been adopted by reference, jurisdictions commit to amending legislation at the same time as Commonwealth legislation is amended.

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

iv. 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. On this basis, the Commonwealth Review recommended that: "The Ministerial Council review the definition of 'dealings' in the Act with a view to clarifying the scope of the regulatory scheme."

Finding 5
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.

v. Activities with GM products are not regulated directly under the Act, although the Regulator may impose a condition on a GM product that is derived from a GMO and there is no express legislative limit on the scope of conditions that can be placed on a GM product. The Commonwealth Review considered that the scope of the Regulator's powers should be clarified where a GM product may not be regulated by another agency and made a recommendation that "The Ministerial Council review the conditioning of GM products in the Act with a view to clarifying the scope of the regulatory scheme."

vi. Changes to Commonwealth Regulations can be slow and may take up to eighteen months to implement. It was therefore recommended that the Department of Health and Ageing explore with the Attorney General's Department and the Ministerial Council (LGFGT) ways in which the process for amending the gene technology legislation could be streamlined. It was noted that delays could limit the ability of the OGTR to move swiftly in relation to new technological developments or newly identified risks, which may result in uncertainty for researchers and users wanting to implement new technologies and a disincentive to investment in new technologies.

vii. Although the Commonwealth Act was amended following the 2006 Commonwealth Review to provide for temporary licences for inadvertent dealings for the purposes of GMO disposal, it needs to again be amended so that the Regulator can authorise other appropriate dealings related to inadvertent dealings.

viii. Some IBCs may need more members and subcommittees to spread the workload in response to the concerns expressed by research institutes and universities about the regulatory burden for IBCs and that IBC members must spend excessive time reading and assessing applications.

ix. Governments in Australia are recommended to maintain a science-based precautionary approach to the regulation of gene technology.

x. Communications to the general public by the OGTR need to increase to raise its profile and build confidence in Australia's regulation of gene technology.

4.3 Summary comments

In summary, the submissions to this Queensland Review along with the interviews and personal discussions undertaken by the Reviewers generally support the view that the object of the Queensland Act is being achieved and although the Queensland Act is generally regarded as an effective and efficient mechanism for regulating GMOs in Queensland, there is scope for some improvement.

Finding 6
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.

The formal all governments' response to the 2011 Commonwealth Review has been finalised and is available on the website of the Australian Government Department of Health[11]. The Australian Government and most State and Territory Governments agreed to the all governments' response to the 16 recommendations made in the final report. However, Queensland has reserved its position on the response pending further consideration by the Queensland Government.

In Queensland, where the Commonwealth Act has not been adopted by reference, there will potentially be a period of inconsistency and uncertainty for State agencies and higher education institutions which are covered by the Queensland gene technology legislation, until such time as the Queensland legislation is amended to bring it back in line with the Commonwealth legislation.

Any lack of consistency and certainty is of particular concern to IBCs, which oversee compliance with the gene technology legislation and regulations within various research and development programs being undertaken by Queensland State agencies and higher education institutions.

It was also noted that there are many changes coming in relation to new and emerging technologies and that it will be important for Queensland to be able to move quickly – ideally in lock-step – in relation to changes to Commonwealth legislation that may be required to deal with these new technologies.

[11] http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-techact-review

There was widespread support by industry and institutions for Queensland to move to have its gene technology legislation in 'lock-step' with Commonwealth gene technology legislation in order to provide certainty and avoid periods of inconsistency. This issue is discussed in detail in Chapter 5.

Some submissions raised the matter of the fee for service / cost recovery proposal that is being tested by the OGTR and indicated that it is of great concern. The generally held view is that it will likely have a negative impact on investment in gene technology research and development.

Finding 7
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.

CHAPTER 5 CONSIDERATION OF ISSUES

This Chapter considers Term of Reference 3 - Consideration of 'lock-step' options; and Term of Reference 4 - Mechanisms to reduce regulatory burden.

As discussed previously in this report (see particularly Chapter 3), the Commonwealth Act is generally regarded as an effective and efficient mechanism for regulating GMOs in Australia and the OGTR is viewed as having gained experience in the implementation of the Commonwealth Act, concomitant with an improvement in the effectiveness and efficiency of its administration.

The 2011 Commonwealth Review, however, commented specifically on structural issues with State legislation and the impact of delays in some jurisdictions in reflecting changes to their legislation following changes to the Commonwealth legislation. In this regard, the Commonwealth Review made recommendations 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; and
- Where the Commonwealth Act has not been adopted by reference, jurisdictions commit to amending legislation at the same time as Commonwealth legislation is amended.

5.1 Consideration of 'lock-step' options

TOR - 3
Propose options on how implementation of the 'lock-step' approach could be achieved

The issue:

The vast majority of organisations conducting dealings with GMOs are covered by the Commonwealth's gene technology legislation (that is, the Act and Regulations) because they are constituted under Australian Government corporations law (for example: PPD Australia Pty Ltd, Sanofi-Aventis Australia Pty Ltd, Monsanto Australia Ltd, Pioneer Hi-Bred Australia Pty Ltd) or they are Federal bodies (for example, CSIRO).

There is sometimes uncertainty about the status of State agencies and higher education institutions – for example, a large and diverse institution like the Queensland University of Technology, which may or may not be categorised as a constitutional corporation depending on the circumstances.

Queensland State agencies, higher education institutions and sole traders which are not operating as bodies under corporations law are covered by the State's gene technology legislation.

See diagrams 1, 2 and 3 for a visual representation of the issue.

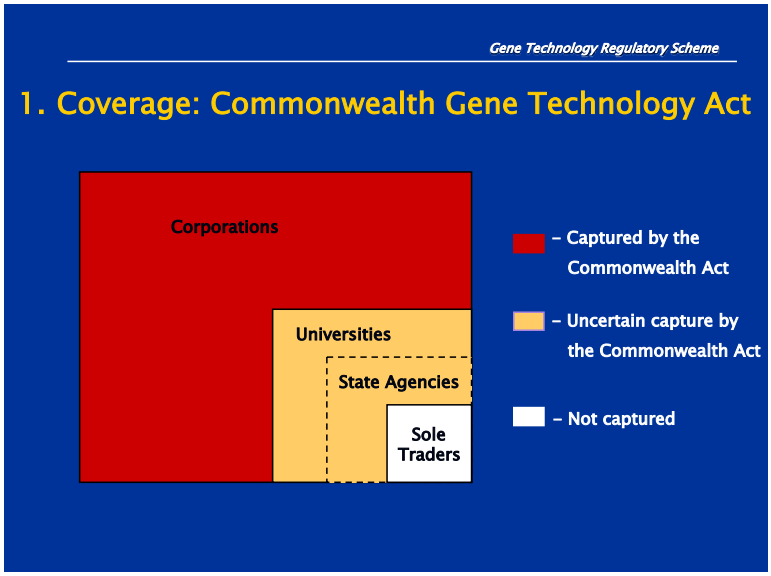


Diagram 1:

Organisations conducting dealings with GMOs which are constituted under Australian Government corporations law are covered by Commonwealth gene technology legislation.

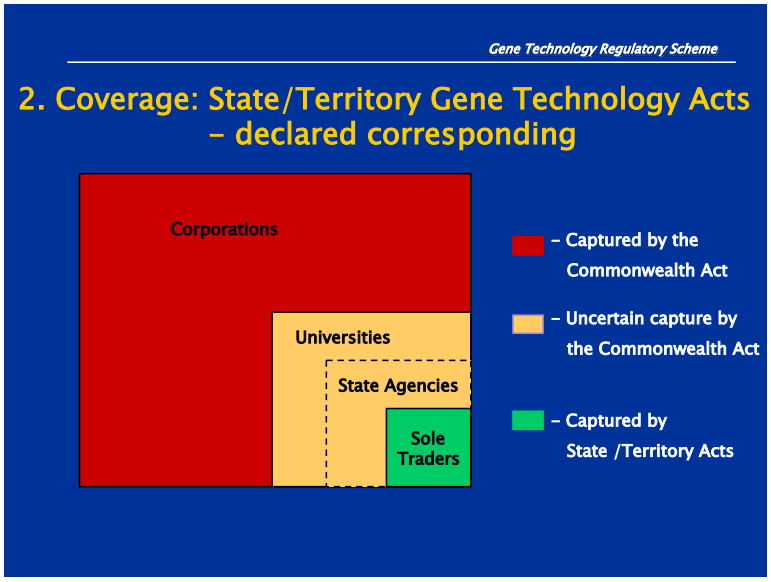


Diagram 2:

The status of State agencies and higher education institutions, which may or may not be categorised as a constitutional corporation depending on the circumstances, is sometimes uncertain.

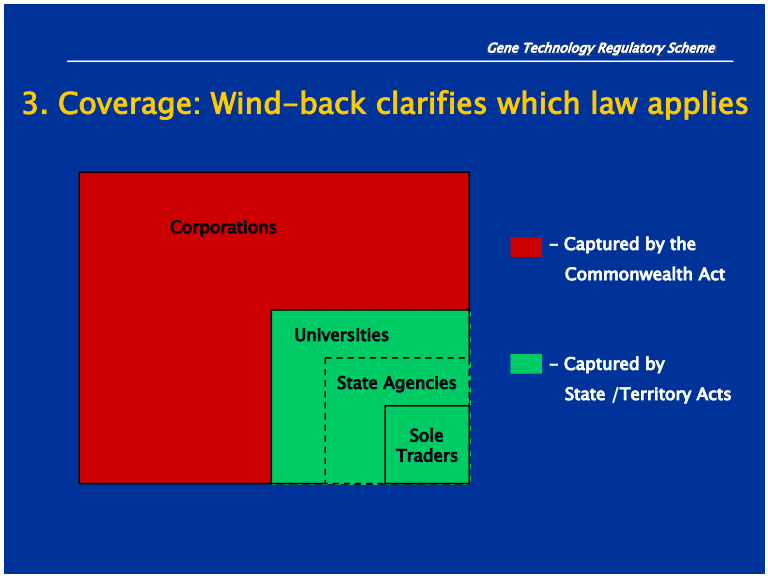


Diagram 3:

Where a wind-back notice has been issued, any uncertainties about jurisdiction with respect to dealings by State agencies and higher education institutions are resolved.

In nationally funded gene technology projects (for example, projects under Cooperative Research Centre (CRC) funding, Australian Research Council (ARC) grants and National Health and Medical Research Council (NHMRC) grants) it is increasingly common practice to have researchers employed by different organisations working together in the same laboratory. However in practice, each of these employees may have to adhere to two different legislative regimes.

Gene technology is advancing more and more rapidly and new and emerging developments are challenging existing legislation. It could be the case that further amendments to the Commonwealth gene technology legislation, such as refinements to definitions, will be required more frequently in the future than has been the case in the past.

Queensland's gene technology legislation has been declared as corresponding and wind-back is in place. However, when changes are made to the Commonwealth legislation, the Queensland legislation needs to be amended as soon as possible after the Commonwealth changes come into force to ensure it remains 'in-step' with the Commonwealth legislation.

At the present time, it may take at least 6 months to have legislative amendments placed before the Queensland Parliament which may result in a period of disadvantage and uncertainty for Queensland and Queensland researchers until the Queensland legislation catches up with the Commonwealth legislation. For example, Queensland researchers could be disadvantaged if the level of regulatory oversight of their work fails to reflect the very latest risk assessments conducted by the OGTR.

If Queensland was to take an 'application of laws' approach for its gene technology legislation (as has been done in New South Wales, Northern Territory and more recently, Tasmania[12]) it would mean that any changes to Commonwealth gene technology legislation would be automatically adopted by Queensland at precisely the same time as those changes come into force in the Commonwealth. That is, Queensland's gene technology legislation would be in 'lock-step' with the Commonwealth gene technology legislation.

The case for moving to lock-step:

(i) Benefits to Queensland researchers and state agencies working with GMOs

While noting that historically Queensland has always made gene technology legislative changes in a timely manner[13], lock-step would guarantee that in the future, there would be no delay between when changes are made to Commonwealth legislation and Queensland legislation (they would be amended at the same time). This would provide continual consistency between the regulatory conditions applied to organisations based in Queensland, irrespective of whether they are covered by the Commonwealth or Queensland legislation.

[12] *Gene Technology (Tasmania) Bill 2012* (Tasmania).
[13] *Gene Technology Amendment Act (2008*) (Queensland) and *Gene Technology Amendment Regulation (2007, 2008, 2011*) (Queensland).

This consistency guarantees certainty for Queensland state agencies and higher education institutions in ensuring they have in place measures to comply with regulatory requirements. It also provides the optimum regulatory environment for them to plan and invest in future research and innovation with confidence. Inconsistency and uncertainty can often translate into delays and additional costs.

Lock-step would also ensure that Queensland State agencies and higher education institutions never lag behind counterparts in other states in terms of the benefits that regulatory certainty and consistency brings.

Lock-step would ensure that Queensland state agencies and higher education institutions can always be confident that the level of regulatory oversight of their work reflects the very latest risk assessments conducted by the OGTR. This is because the periodic changes made to the Commonwealth Regulations often reflect a re-assessment of the risk of certain types of dealings with GMOs based on new information and experience.

Two examples from the 2011 Review of the Commonwealth Regulations exemplify the tightening of safety procedures in response to increased knowledge:

- Some dealings with retroviral vectors that were previously a notifiable low risk dealing (NLRD), but did not have the specified safety features, now require a licence; and
- Avipox vectors (which are able to transduce human cells) were removed from the low risk 'exempt' category and, depending on the modification, may now be either an NLRD or require a licence.

If there is a time delay with adopting changes such as the more stringent safety procedures illustrated by the above examples, people working in State agencies and higher education institutions who continue operating under earlier, unamended legislation may be put at unnecessary risk.

The converse may also apply, in that many of the changes recommended by the 2011 Commonwealth Review involve reducing regulatory requirements. When regulatory requirements are reduced in response to knowledge and experience gained over long periods of safe use of a GMO, research programs and organisations who continue operating under unamended, more stringent legislation will be disadvantaged and may be viewed as a less-appealing investment. This could apply across the board in the medical, agricultural and environmental biotechnology sectors in Queensland.

(ii) Benefits to Queensland (government, bureaucracy)

Having Queensland in lock-step with the Commonwealth avoids the need to prepare new Queensland legislation and have it considered by the Queensland Parliament every time there is a change to the Commonwealth legislation. This means there is less regulatory legislation being considered by the Queensland Parliament, something that is consistent with the Queensland Government's broader stated objectives around reducing red tape. It also frees up resources within the Queensland public service as they will not need to complete the usual drafting, briefing and issue management that accompanies any legislative change.

Put simply, it would avoid the need to duplicate Commonwealth instruments in Queensland, a significant efficiency gain.

The Regulator, Dr Joe Smith, made the point in his submission to this Queensland Review that "It is important to note that amendments to the Commonwealth GT Act and Regulations cannot proceed without the scrutiny and ultimate agreement of the COAG Legislative and Governance Forum on Gene Technology (formerly known as the Gene Technology Ministerial Council), which has ministerial representation from the Commonwealth and all the States and Territories. Reviews of the Commonwealth GT Act and Regulations are also very open and consultative, with all stakeholders, including the States and Territories, being actively engaged in the process. Any proposed changes are also subject to the normal mandated requirements for analysis of regulatory impacts on business."

Any proposed change to the Commonwealth legislation must be approved by the LGFGT by special majority (that is by at least two-thirds of the Parties to the intergovernmental GTA) as elaborated below in Clause 40 of the intergovernmental GTA (see Box 4).

Before the LGFGT discusses and approves the proposed change, it is also placed before the GTSC for discussion and debate. Thus there is considerable opportunity for a jurisdiction to raise issues and seek to resolve any matters of concern.

Box 4. Clause 40 of the intergovernmental GTA:

Any Party that proposes to amend its legislation forming part of the Scheme will submit the proposed amendments to the Council for consideration before introduction of the amendments. The amendments will be submitted at least one month before introduction (unless a different minimum notice period is determined by the Council). Each Party agrees that it will not introduce such an amendment unless the Council has by **special majority** resolved to approve the proposed amendment. For the avoidance of doubt, this Clause does not apply to:
a) the making, amending, suspending, revoking or extension of an emergency dealing determination;
b) the making, amending or revoking of an emergency GMO regulation; or
c) a regulation or determination made by a State or Territory to mirror an emergency dealing determination or emergency GMO regulation made under the Commonwealth Act.
Clause 5 Definitions:
'**special majority**' means at least two-thirds of the Parties.

The gene technology legislation under consideration in this Review covers human health and safety and environmental safety matters. Queensland would still retain the right to act independently on market or trade related gene technology issues under the agreed State - Commonwealth Policy Principle which allows for the designation of areas planted to GM or non-GM crops to be declared by Queensland.

The case against moving to lock-step:

The current status of the Queensland legislation (that is, declared corresponding with wind-back in place) has worked well. Despite the identified limitations, it may be satisfactory for Queensland to retain the *status quo*, but at the same time considering to opt to amend its gene technology legislation contemporaneously with changes to the Commonwealth gene technology legislation.

Moving to lock-step could be perceived as a loss of autonomy by the State of Queensland and therefore contrary to the Queensland Government principles for Commonwealth - State / Territory intergovernmental activities. The principles are underpinned by a desire to improve the well-being of Queenslanders and preserve Queensland's constitutional prerogatives of parliamentary, policy and fiscal sovereignty within the context of the Australian Federation and the Constitution of Australia.

Moving to lock-step could be seen as an opportunity by some of saving oversight resources within DSITIA. At present, there is a relatively low level of departmental resources currently committed but this needs to be retained even if lock-step is adopted to ensure the Queensland biotechnology industry is adequately oversighted and that the continuing development of the Queensland biotechnology industry is effectively supported in its development and contribution to the Queensland economy amidst a necessary framework of government regulation.

New South Wales, Northern Territory and Tasmania have each declared their gene technology legislation to be in lock-step with the Commonwealth gene technology legislation. Other jurisdictions have not yet moved to lock-step and the specific rationale for this is not known. However, one reason may be a general reticence to engage in any 'GMO / gene technology analyses' in view of their previous or current GM crops moratoria issues.

Tasmania's move to lock-step

In 2012, Tasmania reconsidered the operation of its gene technology legislation and ultimately repealed its earlier legislation and in its place passed the *Gene Technology (Tasmania) Act 2012*. The new Tasmanian Act allows for any changes to the Commonwealth Act to be automatically adopted into the Tasmanian Act.

The Fact Sheet[14] published in association with the tabling of the Bill[15] in the Tasmanian Parliament includes the following comment:" The Bill replaces the Tasmanian *Gene Technology Act 2001* and *Gene Technology Regulations 2003,* and like that previous legislation, allows the Commonwealth Gene Technology Regulator to regulate dealings with GMOs in Tasmania that are likely to be outside his or her constitutional reach. Dealings with GMOs in universities are an example.

To quote the third paragraph of the Bill presented to the Tasmanian Parliament prior to the passing of the new Act: "To achieve this object, the Bill takes an 'application of laws'

[14] Gene Technology (Tasmania) Bill 2012 Fact Sheet
[15] Gene Technology (Tasmania) Bill 2012

approach to adopt the Commonwealth *Gene Technology Act 2000*, *Gene Technology (Licence Charges) Act 2000,* and any subordinate legislation, as Tasmanian laws. This approach means that the Tasmanian legislation will always be up to date, in line with Government's commitment under the IGA. It also gives regulatory certainty to Tasmanian researchers who wish to conduct experimental dealings with GMOs in secure laboratories. Avoiding the need to amend our legislation every time the Commonwealth amends its legislation also represents a practical saving in Government time and resources."

In addition to the above, Section 7 of the Tasmanian Act enables Tasmania to make regulations which vary from that of the Commonwealth should the Commonwealth enact something the Tasmanian Government does not agree to.

Finding 8
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.

There is also a provision in the Tasmanian Act which requires that any amendments to the Commonwealth Act and Regulations be "tabled in each House of Parliament within 10 sitting-days from the date on which the amendment commences."

After the Tasmanian Act became law, Tasmania also sought a correspondence declaration from the Commonwealth as well as issuing a wind-back notice pursuant to section 14 of the Commonwealth Act to ensure their new Act operated in law and fact (extending to those state bodies remote to the Commonwealth by virtue of the Constitution).

Western Australia's gene technology legislation

Western Australia is currently different from most other jurisdictions as its legislation has not been declared corresponding and amendments have not been made to reflect the 2007 amendments to the Commonwealth Act. However, in the 2012 Review[16] of the *WA Gene Technology Act 2006*, the Reviewer, Mr Greg Calcutt, AM, SC, noted the lock-step approach taken in Tasmania and included the following quote in the report: *Perhaps this change to an "application of laws" approach in Tasmania makes it an opportune and appropriate time for Western Australia to enact legislation along similar lines.*

<u>Options in relation to a 'lock-step' approach in Queensland</u>:

(A) Maintain *status quo* by keeping Queensland's gene technology legislation declared as corresponding with wind-back in place (but noting that it may take at least six months to have legislative amendments placed before the Queensland Parliament following changes to the Commonwealth legislation);

[16] Western Australia *Gene Technology Act 2006.* Report of the Review of the Act under Section 194 - June 2012

(B) Follow 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);

(C) Follow in a similar way to the example set by Tasmania, automatically adopting changed gene technology regulation by reference to the Commonwealth legislation (that is, in lock-step with the Commonwealth gene technology legislation), but with an added provision which requires that any amendments to the Commonwealth Act and Regulations be tabled in the Queensland Parliament within a specified period (for example, 10 sitting-days) from the date on which the Commonwealth amendment commences;

(D) Investigate an approach similar to option (C) above, subject to Queensland's Parliamentary Counsel's advice which allows the Queensland Government and/or Parliament to decline or 'opt-out' of lock-step within, for example, a 30-day deadline if Queensland does not agree with the change to the Commonwealth legislation; or

(E) Investigate in consultation with Queensland's Parliamentary Counsel an option that allows the Queensland Government and/or Parliament to contemporaneously 'opt-in' to a lock-step approach if Queensland agrees to a change in the Commonwealth legislation.

5.2 Mechanisms to reduce regulatory burden

TOR - 4
Investigate mechanisms to reduce the regulatory burden given the Queensland Government's commitment to red tape reduction.

Recent experience has shown that, as the OGTR continues to gain experience in the implementation of the Commonwealth Act and more information is accumulated about the risks associated with dealings with specific GMOs, some existing regulations may be able to be relaxed with an associated reduction in the regulatory burden to IBCs and researchers. For example, based on new information, a particular GMO dealing may be determined to require a lower level of regulatory oversight. This might result in it being reclassified for example, from a 'Dealing Not involving Intentional Release' (DNIR) to a NLRD.

As outlined in the previous section under the case for moving to lock-step, being in lock-step with the Commonwealth would avoid the need to prepare new Queensland legislation and have it considered by the Queensland Parliament every time there is a change to the Commonwealth legislation. Adopting options (B), (C), (D) or (E) outlined above would, to varying extents, result in a reduction of the regulatory burden for Queensland.

This would mean there is less regulatory legislation being considered by the Queensland Parliament, consistent with the Queensland Government's objectives, around reducing red

tape. It also eases the administrative burden and frees up resources within the Queensland public service, which will not be required to complete the usual drafting, briefing and issue management that accompanies any legislative change.

Finding 9
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.

Other less direct reductions in the regulatory burden can be expected to continue as changes are made to the Commonwealth Act, and as outlined in Chapter 3, the majority of changes recommended by the 2011 Commonwealth Review are aimed at decreasing the regulatory burden for certain licences and assessments.

CHAPTER 6 FINDINGS OF THE QUEENSLAND REVIEW

6.1 Findings

Finding 1
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.

Finding 2
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.

Finding 3
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.

Finding 4
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.

Finding 5
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.

Finding 6
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.

Finding 7

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.

Finding 8
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.

Finding 9
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.

6.2 Recommendations

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

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).

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.

Recommendation 4
That, in view of the challenges to existing legislation by new and emerging developments in gene technology, Queensland supports moves by the LGFGT 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."

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 OGTR, while acknowledging the broader role of the Commonwealth to more effectively communicate a similar message to the Australian public.

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.

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 OGTR will have a negative impact on investment in gene technology research and development in Queensland.

APPENDICES

Appendix 1 THE REVIEWERS

This review of the Queensland Act has been undertaken by:
Mr Michael Taylor AO and Dr Graham Mitchell AO of Foursight Associates; and
Dr Robert Sward of BioBotanicals Consulting.

Michael John Taylor AO BAgSci DipAgEcon FTSE

Mike Taylor is currently a Principal of Foursight Associates, the part time Chair of the Geoffrey Gardiner Dairy Foundation, and Director of the Public Transport Development Authority, Country Fire Authority, Bush Fire Cooperative Research Centre, Crawford Fund for International Agricultural Research and until recently Melbourne University - Melbourne Business School.

Mr Taylor was formerly the Secretary to Australia's Department of Infrastructure, Transport and Regional Services - Australia (2004-09), and Secretary, Department of Agriculture, Fisheries & Forestry - Australia (2000-04). Prior to that, he was responsible for the leadership and management of three Departments for the Government of Victoria (1992-2000) (Agriculture, Energy and Minerals, and Natural Resources and Environment), and was Chairman of Murray Darling Basin Authority (2009-11).

Throughout his career he has been extensively involved in developing and negotiating International, Commonwealth, State and industry agreements and legislation, and in advising the Governments and Commonwealth / State Ministerial Councils on a wide range of policy and management issues.

Mr Taylor's experience in management, marketing, economic policy and planning has resulted in appointments to numerous boards of external organisations. He has also participated in and chaired a wide range of international negotiations, meetings, delegations, projects, policy and trade development work in Asia, North America and Europe. He also speaks at a wide range of industry and management conferences and forums.

Dr Graham Frank Mitchell AO RDA BVSc FACVSc PhD FTSE FAA

Graham Mitchell is a veterinary graduate and University gold medallist of the University of Sydney. At The Walter and Eliza Hall Institute of Medical Research (WEHI) he made discoveries in immunology and obtained a PhD in 1969.

After post-doctoral experience in California (Stanford), England (National Institute for Medical Research, Mill Hill) and Switzerland (Basel Institute for Immunology) he returned to Australia in 1973 and established a new program on the immunology of parasitism at WEHI.

This program became a major component of the global effort to develop new tools for the control of parasitic diseases, and of the 'biotechnology revolution'. Mitchell was instrumental in establishing a long term program on the disease schistosomiasis in the Philippines.

In 1990 Dr Mitchell was appointed Director of the prestigious Royal Melbourne Zoological Gardens where he introduced a number of new initiatives in local and regional conservation.

In 1993 he returned to biomedical research as Director of Research in the R&D Division of CSL Limited, Australia's largest developer, manufacturer and marketer of ethical human biologicals and veterinary products. He was responsible for identifying and assessing new opportunities for CSL, nurturing external research collaborations, and the research component of new product development including vaccines.

Dr Mitchell is recognised as one of Australia's leading biological scientists. His expertise extends over a wide range of science and technology. He has detailed knowledge of the academia-industry interface, has worked in many overseas countries and been involved with tropical disease programs of the World Health Organisation for many years. He is an author of more than 350 publications and has received numerous awards for scientific achievements.

Dr Mitchell has been an advisor on innovation to the Victorian, Commonwealth, Tasmanian and Northern Territory Governments. In another government role the Principals of Foursight, including Mitchell, jointly act as Chief Scientist for the Victorian Department of Environment and Primary Industries (DEPI).

Dr Robert Jeffery Sward, BSc (Hons), PhD.

Robert Sward is a plant pathologist / plant virologist with an extensive R&D background and a publication record which includes more than 200 papers in refereed journals, conference and workshop proceedings, articles in industry newsletters and trade journals, as well as 18 training course manuals and a book chapter.

Dr Sward led the development and implementation of a nationally acclaimed education and training program called Research to Practice®. This award-winning program helped various agricultural sectors to utilise the latest advances in science and to adopt industry best practice for management of pests and diseases, water use, plant nutrition and produce quality.

Over the last decade, Dr Sward gained substantial experience in biotechnology/gene technology policy and was Manager Biotechnology Policy in the Victorian Department of Primary Industries (DPI) from 2003 until late 2012. In this capacity, he participated in the first Victorian Review of GM canola in 2003 and after the Victorian Government declared a four-year moratorium, he led the development and implementation of the *Control of GM Crops Act (2004)*.

Dr Sward chaired the Primary Industries Standing Committee's - Industry Development Committee - GM Taskforce from 2005-2008 and in this role he worked closely with a wide range of stakeholders to ensure that: market and trade concerns were being adequately addressed by both industry and governments throughout Australia.

In 2007, Dr Sward worked closely with Sir Gus Nossal in his role as Independent Chair of the Victorian GM Canola Moratorium Review Panel.

Dr Sward is currently Principal, BioBotanicals Consulting Pty Ltd.

Appendix 2 TERMS AND ABBREVIATIONS

APVMA	Australian Pesticides and Veterinary Medicines Authority
AQIS	Australian Quarantine and Inspection Service
DIR	Dealing involving Intentional Release
DNA	Deoxyribonucleic acid
DNIR	Dealing Not involving Intentional Release
FDA	Food and Drug Administration (USA)
FSANZ	Food Standards Australia New Zealand
GM	Genetically Modified
GMAC	Genetic Manipulation Advisory Committee
GMO(s)	Genetically Modified Organism(s)
GTA	Intergovernmental *Gene Technology Agreement 2001*
GTECCC	Gene Technology Ethics and Community Consultative Committee
GTMC	(former) Gene Technology Ministerial Council
GTTAC	Gene Technology Technical Advisory Committee
IBC	Institutional Biosafety Committee
LGFGT	Legislative and Governance Forum on Gene Technology
NHMRC	National Health and Medical Research Council
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NLRD	Notifiable Low Risk Dealing
OGTR	Office of the Gene Technology Regulator
QIMR	Queensland Institute of Medical Research
RARMP	Risk Assessment and Risk Management Plan
States	The States and Territories of Australia
TGA	Therapeutic Goods Administration
The Regulator	The Gene Technology Regulator

Appendix 3 PUBLIC CONSULTATION - GENE TECHNOLOGY ACT 2001 (QLD)

Review of the *Gene Technology Act 2001* (Qld)

Call for Submissions

The Queensland Government is conducting an independent review of the *Gene Technology Act 2001* (Qld) (the Queensland Act) and invites interested parties and individuals to provide submissions that address the review's terms of reference (see below).

The Queensland Act is part of the nationally consistent legislative scheme for regulating gene technology. The scheme aims to protect the health and safety of people and the environment by identifying risks posed by or resulting from gene technology. The risks are managed through the regulation of dealings with genetically modified organisms. 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.

A statutory review of the Queensland Act is required whenever a review of the *Gene Technology Act 2000* (Cth) (the Commonwealth Act) is undertaken. The Queensland Act was first reviewed in 2006 following the first review of the Commonwealth Act. The Commonwealth Act was reviewed for the second time in 2011.

The purpose of the second review of the Queensland Act is to investigate whether the Queensland Act is operating as an efficient and effective component of the nationally consistent gene technology regulatory scheme.

Terms of Reference for the review of the Queensland Act

Using the submissions from the Commonwealth Review and its 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.

The full Background and Terms of Reference can be viewed on the following internet site:

https://www.getinvolved.qld.gov.au/gi/consultation/1451/view.html

Appendix 4 GENE TECHNOLOGY AND THE NATIONAL GENE TECHNOLOGY REGULATORY SCHEME

Gene technology

Gene technology, in its broader sense, is the term given to a range of activities concerned with understanding how genes function and interact. Gene technology is one component of modern biotechnology - which involves the use of living things and biological processes to make or change products. More specifically, gene technology may involve identifying, isolating or modifying the genes or other genetic material of microorganisms, plants and animals.

Genetic material may be modified by the direct incorporation, deletion or alteration of one or more genes or genetic sequences and transferred to different host organisms to change existing traits or introduce new traits. The modified organisms, which result, are known as genetically modified organisms or GMOs.

Gene technology developed and advanced around the world from the early 1950s following the discovery of the double helix structure of the deoxyribonucleic acid (DNA) molecule, the key component of genetic material. As the rate of advance accelerated in the 1970s and there was an increasing awareness of the potential for the technology to be used to manipulate or modify the genetic material of an organism, scientists and governments worldwide recognised the need to closely monitor and supervise the technology to ensure it was used safely.

In Australia from the 1970s to late 1980s, voluntary committees were set up, initially by the Australian Academy of Science and followed by the federal Department of Science. These committees assessed proposals and monitored projects involving genetic modification.

The voluntary committee structure was replaced in 1987 by the Genetic Manipulation Advisory Committee (GMAC), which was set up as a non-statutory committee to report to the federal Minister for Industry Technology and Commerce. Key functions of GMAC were to examine and report on the risks to human health and the environment arising from the use of gene technology and to advise users on the management of identified risks. It was a condition of federal funding that gene technology research and development projects comply with GMAC recommendations.

Concurrent with significant scientific advances and commercial applications of gene technology in the 1990s, came a wave of public concerns about GMOs. In the late 1990s this led to a cooperative process by the Australian Government and State and Territory Governments to develop a uniform approach to the regulation of gene technology in Australia.

In exploring the development of a uniform approach to gene technology regulation in Australia, governments sought to balance potential benefits to society against community concerns over possible risks related to the deployment of the technology.

A comprehensive and extensive public consultation process accompanied the release of draft legislation in December 1999 and in June 2001 the *Gene Technology Act 2000* and the *Gene Technology Regulations 2001* came into effect.

Today the range of applications of gene technology across research and development activities and in industries is large and diverse.

Gene technology is applied in areas related to human health and medicine, animal health, agriculture, food production and processing, environmental management, as well as many others. (See following Boxes A and B).

Box A Gene technology and human health

Gene technology has enabled the development of more effective therapies for diseases such as diabetes.

Insulin from GM bacterial cells

(Source: Department of Industry, Innovation, Science, Research and Tertiary Education Website Archive).

Diabetes is a common and sometimes fatal disease in which the supply of insulin is insufficient for the body to break down sugar properly. The majority of insulin used by people to manage diabetes http://archive.innovation.gov.au/Biotechnologyonline/topitems/glossary.html - diabetes is produced using biotechnology. Bacterial cells are genetically modified to produce large quantities of human insulin, which is then purified for therapeutic use. Millions of people worldwide now use Humuline, which is a major brand name for 'human' insulin produced from genetically modified bacteria.

For many years, individuals with diabetes were treated with insulin derived from the pancreases of abattoir animals (usually pigs and cows). Although animal insulin is similar to the human form, there are differences, which mean some individuals cannot tolerate it and there are issues regarding the sustainable use of animals for this purpose.

Celebrating a Milestone: FDA's Approval of First Genetically-Engineered Product *(Source: Sept-Oct 2007 issue of Update magazine, the bimonthly publication of the Food and Drug Law Institute, USA.)*

2007 marked the twenty-fifth anniversary of FDA's approval of the world's first recombinant DNA drug product—human insulin (Eli Lilly & Co.'s Humulin).

In 1921, Frederick Banting and Charles Best extracted the hormone insulin, which controls blood sugar levels, from the pancreas' of dogs, and in 1922 administered the extract to a 14-year-old boy suffering from type I diabetes mellitus, saving his life and proving insulin's efficacy in treating human diabetes. Following their discovery, virtually all insulin for human use was harvested from slaughterhouse animals, usually porcine or bovine.

In the 25 years since FDA's approval of Humulin, however, r-DNA human insulin has proven indistinguishable from pancreatic human insulin, has been proven both safe and efficacious for millions of patients, and, as a result, has almost completely displaced animal source insulins.

Box B Gene technology and Australian agriculture

Gene technology has enabled the development of advanced cotton varieties.

Genetically modified cotton in Australia

(Source: Cotton Australia[17])

Biotechnology refers to the use of cotton varieties with transgenic or genetically modified (GM) traits. The use of biotechnology in cotton has made a significant contribution in the dramatic reduction in insecticides applied to Australian cotton crops. In the past decade, Australian cotton growers have reduced their insecticide use by about 80%, with some crops not sprayed for insects at all.

Almost 100% of Australia's cotton crop is grown with transgenic varieties. There are financial rewards for cotton farmers using biotechnology. "Since 2010 the total farm income gain derived by Australian cotton farmers from using this technology has been $395 million, an average of about $180 per hectare". (source: National Press Club Address 2012, Graham Brookes, Director of PG Economics UK).

Cotton incorporating transgenic traits has a sound track record of safe and successful use in Australia, with no adverse incident recorded in over 15 years of growing these varieties. Australia was one of the first cotton producing nations to grow transgenic varieties, starting in 1996 with the Ingard variety (which is resistant to cotton bollworm). The Bollgard II® variety (with improved bollworm resistance) was released in Australia in 2004.

Bollgard II® contains two genes from the naturally occurring soil bacterium Bacillus thuringiensis (Bt) and gives the plant an in-built tolerance to the Helicoverpa caterpillar. When the caterpillar ingests a small part of the cotton plant, the Bt protein disrupts the caterpillar's digestive system and it dies. Bt is a naturally occurring soil organism that produces insecticidal proteins and Bt sprays have been safely used for over 50 years in agriculture.

The cotton industry also uses two other types of transgenic cotton: Roundup Ready Flex® (with genes from the soil bacterium called Agrobacterium tumefaciens) and Liberty Link® (with genes from the soil microorganism Streptomyces hygroscopicus).

Herbicide tolerant cotton (Roundup Ready Flex® and Liberty Link®) can reduce the amount of soil cultivation and herbicide required on cotton crops to control weeds and facilitates healthier soils through less soil disruption and reductions in residual herbicides.

In Australia, each genetic trait is individually assessed on a case by case basis by the Office of Gene Technology Regulator (OGTR), Food Standards Australia New Zealand (FSANZ) and the Australian Pesticides and Veterinary Medicines Authority (APVMA).

Over the last decade new cotton varieties released have contained new features such as improved fibre quality, disease resistance, maturity and regional adaptability – research is being undertaken to develop varieties that require less water and/or are drought tolerant.

The use of transgenic cotton is a key component of grower's Integrated Pest Management (IPM) strategies that use a combination of natural controls and pest specific chemistry to further reduce pesticide use.

Cottonseed oil doesn't require GM food labelling. This is because when cottonseed is crushed to make oil, the oil is separated from the Bt and other transgenic proteins. Cottonseed oil from a transgenic cotton plant variety contains no genetically modified material.

[17] http://cottonaustralia.com.au/cotton-library/fact-sheets/cotton-fact-file-biotechnology

The national gene technology regulatory scheme

The national gene technology regulatory scheme 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), formerly the Gene Technology Ministerial Council (GTMC).

The legislative component of the national regulatory scheme includes a framework to assess the risks to human health and the environment associated with the various dealings of GMOs.

The intergovernmental GTA reflects agreement between the Commonwealth and States and Territories that there is a need for a cooperative national 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 national regulatory scheme for gene technology and provides policy guidance for the operation of the *Gene Technology Act 2000* (the Commonwealth Act) and the *Gene Technology Regulations 2001* (the Commonwealth Regulations), which together provide the foundation for the regulation of gene technology in Australia.

The Commonwealth Act establishes the role of the Gene Technology Regulator (the Regulator) who is responsible for assessing risks to human health and safety and risks to the environment from GMOs proposed for release in Australia. The Department of Health and Ageing has established the Office of the Gene Technology Regulator (OGTR) which supports the Regulator in his/her role.

The OGTR has developed a Risk Analysis Framework[18] which outlines the approach used to conduct risk assessments. In its risk assessment, the OGTR expresses consequences in terms of potential harm to human health and safety and the environment - see Box C.

[18] Risk Analysis Framework (2013). Office of the Gene Technology Regulator, Department of Health and Ageing, Australian Government

Box C **Potential harm to human health and safety and the environment defined by the OGTR in assessing risks associated with GMOs proposed for release in Australia**

** Harm to health and safety of people includes:
- toxicity or allergenicity
- disease
- illness or injury

** Harm to the environment includes:
- toxicity to desirable (valued) organisms that should be protected
- loss of biodiversity, including loss of species diversity or genetic diversity within a species
- adverse impacts of a new or more serious weed, pest or pathogen
- disruption of biotic communities
- degradation of the abiotic environment

** Harm reflects an undesirable condition involving damage or injury. This includes change in the morphology, physiology, growth, development, reproduction or life span of an organism or group of organisms that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences.

The Commonwealth Act establishes two advisory committees to provide advice to the Regulator and the LGFGT:

- The Gene Technology Technical Advisory Committee (GTTAC) - provides expert scientific and technical advice; and
- The Gene Technology Ethics and Community Consultative Committee (GTECCC) - provides advice on ethical issues and on matters of general concern to the community in relation to GMOs.

Interactions required by the Act:

- The LGFGT, which is established by the intergovernmental GTA, comprises Ministers from the Commonwealth and each State and Territory. The LGFGT provides broad oversight of the regulatory framework and guidance on matters of policy that underpin the legislation. High-level support is provided to the LGFGT by the Gene Technology Standing Committee (GTSC), which comprises senior officials from all jurisdictions.
- The Regulator is required to consider policy principles and guidelines issued by the LGFGT when making a decision on whether or not to issue a licence. It is one of the functions of the Regulator to provide advice to the LGFGT.
- The Regulator must prepare a Risk Assessment and Risk Management Plan (RARMP) as part of the assessment of each licence application to deal with GMOs.
- GTTAC provides advice to the Regulator on RARMPs. GTTAC also provides advice on request from the LGFGT. Under the Act, GTTAC must include a person who is a member of GTECCC.

- GTECCC provides advice on request to the Regulator and the LGFGT on ethical issues and on matters of general concern to the community in relation to GMOs. GTECCC must also include a person who is a member of GTTAC and a person who is a member of the Australian Health Ethics Committee.

The objective of the Commonwealth Act

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[19], and by managing those risks through regulating certain dealings with GMOs[20]."

The Regulator is the primary regulator for any dealings or processes involving a GMO, in assessing the risks of GMOs proposed for release in Australia, but must operate in conjunction with, and take into account the views of complementary Commonwealth and State regulatory schemes relevant to GMOs and GM products.

Box D describes the responsibilities of the complementary Commonwealth and State regulatory agencies relevant to GMOs and GM products.

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[19] The Commonwealth Act defines gene technology as:

"any technique for the modification of genes or other genetic material";

but does not include:

(a) sexual reproduction; or
(b) homologous recombination; or
(c) any other technique specified in the regulations.

Gene Technology Act 2000, Section 10

[20] The Commonwealth Act defines *genetically modified organism (GMO)* to mean:

(a) an organism that has been modified by gene technology; or
(b) an organism that has inherited particular traits from an organism (the *initial organism*), being traits that occurred in the initial organism because of gene technology; or
(c) anything declared by the regulations to be a genetically modified organism, or that belongs to a class of things declared by the regulations to be genetically modified organisms.

but does not include:

(d) a human being, if the human being is covered by paragraph (a) only because the human being has undergone somatic cell gene therapy; or
(e) an organism declared by the regulations not to be a genetically modified organism, or that belongs to a class of organisms declared by the regulations not to be genetically modified organisms."

Gene Technology Act 2000, Section 10

Box D Complementary regulatory agencies

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

• *Food Standards Australia and New Zealand (FSANZ)* — FSANZ is responsible for setting standards in the safety, content and labelling of food. All GM foods intended for sale in Australia and New Zealand have to undergo a safety assessment by the FSANZ.

• *The Therapeutic Goods Administration (TGA)* — The TGA administers the Therapeutic Goods Act 1989. This Act provides a national framework for the regulation of medicines, medical devices, blood and tissues in Australia, including GM and GM-derived therapeutic products and ensures their quality, safety and efficacy.

• *The National Industrial Chemicals Notification and Assessment Scheme (NICNAS)* — New and some existing industrial chemicals, including those produced by GMOs, are assessed under NICNAS, which consider their effects on human health and environment.

• *The Australian Pesticides and Veterinary Medicines Authority (APVMA)* — APVMA is responsible for the evaluation, registration, regulation, quality assurance and compliance of pesticides and veterinary medicines up to the point of sale. This includes agricultural products containing or produced by GMOs.

• *Australian Quarantine and Inspection Service (AQIS)* — AQIS regulates the importation of all animal, plant and biological products, that may pose a quarantine pest and/or disease risk.

While Australia's framework for the regulation of GMOs is described by the Commonwealth Act, importantly, additional information is contained within the Commonwealth Regulations. This information covers certain provisions in the Commonwealth Act, including further detail regarding GMO dealings, such as those which are exempt from the national regulatory scheme and those that are Notifiable Low Risk Dealings (NLRDs).

Appendix 5 THE 2011 REVIEW OF THE COMMONWEALTH ACT – THE COMMONWEALTH REVIEW

Section 194 of the Commonwealth Act stipulates that the operation of the 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. This first review was completed in 2006[21]. Clause 44 of the intergovernmental GTA states that further reviews will be conducted at intervals of no more than five years.

The second review of the Commonwealth Act commenced in May 2011. The Department of Health and Ageing[22] engaged the Allen Consulting Group to undertake the Review. The Review report is available on the website of the Australian Government Department of Health at: http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-techact-review

The Review 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.

See box below for the terms of reference for the 2011 Commonwealth Review.

COMMONWEALTH REVIEW TERMS OF REFERENCE

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

TOR 1. The effectiveness and efficiency of the way that the regulatory scheme operates, taking account of developments since 2005-06 including:

a) the national scheme for gene technology regulation in Australia to identify any need for, and opportunities to achieve, improvement in its national consistency, efficiency and effectiveness and coordination; and investigate if the aims of the Agreement to determine these are being achieved;

b) emerging trends and international developments in biotechnology and its regulation and whether the regulatory system stipulated by the Act, including definitions within the Act, is flexible enough to accommodate changing circumstances; and

c) definitions and provisions within the Act to identify possible areas for enhancement in light of experience with the operation of the regulatory system.

TOR 2. Whether the object of the Act is being achieved and whether the regulatory framework stipulated in section 4 of the Act is operating effectively.

TOR 3. The powers of the Act to ensure that they are sufficient to enforce compliance.

[21] Statutory Review of the *Gene Technology Act 2000* [Cwlth] and The Gene Technology Agreement. Commonwealth of Australia, 2006.
[22] Currently known as the Department of Health.

TOR 4. The consultation provisions of the Act to determine:

a) their effectiveness with respect to changes in communication modes, such as various social media tools; the costs and benefits, including the value of advice received; and the transparency and accountability that they provide;

b) the functions and roles of the statutory advisory committees; and

c) the stakeholders for various applications under the Act and the methodology used to engage them.

TOR 5. The interface between the Act and other Acts and schemes in Australia (include all States and Territories) that regulate gene technology and its products; and identify any discrepancies, including regulatory gaps and areas needing consistency and harmonisation of provisions.

TOR 6. The regulatory burden and whether compliance costs for organisations working in gene technology are reasonable and justified compared to benefits achieved and if the regulatory requirements for classes of approval under the Act are commensurate with the level of risk.

TOR 7. Provision of recommendations for amendments to the Act and the Agreement (including consideration of those recommendations made by State or Territory Parliamentary Committees) or alternatives to legislation, which improve the effectiveness, efficiency, fairness, timeliness and accessibility of the regulatory system.

The Commonwealth Review proposed 16 recommendations to improve the effectiveness and efficiency of the operation of gene technology regulation in Australia [see box below].

REVIEW RECOMMENDATIONS

1. The requirement for quarterly reporting to the Commonwealth Minister, to be tabled in Parliament, be discontinued.
2. All jurisdictions reconfirm their commitment to a national regulatory scheme for gene technology.
3. Jurisdictions follow the example of NSW and the Northern Territory, automatically adopting changed gene technology regulation by reference to the Commonwealth legislation.
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.
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.
6. The OGTR continue to be active in OECD and other international fora to stay abreast of international developments in gene technology regulation.
7. The Ministerial Council review the definition of 'dealings' in the Act with a view to clarifying the scope of the regulatory scheme.
8. The Ministerial Council review the conditioning of GM products in the Act with a view to clarifying the scope of the regulatory scheme.
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.
10. The Act be amended so that the Regulator can authorise other appropriate dealings related to inadvertent dealings.

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.
12. Governments in Australia maintain a science-based precautionary approach to the regulation of gene technology.
13. The OGTR increase its communications to the general public to raise its profile and build confidence in Australia's regulation of gene technology.
14. For many DIR applications, advertising in local or state newspapers in the region where the DIR is to occur should be sufficient (given OGTR's established electronic communications channels with interested parties). For issues/licences of national importance it should be sufficient for OGTR to place advertisements in one national newspaper. The OGTR could experiment with using social media to communicate with stakeholders in appropriate situations.
15. The requirement to include GM products approved by APVMA, TGA, FSANZ and NICNAS in the GMO Record be removed.
16. Technical amendments, as described in this report, be made to Sections 30, 71, 74 and 138 of the Act

Submissions from the Commonwealth Review of specific relevance to Queensland

Of the forty-eight submissions to the Commonwealth Review, three were received from people or organisations located in Queensland.

The submissions were:

No. 19	Dr Helen Leonard, Queensland Institute of Medical Research
No. 25	Nina Murray, AgForce
No. 35	James Holden, Pioneer Hi-Bred Australia, Toowoomba

The key points made in these submissions are summarised in part (a) below.

A number of other submissions, although not specifically originating from people or organisations located in Queensland, were considered to carry comments or information of relevance and are summarised in part (b).

Comments about market and trade issues and State moratoria have been generally disregarded as they are outside the TORs of this Review.

(a) Submissions originating from Queensland:

Submission 19: Dr Helen Leonard, Queensland Institute of Medical Research
Key points are:

- Public perception versus scientific endeavour - needs to be balanced
- Regulatory burden - is greater in Australia than many overseas competitor countries.
- Time costs - can be very significant in larger organisations (2-3 days a month)
- Costs of certifying facilities - non budgeted costs increase when guidelines change requiring an organisation to upgrade or build new facilities in order to comply
- Evidence based regulatory changes - there is little or no evidence to suggest a continued tightening of requirements is justified
- Impact statements - should be required as part of any review of the Act or Regulations to determine what it costs

Submission 25: Nina Murray, AgForce
Key points are:

- National scheme **-** inconsistencies in legislation across states affects funding for research and development into gene technology for grain crop specific traits
- Emerging trends and international developments - the amount of gene technology crop research in Australia to date has been limited and more is needed for our farmers to remain viable
- The comprehensive and rigorous science based assessment of GM species and products is supported

Submission 35: James Holden, Pioneer Hi-Bred Australia, Toowoomba
Key points are:

- There should be a clear division between (i) the role of government in regulating the human and animal health and safety and the possible environmental invasiveness of technology; and (ii) the role of the market in determining the acceptability of gene technology to prevailing market conditions
- Continuity and consistency is required in the application of the principles expressed in the Act and reflected in the intergovernmental GTA
- Emerging trends and international developments - the definition of GMOs should be reviewed as the Act currently captures a wide range of related technologies, including processes that do not include the incorporation of novel DNA or that mimic natural processes
- OGTR continues to engage with stakeholders and where possible enhance its communication to ensure that the Australian community recognises the existence and strategic role of the OGTR in independently assessing and adjudicating on the human, health and environmental safety of GM crops and pastures
- The purpose of the amalgamated GTEC and GTCCC should be advisory, and should not place any statutory obligation on the decisions of the OGTR
- The role of city and shire councils in the consultation process lacks credibility and requires a more proactive educated approach to their role in the application process or be replaced by that of farmer-based organisations that represent the majority of stakeholders in rural environments
- Interface with other regulators - there is undue duplication between regulatory agencies such as the OGTR and the APVMA, when dealing with insect, fungal and/or herbicide tolerant crops, which is undesirable because it increases regulatory costs with no associated benefit
- There needs to be a fundamental realignment of the operating principles of the OGTR and that of State and Territory governments, in relation to compliance

(b) Submissions originating outside Queensland:

In general terms, many of the forty-eight submissions to the Commonwealth Review indicated a broad level of satisfaction with the way the gene technology legislation is being administered by the OGTR.

A number of submissions raised concerns about the lack of national consistency in regard to state-based moratoria and the designation of GM and non-GM crops for the purposes of protecting markets and trade.

Submissions or sections of submissions focussed on market and trade related issues are considered to fall outside the terms of reference and scope of the Queensland Review which, by the nature of the Queensland Act, is focussed on matters related to the impact of GMOs on health and safety of people and the environment.

Gene Technology Act 2001 (Queensland)
The object of this Act is to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing the risks by regulating certain dealings with GMOs.
Gene Technology Act 2001 (Queensland), Part 1, Section 3, page 11

The summaries below are provided under the headings used in the Commonwealth Review report and also deal with issues that are particularly relevant to the Queensland Review.

[CR[23] - TOR 1] Effectiveness and efficiency of regulatory arrangements

The effectiveness and efficiency of the regulatory scheme was a major focus of the Commonwealth Review, with particular attention to improvements to the national scheme in relation to its national consistency, overall efficiency and effectiveness, and coordination. This TOR also addressed emerging trends and international developments, and examined definitions and other provisions of the Act.

Many submissions described the Act as an effective and efficient mechanism for regulating GMOs in Australia (for example DIISR / CSIRO - Submission 47). Stakeholders noted that the OGTR has gained experience in the implementation of the Act, concomitant with an improvement in the effectiveness and efficiency of its administration. The OGTR (submission 26) reported that the diversity in the nature of licence applications has grown, and with this the risk analysis and approval activities, as well as monitoring and compliance programs.

Some submissions outlined concerns about new players in GM related business in other countries that have less stringent regulatory requirements than Australia which may exacerbate any risk of Australia importing products containing GM material that may not have been approved by the OGTR (CropLife Australia – Submission 24).
In response, the Reviewers noted that to be fully effective, OGTR must work with other Commonwealth agencies such as FSANZ, AQIS and APVMA.

Structural issues identified with the Commonwealth / State legislative framework

[23] CR denotes Commonwealth Review Term of Reference as identified in the Allen Consulting Group Review Final report (August 2011).

The Review commented on structural issues with the legislation and the impact of delays in some jurisdictions to the adoption of changes to the legislation that have been agreed by the (former) Ministerial Council and passed by the Commonwealth Parliament following earlier reviews.

The structural issues identified have arisen as a consequence of the nature of the interface between the Commonwealth and State / Territory legislation and relate to the limits of the constitutional reach of the Commonwealth gene technology legislation.

Wind-back

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

"For a wind-back notice to be issued, a corresponding State/Territory law must be in force and the notice applies regardless of whether the corresponding State/Territory legislation is corresponding 'in fact' or not."

At the time of the 2011 Commonwealth Review, Queensland was the only jurisdiction to have wind-back in place. At the present time, Queensland and Tasmania have wind-back in place.

On the basis of the above issues, the Commonwealth Review made three recommendations:

- All jurisdictions reconfirm their commitment to a national regulatory scheme for gene technology;
- Jurisdictions follow the example of NSW and the Northern Territory, automatically adopting changed gene technology regulation by reference to the Commonwealth legislation; and
- Where the Commonwealth Act has not been adopted by reference, jurisdictions commit to amending legislation at the same time as Commonwealth legislation is amended.

International developments in gene technology regulation

The Review noted that stakeholder submissions had commented on the importance of the OGTR keeping abreast of international gene technology developments, and that stakeholders provided positive comments on the OGTR's performance in this area. This suggested that "the OGTR has followed international developments in gene technology well, which has been critical for the success of Australia's gene technology regulatory environment."

It was commented that since the 1980s, much of the current regulation of gene technology, including that of Australia, is based on the work of the Organisation for Economic Development and Cooperation (OECD). Since that time, the OECD has issued a series of consensus documents on the safety of novel foods and feeds (OECD 2011) and continued its work on the harmonisation of regulatory oversight in biotechnology. An OECD paper (OECD 2007) provides snapshots of national gene technology regulation in nineteen countries. In this report, Australia's regulation of gene technology appeared comparable with that of most other leading OECD countries.

The Commonwealth Review also reported that several Australian stakeholders had advised that there is considerable overseas interest in Australia's approach and that the OGTR had received a number of overseas visitors seeking first-hand information. In addition, staff of the OGTR have conducted risk assessment and risk management capacity building activities to assist other countries that are developing regulatory systems for gene technology.

On the basis of the above points, the Commonwealth Review recommended that "The OGTR continue to be active in OECD and other international fora to stay abreast of international developments in gene technology regulation."

Issues regarding definitions and provisions within the Act

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.

It was further commented that a number of activities with GMOs have emerged in other countries over the last ten years that are potentially outside the coverage of the Commonwealth Act should these activities be proposed in Australia. For example:

- The experimental releases in the Cayman Islands and Malaysia of GM mosquitoes for biocontrol of mosquito populations to limit the transmission of dengue fever; and
- The contained laboratory tests in Europe of GM *Pseudomonas fluorescens* bacteria for bioremediation of polychlorinated biphenyls (PCBs) in soil.

It appears unclear whether the definition of 'deal with' in section 10 of the Commonwealth Act would capture the use of such GMOs in an unrestricted manner in the environment in the same way as GM plants.

On this basis, the Commonwealth Review recommended that "The Ministerial Council review the definition of 'dealings' in the Commonwealth Act with a view to clarifying the scope of the regulatory scheme."

It was also noted that activities with GM products are not regulated directly under the Commonwealth Act, although the Regulator may impose a condition on a GM product that is

derived from a GMO and there is no express legislative limit on the scope of conditions that can be placed on a GM product.

However, the Commonwealth Review considered that the scope of the Regulator's powers should be clarified where a GM product may not be regulated by another agency and made a recommendation that "The Ministerial Council review the conditioning of GM products in the Commonwealth Act with a view to clarifying the scope of the regulatory scheme."

Flexibility of the Act to address changing circumstances

The Commonwealth Review noted that some stakeholders (for example, Australian Seed Federation-submission No 37; Bayer CropScience-submission No 38) raised concerns that the definition of GMOs in the Commonwealth Act may not be adequate to allow for the emergence of new technologies.

However, even though the Commonwealth Act already allows for the emergence of new gene technologies by providing the Regulator the ability, through Commonwealth Regulations, to exclude a gene technology technique from regulation, or to declare a thing to be a GMO or not to be a GMO, changes to Commonwealth Regulations can be slow and may take up to eighteen months to implement. The lengthy and complex process could limit the ability of the OGTR to move swiftly in relation to new technological developments or newly identified risks. Furthermore, time delays of this sort can result in uncertainty for researchers and users wanting to implement new technologies which may be a disincentive to investment in new technologies.

The same time delays can occur when an existing technology has been in use for some time and the Regulator believes the level of regulation can be relaxed because knowledge of its safety has been built up over time and through experience. The time delays in implementing such a change disadvantage Australian GM researchers and users compared to their international counterparts.

Based on the concerns and issues described above, the Commonwealth Review recommended that the Department of Health and Ageing explore with the Attorney General's Department and the Ministerial Council (now the LGFGT) ways in which the process for amending the gene technology legislation could be streamlined.

Inadvertent dealings

The Commonwealth Review noted that, following the 2006 Review, the Commonwealth Act was amended to provide for temporary licences for inadvertent dealings for the purposes of GMO disposal. The OGTR (submission No. 26) commented in its submission that this needs to be extended so that other dealings incidental to disposal can be authorised; for example, where testing or storage of inadvertently obtained GMOs may be necessary. The

Commonwealth Review recommended that the Act be amended so that the Regulator can authorise other appropriate dealings related to inadvertent dealings.

Institutional Biosafety Committees

Some stakeholders raised concerns in relation to the clarity of the role and functions and also the costs and benefits of IBCs. There were also questions raised about how the IBC of an organisation overseeing a multiuser site should operate.

The Commonwealth Review recommended that the OGTR continue to provide information to IBCs to assist them in understanding their responsibilities under the Commonwealth Act, and that IBCs should differentiate this aspect of their work from other activities for which they may also be responsible.

[CR-TOR 2] Achievements of the objective of the Act

As noted in Chapter 2, the object 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.

The Commonwealth Review noted that, while many stakeholders feel that the Commonwealth Act's objectives are being achieved, there were a number of submissions alleging failures of the Commonwealth Act in achieving its objectives. Some of these submissions raised matters that are outside the TOR of the Commonwealth Review.

It was also noted that the previous Commonwealth Review considered matters such as a call for a liability regime to be imposed on farmers growing GM crops, to protect organic farmers and concluded that it is appropriate that they remain outside the scope of the Commonwealth Act.

Effectiveness of the regulatory framework of the Act

Regulatory framework to achieve object (Part 1, Section 4)

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

(aa) provides that where there are threats of serious or irreversible environmental damage, a lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation; and

(a) provides an efficient and effective system for the application of gene technologies; and

(b) operates in conjunction with other Commonwealth and State regulatory schemes relevant to GMOs and GM products (such as those that regulate food, agricultural and veterinary chemicals, industrial chemical and therapeutic goods.

Source: *Gene Technology Act 2000*

The Precautionary Principle

The regulatory framework provides for a precautionary approach to gene technology regulation to protect against environmental damage.

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

The Commonwealth Review noted that submissions argued both for and against this approach. It also commented that scientific evidence underpins a precautionary approach to gene technology regulation and that many submissions affirmed a desire for the science-based approach to regulation not to be compromised. The OECD (OECD 2007) has discussed the precautionary approach and found that this approach has generally worked successfully.

However it expressed concern that, while biotechnology has now enjoyed an excellent safety record over an extended period, this is not reflected in the action of some countries that have introduced ever more stringent regulation.

The Commonwealth Review recommended that Governments in Australia maintain a science-based precautionary approach to the regulation of gene technology.

[CR-TOR 3] Powers of the Act to enforce compliance

Very few submissions commented on the power of the Commonwealth Act to enforce compliance. The present approach of the OGTR is to achieve compliance through consultation with a view to achieving cooperative compliance.

The OGTR's active monitoring and inspection program includes audits and practice reviews. To date there has been no need for prosecutions since the regulated community has shown a willingness to meet the requirements of the gene technology legislation. The Commonwealth Review commented that, until the legislation has been the subject of litigation, it will be difficult to form a definitive view of the compliance powers of the Commonwealth Act.

[CR-TOR 4] Consultation provisions of the Act

The Commonwealth Review examined the effectiveness of the consultation provisions of the Commonwealth Act (including methods to communicate, the costs and benefits of the consultation provisions, and the transparency of the consultation provisions), the roles of the statutory advisory committees (GTTAC and GTECCC), and issues relating to the stakeholders consulted with during the application process.

Effectiveness of consultation arrangements

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

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

However, some concerns were raised that the community remains confused about GMOs and GM crops, in particular about their safety and impact on the environment. There are also considerable sections of the community who remain unaware that there is a regulatory framework in place.

The Commonwealth Review noted that some stakeholders commented that the OGTR could be much stronger and more proactive in its communications activities. It was felt that there is a need for more public confidence in the OGTR's processes, which could be achieved if the OGTR directly addressed misinformation about the regulatory processes by opponents of gene technology.

While the OGTR is expected to take a neutral position on the technology itself, these stakeholders would like the OGTR to be clearer about the extensive review and testing required before GMOs are released.

Based on these views, the Commonwealth Review recommended that the OGTR increase its communications to the general public to raise its profile and build confidence in Australia's regulation of gene technology.

Consultations on individual proposals

The Commonwealth Review noted that the communication strategy followed by the OGTR in relation to individual proposals exceeds that required by the Commonwealth Act and commented that while some newspaper advertising should remain, it is apparent that most interest generated from the public consultation process arises from the OGTR contacting and advising those on their circulation email list of 700 people and organisations.

A number of submissions were concerned about the requirements to consult local councils about specific licence applications in their region and raised concerns that councils do not have the appropriate background and expertise to comment on details of a particular licence and that this process represents a cost to the OGTR that is not providing net benefits. The

Commonwealth Review raised doubts that bringing local councils into consultations is necessary or useful.

Two issues were raised about the public availability of licence application information submitted by applicants. One is the large volume of material provided with some applications, which makes it difficult for the OGTR to provide information electronically. The second problem is the issue of the confidential commercial information (CCI) exemption for some scientific data, which some stakeholders consider compromises the transparency of the regulatory system.

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

The Commonwealth Review recommended that for many applications for Dealings involving Intentional Release (DIR), advertising in local or state newspapers in the region where the DIR is to occur is sufficient (given the OGTR's established electronic communications channels with interested parties). For issues/licences of national importance it should be sufficient for the OGTR to place advertisements in one national newspaper. The OGTR could experiment with using social media to communicate with stakeholders in appropriate situations.

Functions and roles of the advisory committees

The Commonwealth Review noted that the GTTAC appears to be working well; and that most discussion surrounding the advisory committees concerned the GTECCC (formed by the amalgamation of the GTEC and the GTCCC following the 2006 Commonwealth Review).

Comments were made regarding the value of the GTECCC. Many supported the amalgamation and formation of the new GTECCC, while some still questioned its role, purpose and membership.

The Commonwealth Review noted that advisory arrangements had been discussed with the chairs of the two committees and considered that the present advisory arrangements are satisfactory.

[CR-TOR 5] Interaction with other regulation

The Commonwealth Review noted that some submissions raised concerns regarding interaction between the Commonwealth Act and other relevant Acts and schemes, such as:

- the lack of harmonisation between the OGTR and AQIS legislative requirements;
- a claim that the OGTR does not have to consider safety issues that are dealt with by the TGA and FSANZ;

- suggestions that there may be some duplication between APVMA and the OGTR; and
- the differences in the GMO definition between the Commonwealth Act and that used by agencies such as FSANZ and APVMA.

It was noted that, following passage of the *Gene Technology (Consequential Amendments) Act 2000*, the Commonwealth Act, APVMA, FSANZ, the TGA and NICNAS all now use the same definitions of GMOs and GM products; and that no evidence was seen to suggest that there are real problems in relation to the other issues.

However, it was commented that the OGTR needs to be more effective in communicating to stakeholders how it works with other regulatory agencies.

The GMO Record

The Commonwealth Review noted that the Regulator is obliged to maintain the GMO Record under Section 138 of the Commonwealth Act, and that the Record includes authorisations of GMO dealings made under the Commonwealth Act as well as GM product approvals of APVMA, TGA, FSANZ and NICNAS.

It was commented that maintaining GM products approved by these other agencies on the GMO Record duplicates the record keeping of these other agency record and it was recommended that the requirement to include GM products approved by APVMA, TGA, FSANZ and NICNAS in the GMO Record be removed.

[CR-TOR 6] Regulatory burden of the legislation

It was noted that almost all regulations have the potential to impact on productivity and it is therefore essential for regulations (concerning any industry or sector) to be effective and efficient.

In the case of gene technology regulation, the regulatory burden should be commensurate with risk so that the health and safety of people and the environment are maintained, while industries and organisations that involve gene technology are able to be productive.

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

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

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

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

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

Research institutes and universities spoke of the regulatory burden for IBCs and that IBC members must spend excessive time reading and assessing applications. This suggested to the Commonwealth Review that some IBCs may need more members and subcommittees to spread the workload.

[CR-TOR 7] Proposed amendments to the Act

Technical amendments

Based on the findings of the Commonwealth Review, a number of technical amendments, essentially described as 'housekeeping', were proposed to be made to Sections 30, 71, 74 and 138 of the Commonwealth Act.

Concluding comment:

An Australian, State and Territory Governments' (all governments') response to the Commonwealth Review recommendations has been prepared and was considered by the LGFGT in April 2013 and is available on the website of the Australian Government Department of Health at: http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-techact-review.

Queensland has reserved its position on the response to the review of the Commonwealth Act, pending further consideration by the Queensland Government.

Appendix 6 ORGANISATIONS AND INDIVIDUALS WHO PROVIDED WRITTEN PUBLIC SUBMISSIONS

1. Dr Joe Smith, Gene Technology Regulator
2. Griffith University
3. CropLife Australia Limited
4. AusBiotech Ltd
5. Frog Safe Inc

Appendix 7 SUMMARY OF ISSUES RAISED IN SUBMISSIONS

There were five written submissions received, along with a range of information and comments provided by way of personal interview to the Reviewers.

The majority of submissions as well as individuals consulted indicated satisfaction with the way the gene technology legislation is being administered by the OGTR. Most parties strongly supported a key finding of the 2011 Commonwealth Review which noted that, while the object of the Commonwealth Act is being met, improved harmonisation of Australia's arrangements to regulate gene technology would lead to improved efficiency and effectiveness.

Most submissions supported Recommendation 3 of the Commonwealth Review proposing that jurisdictions (for example Queensland) follow the example of New South Wales and the Northern Territory (and subsequently Tasmania), automatically adopting changed gene technology regulation by reference to the Commonwealth legislation in order to achieve further administrative and efficiency gains.

It was clear that most of those responding to the Review felt that Queensland should move to 'lock-step' with Commonwealth gene technology legislation in order to avoid periods of inconsistency and uncertainty. These periods of inconsistency and uncertainty, during which the existing Queensland legislation operates out of step with the Commonwealth legislation until necessary amendments can be passed to bring it into line, are of particular concern for IBCs.

Many also commented that, due to the large number of changes coming in relation to new and emerging technologies, it will be important for Queensland to be able to move quickly – ideally in lock-step – in relation to changes to Commonwealth legislation that may be required to deal with these new technologies.

A number of those consulted expressed concern about the recent fee for service proposal being tested by the OGTR, however this is regarded as outside the TORs of this Review.