Western Australia

GENE TECHNOLOGY ACT 2006

REVIEW OF THE ACT UNDER SECTION 194

REPORT

JUNE 2012
# Contents of Report

**Overview**

<table>
<thead>
<tr>
<th>Part</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>About the review</td>
<td>2</td>
</tr>
<tr>
<td>1.1</td>
<td>Requirement for review and report</td>
<td>2</td>
</tr>
<tr>
<td>1.2</td>
<td>The reviewer and the review process</td>
<td>2</td>
</tr>
<tr>
<td>1.3</td>
<td>Findings of the review</td>
<td>3</td>
</tr>
<tr>
<td>1.4</td>
<td>Reference material</td>
<td>3</td>
</tr>
<tr>
<td>1.5</td>
<td>Terms and abbreviations</td>
<td>3</td>
</tr>
</tbody>
</table>

**Part 2 — Gene technology and its regulation**

<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>Gene technology</td>
<td>4</td>
</tr>
<tr>
<td>2.2</td>
<td>Monitoring gene technology: from voluntary oversight to government involvement</td>
<td>5</td>
</tr>
</tbody>
</table>

**Part 3 — The national legislative scheme on gene technology**

<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1</td>
<td>How the scheme came into being</td>
<td>6</td>
</tr>
<tr>
<td>3.2</td>
<td>Outline of the Commonwealth GT Act</td>
<td>7</td>
</tr>
<tr>
<td>3.3</td>
<td>The State and Territory gene technology laws</td>
<td>8</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1</td>
<td>How the Act came into being</td>
<td>12</td>
</tr>
<tr>
<td>4.2</td>
<td>Operation of the Act</td>
<td>13</td>
</tr>
</tbody>
</table>

**Part 5 — Review of submissions**

<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1</td>
<td>Introductory comments</td>
<td>14</td>
</tr>
<tr>
<td>5.2</td>
<td>Notes on submissions</td>
<td>14</td>
</tr>
<tr>
<td>5.3</td>
<td>Summary of issues raised in submissions</td>
<td>20</td>
</tr>
</tbody>
</table>

**Part 6 — Consideration of issues**

<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.1</td>
<td>The corresponding State law issue</td>
<td>22</td>
</tr>
<tr>
<td>6.1.1</td>
<td>Impact on the administration of the scheme</td>
<td>22</td>
</tr>
<tr>
<td>6.1.2</td>
<td>Action needed</td>
<td>23</td>
</tr>
<tr>
<td>6.2</td>
<td>Consistency of provisions</td>
<td>23</td>
</tr>
<tr>
<td>6.2.1</td>
<td>The need for consistency</td>
<td>23</td>
</tr>
<tr>
<td>6.2.2</td>
<td>Methods of achieving consistency</td>
<td>25</td>
</tr>
<tr>
<td>6.3</td>
<td>Wind-back of Commonwealth legislation</td>
<td>29</td>
</tr>
</tbody>
</table>
Report of review of *Gene Technology Act 2006*

**Part 7 — Findings**

<table>
<thead>
<tr>
<th>Appendix</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appendix 1 — The reviewer</td>
<td>31</td>
</tr>
<tr>
<td>Appendix 2 — Reference material</td>
<td>32</td>
</tr>
<tr>
<td>Appendix 3 — Terms and abbreviations</td>
<td>34</td>
</tr>
</tbody>
</table>

Overview

This is the report of a review undertaken on the operation of the Western Australian Gene Technology Act 2006.

The review looked into the history of the Act, its current status, and its place within the cooperative national legislative arrangements relating to the application of gene technologies agreed to by the Commonwealth, the States and the Territories.

The main conclusions to be drawn from the review are:

- It is important that the State’s gene technology laws should operate effectively as part of the national legislative scheme for the regulation of activities involving gene technology.

- For the benefit of organisations participating in activities involving gene technology, and authorities regulating those activities, there needs to be consistency between the relevant Commonwealth and State laws and certainty as to which laws govern particular activities.

- Legislative and administrative action is needed to address these matters.
Part 1 — About the review

1.1 Requirement for review and report

Under section 194 of the Western Australian Gene Technology Act 2006 (the WA GT Act), the Minister administering it must cause an independent review of its operation to be undertaken as soon as possible after the fourth anniversary of its commencement. That fourth anniversary occurred on 28 July 2011.

The person who undertakes the review must give the Minister a written report of the review.

The Minister must cause a copy of the report of the review to be laid before each House of Parliament within 12 months after the fourth anniversary of the commencement of the Act (i.e. by 28 July 2012).

1.2 The reviewer and the review process

Mr Greg Calcutt AM, SC was engaged to undertake the review. Under section 194(4) of the WA GT Act the reviewer must be considered by the Minister to have appropriate qualifications to conduct the review and must not be employed by the State of Western Australia, a State agency, the Commonwealth or a Commonwealth authority. The reviewer had extensive experience with inter-governmental legislative schemes while he was Parliamentary Counsel for Western Australia from 1989 until 2009. He is not currently an employee of any government, agency or authority. He has previous experience in undertaking a review of this kind having reviewed and reported on the operation of the Genetically Modified Crops Free Areas Act 2003 (WA) in 2009. More information about the reviewer is set out in Appendix 1.

The Department of Agriculture and Food assisted the reviewer by providing advice, information and technical support to him at his request. In other respects, the review was conducted independently of the Department and of the office of the Minister.

The review was initiated in October 2011 by the publication on the Department’s website of an information paper with an invitation to interested persons and bodies to make written submissions to the review. Advertisements about the review were also placed in relevant newspapers. Copies of the information paper were sent by the Department to all Western Australian Institutional Biosafety Committees known to the Department and to other interested parties.
The period for making submissions originally ran from 10 October 2011 to 21 November 2011. By the end of that period 8 submissions had been received. A further invitation for submissions was issued on 23 November 2011 extending the closing date to 16 December 2011 and an additional 13 submissions were received on or before that date. The 21 submissions and details of the persons and bodies by whom they were made can be viewed on the Department’s website.

In conducting the review:

- gene technology, its applications and developments in its regulation in Australia were briefly examined, (See Part 2)
- the national legislative scheme for the regulation of activities involving gene technology was studied, with particular reference to the operation of the Commonwealth Gene Technology Act 2000 (the Commonwealth GT Act), (See Part 3)
- the history of the WA GT Act was examined, and issues regarding its operation and its compliance and compatibility with the national legislative scheme were identified, (See Part 4)
- discussions were held with the Gene Technology Regulator (the Regulator), officers of the Department (which assists the Minister to administer the WA GT Act) and officers of an Institutional Biosafety Committee,
- a gene technology research facility was visited,
- the submissions made to the review were considered and issues raised in them were identified, (See Part 5)
- issues relating to the State’s gene technology laws were considered in detail and ways of ensuring that those laws achieve their intended purpose were investigated. (See Part 6)

1.3 Findings of the review

The findings of the review and recommendations resulting from it are set out in Part 7.

1.4 Reference material

Various publications, documents and legislative instruments referred to in the course of the preparation of this report are listed in Appendix 2.

1.5 Terms and abbreviations

Appendix 3 lists some terms and abbreviations used in this report.
Part 2 — Gene technology and its regulation

2.1 Gene technology

Biotechnology involves the use of living things to make or change products. Biotechnology has been used for centuries in activities ranging from plant and animal breeding through to brewing and baking.

As understanding of how living things function, grow and reproduce has developed, and particularly since the discovery of the structure of DNA in 1953, that area of biotechnology known as gene technology has become increasingly important.

In its wider sense gene technology is the term given to activities concerned with:

- understanding how genes function and interact, and
- learning how to take advantage of natural genetic variations, and
- manipulating and modifying genes and other genetic material.

It is the third set of activities that has been the focus of public attention and regulatory action. Gene technology in this sense involves the modification of organisms by the direct incorporation, deletion or alteration of one or more genes or genetic sequences to introduce or alter a specific characteristic or characteristics.

Genetically modified organisms produced using gene technology are known as GMOs. Other products can be derived or produced from GMOs. They are known as GM products.

Gene technology has already led to achievements in a wide range of areas particularly in human health and food production. For example gene technology has enabled:

- the development of therapies for diseases,
- the production of vaccines,
- the location and study of genes that cause diseases or increase susceptibility to them,
- the production of crop varieties with pest or virus resistance or herbicide or salt tolerance.

Both from a scientific point of view and as a matter of public perception, developments in gene technology, and the potential scope and implications
of future developments, give rise to an obvious need for ongoing monitoring and supervision.

2.2 Monitoring gene technology: from voluntary oversight to government involvement

Oversight of gene technology in Australia began on a voluntary basis in the 1970s. Committees of scientific experts were set up first by the Australian Academy of Sciences and then by the federal Department of Science. These committees effectively provided peer review assessments of proposals to conduct experiments with GMOs between 1975 and 1987.

The committees were superseded in 1987 by the Genetic Manipulation Advisory Committee (GMAC), a non-statutory body set up on the initiative of the federal Minister for Industry, Technology and Commerce. The GMAC’s task was to assess risks to human health and the environment in connection with gene technology and provide advice to proponents on how risks associated with work with GMOs could be managed. Though it had no statutory powers, the GMAC’s advice was sought and followed by researchers and compliance with its recommendations was a condition of research and development funding from the Commonwealth government.

Advances in gene technology led to an increase in commercial involvement, and an accompanying increase in community awareness and concerns about the application of gene technology generally and the release of GMOs in particular. Recognising this, in 1988 the Commonwealth and State governments initiated a cooperative process to develop a national approach to gene technology regulation.

The process was comprehensive and included issues papers, discussion papers, a draft Bill for public comment, public forums and the consideration of numerous written submissions. This extensive public input and participation proved to be well worthwhile as it led to general acceptance of a proposed regulatory system that sought to balance the potential public benefits of gene technology with community concerns about its development and deployment. The system is discussed in Part 3.
Part 3 — The national legislative scheme on gene technology

3.1 How the scheme came into being

The Gene Technology Agreement entered into between the Commonwealth, the States and the Territories recites, in Recital A:

A. there is a need for a co-operative national legislative scheme to protect the health and safety of people and to protect the environment, by identifying risks posed by, or as a result of, gene technology and by managing those risks through regulating certain dealings with genetically modified organisms;

and, in Recital B, that the scheme should:

(c) be nationally consistent, drawing on power conferred by the Commonwealth, State and Territory Parliaments;

To implement the agreed legislative scheme the Commonwealth enacted the Gene Technology Act 2000 which commenced operation on 21 June 2001. As the Commonwealth has no specific legislative powers in the field of gene technology, the Commonwealth GT Act relies for its validity on a variety of general powers. These are described in section 13(1)(a) to (f) of the Act. Section 13 reads:

13 Operation of Act

(1) This Act applies as follows:

(a) to things done, or omitted to be done, by constitutional corporations;

(b) to things done, or omitted to be done, in the course of constitutional trade or commerce;

(c) to things done, or omitted to be done, by a person that may cause the spread of diseases or pests;

(d) for purposes relating to the collection, compilation, analysis and dissemination of statistics;

(e) to the Commonwealth and Commonwealth authorities;

(f) to things authorised by the legislative power of the Commonwealth under paragraph 51(xxxix) of the Constitution, so far as it relates to the matters mentioned in paragraphs (a) to (e) of this subsection.

(2) In this section:

constitutional corporation means a trading, foreign or financial corporation within the meaning of paragraph 51(xx) of the Constitution.

constitutional trade or commerce means trade or commerce:

(a) between Australia and places outside Australia; or

(b) among the States; or
(c) by way of the supply of services to the Commonwealth or to a Commonwealth authority.

The enumerated powers, especially those relating to corporations and trade and commerce, mean that the Commonwealth GT Act has a wide reach and will cover most gene technology issues in Australia. However to ensure that there are no gaps in the coverage of the scheme, the States have each enacted legislation applying or complementing the Commonwealth legislation.

### 3.2 Outline of the Commonwealth GT Act

Part 2 of the Commonwealth GT Act contains interpretation provisions and provisions explaining how the Act operates and how it and State laws interact to form the national legislative scheme. Because of the importance of these provisions to the scheme some of them are examined in greater detail later in this report.

Part 3 creates the position of Gene Technology Regulator. The Regulator is central to the operation of the legislation having key roles in:

- administering the licensing and other regulatory provisions (which includes making decisions about the development and use of GMOs), and
- developing policy principles and guidelines for the Ministerial Council, and
- developing codes of practice, and
- providing information and advice on gene technology matters to the Ministerial Council, other agencies and the public.

As the holder of an independent statutory office the Regulator is not subject to direction from anyone in performing his or her functions. However the Regulator has regard to a “Statement of Expectations” issued by the Commonwealth government.

Part 4 provides that, subject to certain exceptions, a person dealing with a GMO will commit an offence unless the dealing is authorised by a GMO licence issued by the Regulator. The term “deal with” has a wide meaning but, for the purposes of this report, it is sufficient to say that it includes the propagation, growing, raising or culturing of a GMO.

Part 5 sets up a system for the licensing of GMO dealings. A distinction is drawn between dealings that involve an intentional release of a GMO into the environment and those that do not. An important element of the system
is that, before issuing a licence for dealings with a GMO, the Regulator must be satisfied that any risks posed by the dealings are able to be managed in such a way as to protect:

- the health and safety of people, and
- the environment.

Under Part 5A, an important new Part added in 2007, the Commonwealth Minister can make determinations relating to dealings with GMOs in emergency situations.

Part 6 allows for the regulation of GMO dealings known as “notifiable low risk dealings” and also establishes the GMO Register. If a dealing is included on the GMO Register anyone can undertake the dealing, subject to any specified conditions.

Part 7 provides for the certification and accreditation of facilities and organisations used for or engaged in dealings with GMOs.

Under Part 8 technical and consultative committees are set up to assist and advise the Regulator and the Ministerial Council.

Parts 9 to 12 contain administrative, enforcement and miscellaneous provisions.

### 3.3 The State and Territory gene technology laws

New South Wales and the Northern Territory enacted legislation applying the Commonwealth GT Act as in force from time to time. The wording of the original State gene technology Acts in the other jurisdictions closely followed that of the Commonwealth Act except that as the Regulator and the technical and consultative committees are Commonwealth entities, the provisions establishing them were not included.

There have been a number of amendments to the Commonwealth GT Act since it was enacted. These amendments apply automatically in New South Wales and the Northern Territory and they have been reflected in the Victorian, South Australian, Queensland and Australian Capital Territory legislation.

As the State 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 matters on the Regulator and other Commonwealth authorities and officers. To understand how this can be achieved it is necessary to look at provisions in Part 2 of the Commonwealth GT Act.
This is section 17 (note that in the Commonwealth GT Act “State” includes the Australian Capital Territory and the Northern Territory):

17 Conferral of functions on Commonwealth officers and bodies

(1) A corresponding State law may confer functions, powers and duties on the following:
   
   (a) the Regulator or another officer of the Commonwealth;
   (b) a Commonwealth authority;
   (c) the Ethics and Community Committee;
   (e) the Gene Technology Technical Advisory Committee.

(2) If a function, power or duty is conferred on a person or body under subsection (1), the person or body may perform the function or duty or exercise the power, as the case requires.

(3) If a corresponding State law is expressed to confer on the Regulator the power to determine that dealings be included on the GMO Register, the Regulator may include the dealings on the GMO Register in accordance with the corresponding State law.

(4) If a corresponding State law is expressed to confer on the Regulator the power to vary the GMO Register, the Regulator may vary the GMO Register in accordance with the corresponding State law.

(5) If a corresponding State law is expressed to confer on the Regulator the power to enter information on the Record of GMO and GM Product Dealings, the Regulator may enter the information on the Record in accordance with the corresponding State law.

(6) The Regulator may:
   
   (a) make any notations in the GMO Register that the Regulator considers necessary to identify entries that relate to dealings included on the Register as mentioned in subsection (3) or (4); and
   (b) make any notations in the Record of GMO and GM Product Dealings that the Regulator considers necessary to identify entries that relate to information entered on the Record as mentioned in subsection (5).

To be a “corresponding State law” a State law must be the subject of a declaration to that effect by the Commonwealth Minister. See section 12(1):

12 Meaning of corresponding State law

(1) For the purposes of this Act, corresponding State law means a State law that is declared by the Minister, by notice in the Gazette, to correspond to this Act and the regulations, including such a law as amended from time to time.

Declarations of corresponding State law status under section 12(1) of the Commonwealth GT Act were made in 2002 in relation to the Victorian and
South Australian legislation and in 2008 in relation to the New South Wales, Queensland, Northern Territory and Australian Capital Territory legislation.

If a State has a corresponding State law (which will comprise an Act and regulations made under it) then, in broad terms:

- the Commonwealth’s GT laws will apply to dealings with GMOs by constitutional corporations (probably the vast majority of dealings), and
- the corresponding State law will apply to dealings with GMOs by individuals and by bodies that are not constitutional corporations.

The operation of the corresponding State law may be further restricted if the Commonwealth GT Act applies under any of paragraphs (b) to (f) of section 13(1) of that Act (see Part 3.1).

The boundaries of these jurisdictional areas are not necessarily clear and may result in different laws applying to bodies that are generally similar in character. For instance, some higher educational institutions might be constitutional corporations and thus covered by the Commonwealth’s GT laws, but others may not be.

The national legislative scheme recognises the desirability of similar organisations being dealt with under one law so section 14 of the Commonwealth GT Act provides:

14 Wind-back of reach of Act

(1) This section applies to a State (the notifying State) at a particular time if:

(a) a corresponding State law is in force in the notifying State at that time; and
(b) a wind-back notice in relation to that State is in force at that time.

(2) This Act applies as a law of the Commonwealth in the notifying State with the following modifications:

(a) this Act applies as if paragraph 13(1)(c) (which deals with the spread of pests and diseases) had not been enacted;
(b) this Act does not apply to a dealing with a GMO undertaken:
   (i) by a higher education institution or a State agency; or
   (ii) by a person authorised to undertake the dealing by a licence held under the corresponding State law by a higher education institution or a State agency.
(3) In this section:

wind-back notice, in relation to a State, means a notice given by the State to the Minister, under the Gene Technology Agreement, stating that this section is to apply to the State.

Thus if a State that has a corresponding State law issues a wind-back notice to the Commonwealth, the State law will apply to all GMO dealings undertaken or authorised by higher education institutions and State agencies in that State. A wind-back notice is in place in Queensland.
Part 4 — The Gene Technology Act 2006 (WA)

4.1 How the Act came into being

Western Australia’s first attempt to enact legislation to participate in the national legislative scheme on gene technology began with the introduction of a Gene Technology Bill in 2001. That Bill received detailed consideration by the Legislative Council’s Standing Committee on Environment and Public Affairs which delivered its report in July 2003. The Committee made 20 recommendations a number of which would have involved amendments to the Bill. However, while making these recommendations, the Committee correctly recognised the very limited ability of the State to legislate otherwise than in conformity with the agreed national scheme (see the Executive Summary and Recommendations of the report, paragraphs 28 to 30).

The 2001 Bill was not proceeded with. The Bill for the current Act, the Gene Technology Bill 2005, was introduced in and passed by the Legislative Assembly in April and May 2005. It took a further year for the Bill to complete its passage through the Legislative Council and be assented to as the Gene Technology Act 2006. Another year elapsed before the Act was brought into operation on 28 July 2007.

The Act is entitled:

An Act to regulate activities involving gene technology and for other purposes.

Its wording generally follows the form of the Commonwealth GT Act as it was at the time of the introduction into Parliament of the Gene Technology Bill 2005. If Commonwealth provisions have been modified or omitted, those changes are mentioned in notes in the text.

No substantive amendments have been made to the WA GT Act since it was enacted meaning that there are now significant differences between it and the current Commonwealth GT Act.

Regulations made under the WA GT Act, the Gene Technology Regulations 2007, also came into operation on 28 July 2007.

Under section 10 of the WA GT Act the following matters are excluded from the meaning of “gene technology”:

- sexual reproduction,
- homologous recombination,
• certain techniques specified in the regulations (see the Gene Technology Regulations 2007 Schedule 1A).

Section 10 of the WA GT Act also contains a definition of the term “genetically modified organism”.

4.2 Operation of the Act

The way in which a State law can operate as part of the national legislative scheme on gene technology is explained in Part 3.3.

In order for it to take its place in the national legislative scheme a State law must be declared by the Commonwealth Minister to be a corresponding State law (see section 12 of the Commonwealth GT Act). Until that is done no functions, powers or duties under the State law are conferred on the Regulator or other Commonwealth entities.

So while the State’s GT laws purport to confer functions, powers and duties on the Regulator and other Commonwealth entities, they are not, and have never been, declared under section 12(1) of the Commonwealth GT Act to be a corresponding State law. That being the case, the Regulator does not have authority to administer their provisions as part of the national legislative scheme.

Nor can the State’s GT laws operate independently of the national legislative scheme as the WA GT Act does not contain any default provisions that would provide for its administration by someone other than the Regulator in the absence of a declaration under section 12 of the Commonwealth GT Act.

For the sake of completeness it may be added that Western Australia has never given the Commonwealth Minister a wind-back notice referred to in section 14 of the Commonwealth GT Act. As the State’s GT laws have not been declared to be a corresponding State law, such a notice would serve no purpose.
Part 5 — Review of submissions

5.1 Introductory comments

As mentioned in Part 1.2, the invitations for submissions to the review attracted 21 submissions. The submissions can be viewed on the Department’s website.

Each of the submissions was read and due consideration was given to all of them to the extent to which they addressed the issues under review.

Approximately equal numbers of submissions came from national or local organisations on the one hand and private individuals on the other hand. In addition, there was a very informative submission from the Gene Technology Regulator and there were submissions from groups involved in monitoring gene technology activities in health, university and governmental institutions. There was also a lengthy submission from a member of the Legislative Council.

5.2 Notes on submissions

1. C Coombs

This submission opposed the use of GMOs and the application of funding to GMO technology. It did not address the operation of the WA GT Act or the national legislative scheme on gene technology.

2. University of Western Australia Institutional Biosafety Committee

This submission expressed confidence in the Commonwealth regulatory system for gene technology overseen by the Gene Technology Regulator and called for the WA GT Act to mirror the Commonwealth GT Act to provide a consistent regulatory framework for researchers.

3. Royal Perth Hospital Institutional Biosafety Committee

This submission suggested that the WA GT Act be brought into line with changes made to Commonwealth GT Act as a matter of urgency. It claimed that lack of consistency is causing projects in the State to be in limbo.

The submission also made some detailed suggestions as to amendments that might be made to the national legislative scheme on gene technology. These included suggestions about the need to consider potential global impacts of GMOs, the need to refer to a National Ethics Framework, and the need to ensure that intellectual property rights over GMOs do not stifle scientific developments and knowledge.
4. Dr J Smith, Gene Technology Regulator

The main recommendations made in this submission were:

- That the necessary steps be taken to have the State’s GT laws declared under the Commonwealth GT Act as a corresponding State law so that the State’s GT laws can be administered by the Gene Technology Regulator.
- That a mechanism be put in place to ensure that amendments made in future to the Commonwealth’s GT laws are automatically mirrored in the State’s GT laws to avoid confusion that can arise during periods of inconsistency.
- That a wind-back notice be issued by the State under section 14 of the Commonwealth GT Act to provide certainty that the provisions of the State’s GT laws apply to the regulation of the affairs of State agencies and higher education institutions.

This was an important submission directly addressing the issues under review. The matters raised in it were discussed at a teleconference held with Dr Smith and other officers of the OGTR and in subsequent correspondence. They are dealt with in more detail in Part 6.

5. National Association for Sustainable Agriculture WA Inc

This submission asserted that the current regulatory system has failed in Western Australia in relation to contamination by GM crops and associated liability issues. However that assertion would have to be regarded as relating to the operation of the Commonwealth’s GT laws because, as discussed in Parts 4 and 6, the State’s GT laws currently have little effective part in the national legislative scheme on gene technology.

The submission also recommended a number of specific amendments that should be made to the WA GT Act on a range of matters such as containment, transportation, compensation and public notification.

6. Department of Agriculture and Food and WAGTIDC

This submission from members of the Western Australian Gene Technology Interdepartmental Committee and the Department of Agriculture and Food Western Australia’s Institutional Biosafety Committee contained a clear explanation of the way in which the Commonwealth, State and Territory legislation together form a regulatory scheme covering gene technology activities of corporations, higher education institutions, State agencies and individuals.
The submission addressed issues similar to those dealt with in submission 4. It noted that the Commonwealth GT Act had been amended 6 times since 2000 and that Western Australia and some other jurisdictions had not kept up with all the changes. According to the submission there would be clear advantages in altering the WA GT Act so as to automatically adopt changes made to the Commonwealth GT Act.

7. Gene Ethics

This was lengthy and comprehensive submission supported by 155 persons and bodies whose names and contact details were supplied to the reviewer. It included 22 paragraphs detailing recommendations on gene technology regulation in relation to the precautionary principle, scientific rigour, farmer protection and many other matters. Rather than being addressed to the WA GT Act in particular, the recommendations related to the national legislative scheme on gene technology.

8. The Western Australian Farmers Federation (Inc.)

This submission considered that the WA GT Act had sufficient regulatory processes to achieve its object in that it established a clear framework of licensing, certification and enforcement for dealings with GMOs. That being the case the submission did not list any issues with, or amendments to, the Act for consideration in the review.

9. H Scott

This submission expressed strong concern about the introduction of GM canola and the lack of labelling requirements for products containing GMOs. It did not address the operation of the WA GT Act or the national legislative scheme on gene technology.

10. G Kehl

This was another strongly worded submission opposing the use of gene technology in food production and criticising the lack of labelling requirements for products containing GMOs. It did not address the operation of the WA GT Act or the national legislative scheme on gene technology.

11. J Pommerin

This submission showed evidence of a good deal of research and referred to various studies and sources. It made a number of points in relation to contamination by GMOs and possible long-term ill-effects arising from their use. It asked that the WA GT Act “be amended to prohibit the production of
genetically modified plants whether it is for food crops or flowers for garden centres”. Other than in that respect it did not address the operation of the WA GT Act or the national legislative scheme on gene technology.

12. Agrifood Awareness Australia Ltd

Agrifood Awareness Australia Ltd is an organisation supported by or linked to a number of primary industry bodies. While the submission praised Australia’s gene technology regulation system it urged Western Australia and other members of the Ministerial Council to “move quickly to deliver a truly national scheme for the regulation of gene technology”. The primary concern of the submission seemed to be the removal of moratoria on the growing of GM crops.

13. H Auld

This short submission asked that the powers of the Regulator be increased to provide greater protection from the risk of contamination of the environment from GMOs.

14. P Green

This submission set out arguments in favour of GM crops and asked for less regulation of their cultivation. It did not address the operation of the WA GT Act or the national legislative scheme on gene technology.

15. Bayer CropScience Pty Ltd

The main theme of this submission was the need for uniformity between State and Commonwealth gene technology laws. It noted that the WA GT Act:

- does not deal with the matters of emergency dealings, inadvertent dealings, limited and controlled release applications and confidentiality that are dealt with in the Commonwealth GT Act, and
- still has extensive provisions in section 49 relating to dealings that may pose a risk even though those provisions no longer appear in section 49 of the Commonwealth GT Act.

The submission recommended that, rather than enacting mirror legislation, the State should enact legislation that “refers to and adopts” the Commonwealth GT Act as has been done in New South Wales.

16. AusBiotech Ltd

AusBiotech Ltd is an industry organisation representing members in various biotechnology sectors. Its submission was similar in content to
submission 15. The submission supported the continuance of the WA GT Act but called for greater uniformity with the Commonwealth GT Act. Like submission 15, it recommended that the State’s legislation should refer to and adopt the Commonwealth GT Act to ensure ongoing consistency with the Commonwealth legislation.

17. **CropLife Australia Limited**

CropLife Australia Limited is an industry organisation representing the agricultural chemical and biotechnology (plant science) sector in Australia. Its submission supported a nationally harmonised approach to regulating gene technology in Australia but claimed that State legislation to address marketing concerns has undermined the scheme. The submission drew attention to section 21(1)(aa) of the WA GT Act which contemplates State laws designating areas to preserve the identity of GM crops, or non-GM crops, for marketing purpose. According to the submission this creates an uncertain path to market that acts as a major disincentive for private investment. The submission recommended the removal of section 21(1)(aa) from the WA GT Act.

18. **J Newman, Network of Concerned Farmers**

The Network of Concerned Farmers is a voluntary alliance the aims of which relate to risk management regarding the introduction of GM crops. This submission ranged over a number of issues relating to GM crops but did not focus on the operation of the WA GT Act. Nevertheless it recommended:

- That the Act remain and be strengthened to prevent the commercial release of GM crops without there being a coexistence plan imposing no cost or liabilities on existing farming systems.
- That provisions be integrated into the Act to compensate non-GM farmers for any adverse impacts caused by GM.

The submission was concerned that this report be “balanced” and not give any support to “lifting bans”.

19. **Hon L MacLaren MLC**

Ms MacLaren is the spokesperson on GMOs for the Greens party in the Parliament of Western Australia. Her comprehensive submission identified what it claimed were 3 primary problems with the WA GT Act:

1. The pro-GM ideology underpinning the Act.
2. Omissions and inadequacies in the Act.

As to the first point, the submission recommended that the Act be amended “to remove the pro-industry bias and require the equal assessment of both the potential benefits and risks of all proposed dealings with GMOs”.

On the second point, extensive reference was made to the report of the Legislative Council’s Standing Committee on Environment and Public Affairs on the Gene Technology Bill 2001 and, on that basis, 13 detailed recommendations were made. These covered a range of matters including:

- responsibility for risks, costs and the prevention of contamination,
- liability and protection from liability,
- community involvement in decision-making,
- stronger enforcement,
- public appeal rights,
- peer review of safety assessments.

As to the third point, the submission recommended that the Act be amended:

- to include a much broader and more robust definition of the term “environment”, and
- to ensure that the full environmental impacts of the release of GMOs are properly assessed.


This submission asserted that legislative attempts to protect the public and the environment from the risks of GM have failed. It recommended that the legislation be “thrown away altogether, or substantially strengthened”. No specific suggestions were made as to how the legislation might be strengthened.

21. D Burnside

This submission expressed general concerns about the release of GMOs and particular concerns about the efficacy of pre-release testing procedures. It did not address the operation of the WA GT Act or the national legislative scheme on gene technology.
5.3 Summary of issues raised in submissions

In its report in 2003 on the Gene Technology Bill 2001 the Legislative Council’s Standing Committee on Environment and Public Affairs prefaced its Executive Summary and Recommendations with the following assessment of community views about gene technology:

1. Gene technology is a highly complex, contentious and divisive issue. It is an issue in which the views of proponents of the technology and those against it have become polarized. Gene technology is advancing at a rate that is much greater than the community understanding of its long-term effects. It offers considerable potential benefits to industry, the State and its people, while similarly posing considerable potential risks through unintended consequences.

2. Gene technology raises many scientific and ethical questions but also important questions about balancing the interests of the proponents of the technology with those of the State and the wider community, which may be more reluctant to adopt or accept the technology and its potential consequences – be they benefits or costs.

That disparity of views was reflected in the submissions made to the review. Submissions tended to take a stance either in strong support of, or strong opposition to, the development of gene technology and the release of GMOs. There was some discussion of the national legislative scheme but little consideration was given to the actual subject of the review, that is to say, the operation of the WA GT Act. Submissions from the public perhaps indicated a general lack of understanding as to how the components of the national legislative scheme are intended to operate. It would be useful for more public information about the scheme to be disseminated in due course.

Some submissions made detailed recommendations as to amendments that might be made to the WA GT Act (see for example submissions 3, 5, 7, 17, 18 and 19). Given the wide constitutional reach of the Commonwealth GT Act, the great majority of gene technology issues in the State will be dealt with under the Commonwealth GT Act. Thus there would be little point in amending the WA GT Act without similar amendments being made to the Commonwealth GT Act. Furthermore, if the State were to independently make significant legislative amendments, it is unlikely that the WA GT Act could be regarded as a corresponding State law for the purpose of the national legislative scheme. It may be that some issues of the kind raised could be dealt with by the State by way of separate legislation, but assessing the need for that is beyond the scope of this review.

It would be understandable if this practical inability to effect change to the national legislative scheme by way of amendments to State legislation generated some frustration with the review process. In this context it might
be noted that the Gene Technology Agreement provides for there to be periodic reviews of “this agreement and the Scheme” whereas the relevant sections in the Commonwealth and State Acts provide for the “review of the operation of this Act”. That means that each of the Acts is reviewed in isolation. If future reviews of the Commonwealth and State Acts were coordinated as the Gene Technology Agreement contemplates, the operation of the national legislative scheme as a whole could be examined and submissions for amendments applying across the whole of the scheme could be made and considered.

There seems to be an assumption, common to a few submissions from both points of view, that the State’s GM moratorium is somehow a part of, or related to, the WA GT Act and its Commonwealth counterpart (see for example submissions 12, 17, 18 and 19). This view appears to be based on the provision designated as section 21(1)(aa) in each of those Acts, but it is a misconception. The *Genetically Modified Crops Free Areas Act 2003* (WA) operates independently and hence the GM moratorium is beyond the scope of this review.

A number of submissions, notably submissions 4 and 6, raised significant issues as to the State’s participation in the national legislative scheme and those issues are considered in Part 6.
Part 6 — Consideration of issues

6.1 The corresponding State law issue

6.1.1 Impact on the administration of the scheme

As identified in Part 4, the State’s GT laws have not been declared to be a corresponding State law under the Commonwealth GT Act and therefore the Regulator is not authorised to administer them. This and other issues raised in the Regulator’s submission were discussed with the Regulator in more detail in the course of the review.

The Regulator noted that his inability to administer the State’s GT laws leads to uncertainty about the regulatory coverage of certain dealings with GMOs in the State, for example, those conducted by State agencies.

He pointed out possible implications of an absence of corresponding State law status on the operation of multi-user facilities. Suppose that a State agency, or a university in the State, operated a facility at which both it and an another organisation conducted field trials involving dealings described under the gene technology legislation as “dealings involving intentional release”. If the other organisation was a constitutional corporation, dealings conducted by it at the facility would be licensable under the Commonwealth’s GT laws but, in the absence of a corresponding State law, the other dealings at the facility could be conducted without a licence (unless they happened to relate to activities involving constitutional trade or commerce or the spreading of pests and diseases). That would be an anomalous and uncertain situation both for those conducting the trials and for those whose task it was to maintain regulatory scrutiny and control over them. It would have the potential to undermine compliance and enforcement actions that might be warranted, and to create legal uncertainties as to the ability to take criminal proceedings against persons who might interfere with the trials.

Even apart from particular concerns, it is confusing and misleading for the public for there to be State laws that purport to be in operation when, in reality, there are unresolved questions as to what, if any, effect they may have. The likelihood of adverse consequences arising out of the current status of the State’s GT laws could be assessed as being fairly low as State agencies (principally the Department) and universities observe the spirit of the laws, have Institutional Biosafety Committees and maintain links with the OGTR. Nevertheless the situation is unsatisfactory and should be remedied.
6.1.2 Action needed

In order for the State’s GT laws to attain corresponding State law status they will need to be the subject of a notice under section 12(1) of the Commonwealth GT Act. Section 12 is silent as to the criteria for the issue of a notice but it might be logical to assume that substantial consistency with the current provisions of the Commonwealth’s GT laws would be a prerequisite. The Department should contact the relevant Commonwealth Department (currently the Department of Health and Ageing) to confirm that this is the case. If it is not, the State government could forthwith request the Commonwealth Minister to issue a notice declaring the State’s GT laws to be a corresponding State law.

However if, as seems more likely, legislative action is required, the State government should take all necessary steps to secure the enactment of any State legislation needed to achieve consistency with the Commonwealth’s GT laws. When that has occurred, it should request the Commonwealth Minister to issue a notice declaring the State’s GT laws to be a corresponding State law.

Assuming that the State’s GT laws are given corresponding State law status, the next issues to be considered are:

- the need for them to remain consistent with the Commonwealth’s GT laws, and
- how that ongoing consistency might be achieved.

6.2 Consistency of provisions

6.2.1 The need for consistency

Significant amendments have been made to the Commonwealth’s GT laws in the past and it can be expected that further amendments will occur in the future. If States lag behind in reflecting the amendments then, as pointed out in the Regulator’s submission, during any period of inconsistency the Regulator will be simultaneously applying the amended law in some jurisdictions and the unamended laws in others. Operational experience in the OGTR indicates that inconsistency between the Commonwealth and State legislation leads to confusion within parts of the regulated community as to which legislation is applicable with resulting uncertainty and potential compliance issues. The same GMO dealing might attract different requirements depending on where it is undertaken and who is undertaking it.
In further comments given to the reviewer, the Regulator expanded on the need to be able to make timely regulatory adjustments to changes in the risk status of a particular dealing with a GMO. For example, with new information and experience, and following a considered assessment of the risk of a particular dealing, the Regulator may conclude that the dealing should have increased regulatory requirements to manage risk (e.g. should become a licensable “dealing not involving intentional release” (DNIR) instead of being a “notifiable low risk dealing” (NLRD)). This would result in a change to the regulations under the Commonwealth GT Act. If the regulations under the WA GT Act did not also change, there could be a situation where people in, say, a State agency were still legally able to treat the dealing as an NLRD, while others in the State conducting the same dealing would be appropriately conducting it as a licensable DNIR. This means that one group of people could legally do the work without the level of risk management the Regulator has deemed necessary, thereby posing a potential risk to health and safety.

Conversely, based on new information, it is possible that a particular dealing may be determined to warrant a lower level of regulatory oversight, and for example be reclassified from DNIR to NLRD. In this case, there is clearly not so much of a concern about inadequate risk management. Rather, there is a concern that the people doing the work in, say, a State agency might be hampered by additional regulation and cost compared with their counterparts working for a constitutional corporation. The Regulator considered that this might unnecessarily stifle innovation.

The Regulator also spoke of the advantages of certainty about the timing and application of amendments to State legislation. Without certainty around the regulatory requirements, organisations can have difficulty in deciding when to proceed with their planned GMO work and what preparations they need to make to do the work. This can cause delays, add cost and inhibit research activities. Ambiguity around what regulations apply, and when they apply, creates particular difficulties for Institutional Biosafety Committees which are a vital component of the regulatory system. An Institutional Biosafety Committee carries a significant responsibility for ensuring that its institution is complying with the legislation.

It should also be noted that the State is obliged under the Gene Technology Agreement to ensure that its gene technology legislation remains nationally consistent.
6.2.2 Methods of achieving consistency

Consistency and certainty would be assured if the State followed the example of New South Wales and the Northern Territory and applied the Commonwealth’s GT laws, as amended from time to time, as a law of the State. Section 5 of the Gene Technology (New South Wales) Act 2003 reads as follows:

5 Application of Commonwealth gene technology laws to this State

(1) The Commonwealth gene technology laws, as in force for the time being, apply as a law of this State.

(2) Those Commonwealth gene technology laws so apply as if they extended to matters in relation to which this State may make laws:

(a) whether or not the Commonwealth may make laws in relation to those matters, and

(b) even though the Commonwealth gene technology laws provide that they apply only to specified matters with respect to which the Commonwealth may make laws.

The Regulator strongly favours this approach which he refers to as the “lock-step” approach. In support of it he points out that, under the Gene Technology Agreement, amendments to the legislation comprising the national legislative scheme (both Commonwealth and State) cannot proceed without the scrutiny of the Ministerial Council which has representation from the Commonwealth and all States. The provisions for submission, scrutiny and approval of amendments to the legislation are set out in Part 5 of the Gene Technology Agreement.

The report of the 2011 review of the Commonwealth GT Act also favoured the lock-step approach. It recommended:

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

Historically the Western Australian Parliament has been reluctant to participate in national legislative schemes in a manner that involves the application of the legislation of another jurisdiction on an “as amended from time to time” basis.

An exception was made in the case of the national legislative scheme as to agricultural and veterinary chemicals. See the Agricultural and Veterinary Chemicals (Western Australia) Act 1995, sections 5 and 6:
5. **Application of Agvet Code in this jurisdiction**

The Code set out in the Schedule to the Agricultural and Veterinary Chemicals Code Act as in force for the time being —

(a) applies as a law of Western Australia; and

(b) as so applying, may be cited as the Agvet Code of Western Australia.

6. **Application of Agvet Regulations in this jurisdiction**

The regulations in force for the time being under section 6 of the Agricultural and Veterinary Chemicals Code Act —

(a) apply as regulations in force for the purposes of the Agvet Code of Western Australia; and

(b) as so applying, may be referred to as the Agvet Regulations of Western Australia.

Making a similar exception for gene technology legislation may be seen to be justified given the importance of maintaining consistency in the regulation of all gene technology activities in the State.

Alternatively, there are other possible approaches under which the Commonwealth’s GT laws would be applied as a law of the State but the State government would be able to decide whether or not to allow future amendments to the Commonwealth’s GT laws to have effect in relation to the State’s applied version.

For example, the body of law that is referred to as the “Competition Code” is composed of various provisions of the Commonwealth’s *Competition and Consumer Act 2010* (which was formerly called the *Trade Practices Act 1974*). The *Competition Policy Reform (Western Australia) Act 1996* applies the Competition Code as a law of the State but provides for a delay period of 2 months before the commencement of the application of any future Commonwealth modifications to the Code. During that period of 2 months the government can make a proclamation providing that the modification does not apply at all as a law of the State. Sections 5 and 6 of the Act are set out below:

5. **Application of Competition Code**

(1) The Competition Code text, as in force for the time being, applies as a law of Western Australia.

(2) This section has effect subject to section 6.

6. **Future modifications of Competition Code text**

(1) A modification made by a law of the Commonwealth to the Competition Code text after the commencement of this section —
(a) does not apply under section 5 until at least the end of the period of 2 months after the date of the modification, unless a proclamation appoints an earlier day; and
(b) does not apply under that section at all, if the modification is declared by a proclamation to be excluded from the operation of that section.

(2) A proclamation under subsection (1)(b) has effect only if published before the end of 2 months after the date of the modification.

(3) If, after a proclamation is made under subsection (1)(b), a further proclamation is made appointing a day on and from which the modification of the text is to apply under section 5, subsection (1)(b) ceases to apply to the modification immediately before that day.

(4) A proclamation under subsection (1)(a) or (3) —
(a) cannot appoint any day that is earlier than the day of publication of the proclamation or that is earlier than the day on which the modification of the text takes effect; and
(b) is to be regarded in such a case as appointing the day of publication of the proclamation or the day on which the modification of the text takes effect, whichever is the later.

(5) For the purposes of this section, the date of the modification is —
(a) the day on which the Commonwealth Act effecting the modification receives the Royal Assent or the regulation effecting the modification is notified in the Commonwealth of Australia Gazette; or
(b) the day on which this Act receives the Royal Assent,

whichever is the later.

There is another variation of this approach that gives the State even greater control. Under this approach, which is used in the New Tax System Price Exploitation Code (Western Australia) Act 1999, a Commonwealth modification does not apply at all as a law of the State unless the government issues an instrument declaring that it does.

Any adoption by the State of an “application of laws” approach to participation in the national legislative scheme on gene technology would involve the repeal and re-enactment of the current WA GT Act. That would be the case whether the approach adopted was the full lock-step approach or a modified version.

If, on the other hand, the current mirror legislation approach is retained, problems will soon arise if, as in the past 6 years, amendments made to the Commonwealth’’s GT laws are not reflected in the State’s GT laws in a timely manner in compliance with the State’s obligations under the Gene
Technology Agreement. Having regard to all the stages involved in the legislative process, adherence to desired timetables can be difficult, and it is not possible to recommend a mechanism that would ensure early legislative action. However at all levels of the process: departmental, ministerial and parliamentary, there needs to be an awareness of the administrative and compliance difficulties likely to arise from disparities between the Commonwealth and State laws and a readiness to try to minimise those difficulties.

Given that the form and content of any necessary changes to the State’s GT laws will be dictated by changes to the Commonwealth’s GT laws, normal legislative procedures could be modified to expedite the introduction of the State legislation. For example, if Cabinet gave “standing” approval for the drafting of amendments to the WA GT Act to mirror changes to the Commonwealth GT Act, the Department could instruct the Parliamentary Counsel to commence drafting a Bill once the form of any Commonwealth amending legislation was finalised. That would mean that when the Commonwealth legislation was passed, the State Bill would be ready for introduction into Parliament.

It is noted that Victoria, Queensland, South Australia and the Australian Capital Territory have been able to maintain consistent laws by amending their legislation when necessary.

However there has been a significant recent development in Tasmania which, like Western Australia, has had “mirror” gene technology legislation that has never been declared to be a corresponding State law under the Commonwealth GT Act. Earlier this year a Bill to repeal that legislation and replace it with legislation on the New South Wales “application of laws” model was introduced into, and passed by, the Tasmanian House of Assembly. The Tasmanian Legislative Council subsequently passed the Bill with an amendment requiring any amendments to the Commonwealth’s GT laws to be tabled in the Tasmanian Parliament within 10 days after their commencement. The House of Assembly agreed to this amendment on 24 May 2012 and, at the time of completion of this report, the Bill was awaiting assent by the Governor of Tasmania.

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.
6.3 Wind-back of Commonwealth legislation

As pointed out in the Regulator’s submission, the vast majority of organisations conducting dealings with GMOs are covered by the Commonwealth’s GT laws because they are constitutional corporations. State agencies and higher education institutions that are not constitutional corporations would be covered by the State’s GT laws but there is sometimes uncertainty about their status. Large and diverse institutions like the University of Western Australia are likely to be categorised as constitutional corporations, but that may not be the case in relation to other higher education institutions in the State. There is no good reason for researchers doing similar work in 2 or more different institutions to be regulated under different laws. If they happened to be participating jointly in the same project, the situation would be even more anomalous.

Cases like this need not arise if the application of the Commonwealth’s GT laws is wound-back under section 14 of the Commonwealth GT Act. State agencies and higher education institutions then become unambiguously subject to regulation under the State’s version of the laws. Providing greater certainty of application benefits both the regulated community and the Regulator.

Assuming that the steps necessary to enable the State’s GT laws to become a corresponding State law are taken, the State government should follow Queensland’s example and issue a wind-back notice to the Commonwealth Minister under section 14 of the Commonwealth GT Act.
Part 7 — Findings

Finding 1
It is essential that both the Commonwealth and State components of the national legislative scheme for the regulation of activities involving gene technology operate effectively in the State. All appropriate legislative and administrative steps need to be taken to ensure that the State has gene technology laws that are a corresponding State law for the purposes of the scheme.

(See Parts 4.2 and 6.1)

Finding 2
The State needs to meet its obligation under the Gene Technology Agreement to keep its gene technology laws consistent with the national legislative scheme. This could be achieved simply by way of applying the Commonwealth gene technology laws as a law of the State. If that is not done, there needs to be an ongoing commitment to ensuring that the State laws are changed when changes are made to the Commonwealth laws.

(See Parts 4.1 and 6.2)

Finding 3
Assuming that the State’s gene technology laws become a corresponding State law for the purposes of the national legislative scheme, the State government should issue a wind-back notice to the Commonwealth Minister under section 14 of the Gene Technology Act 2000 (Cwlth) so that there is certainty as to whether particular gene technology activities are covered by State laws, or by Commonwealth laws.

(See Part 6.3)

Finding 4
More information should be given to the public about the way in which the national legislative scheme operates. Any future reviews of the operation of the Gene Technology Act 2006 (WA) should be conducted in conjunction with reviews of the Gene Technology Act 2000 (Cwlth), as contemplated in the Gene Technology Agreement. That would enable the reviews, and public submissions to them, to properly address both the Commonwealth and the State components of the national legislative scheme.

(See Part 5.3)
Appendix 1

The reviewer

Mr Greg Calcutt was educated in Western Australia and admitted as a Barrister and Solicitor of the Supreme Court of Western Australia in 1968.

From 1971 to 2009 he drafted legislation for the Western Australian Government on a wide range of topics. He also provided high level advice on legislative drafting matters, and parliamentary issues generally, to:

- Attorneys General and other Ministers,
- State government agencies, and
- members and officers of Parliament.

He was Parliamentary Counsel for Western Australia from 1989 until his retirement in January 2009.

As a member of the Parliamentary Counsel’s Committee made up of the heads of office of the legislative drafting offices of the Commonwealth, the States, the Territories and New Zealand, Mr Calcutt represented the State in the formulation of national legislative schemes and the drafting of uniform and complementary legislation to give effect to them.

He was made a Member of the Order of Australia in 2003 in recognition of his role in the development of statute law and, in 2004, was appointed by the Chief Justice of Western Australia as a Senior Counsel.
Appendix 2

Reference material

Legislation

Agricultural and Veterinary Chemicals (Western Australia) Act 1995 (WA)

Competition and Consumer Act 2010 (Cwlth)

Competition Policy Reform (Western Australia) Act 1996 (WA)

Gene Technology Act 2000 (Cwlth).

Gene Technology Act 2001 (Queensland).

Gene Technology Act 2001 (South Australia).

Gene Technology Act 2001 (Tasmania).

Gene Technology Act 2001 (Victoria).

Gene Technology Act 2003 (Australian Capital Territory).


Gene Technology (Northern Territory) Act 2004 (Northern Territory).

Gene Technology (Tasmania) Bill 2012 (Tasmania).

Genetically Modified Crops Free Areas Act 2003 (WA).

New Tax System Price Exploitation Code (Western Australia) Act 1999 (WA)

Other

CSIRO website: CSIRO Gene Technology Fact Sheet, 24 June 2010 | Updated 24 February 2012.


Inter-governmental Agreement on Gene Technology as originally made on 11 September 2001 and also the printable version of the agreement accessible on the website of Australian Government Department of Health and Ageing.


Appendix 3

Terms and abbreviations

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Commonwealth GT Act</strong></td>
<td>Gene Technology Act 2000 (Cwlth).</td>
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<tr>
<td><strong>Commonwealth Minister</strong></td>
<td>the Minister administering the <em>Gene Technology Act 2000</em> (Cwlth).</td>
</tr>
<tr>
<td><strong>the Commonwealth’s GT laws</strong></td>
<td>Gene Technology Act 2000 (Cwlth) and the subsidiary legislation in force under it.</td>
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<tr>
<td><strong>Cwlth</strong></td>
<td>Commonwealth.</td>
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<tr>
<td><strong>Department</strong></td>
<td>Department of Agriculture and Food, Western Australia.</td>
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<tr>
<td><strong>Gene Technology Agreement</strong></td>
<td>Inter-governmental Agreement on Gene Technology.</td>
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<tr>
<td><strong>GM</strong></td>
<td>genetically modified or genetic modification.</td>
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<tr>
<td><strong>GMO</strong></td>
<td>an organism produced using gene technology.</td>
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<tr>
<td><strong>GM crop</strong></td>
<td>a crop that consists of or includes plants that are GMOs.</td>
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<tr>
<td><strong>GM moratorium</strong></td>
<td>the moratorium on GM crops imposed by the <em>Genetically Modified Crops Free Areas Order 2004</em> published on 22 March 2004 under the <em>Genetically Modified Crops Free Areas Act 2003</em> (WA).</td>
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<tr>
<td><strong>Ministerial Council</strong></td>
<td>the council of Ministers under the Gene Technology Agreement.</td>
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<tr>
<td><strong>OGTR</strong></td>
<td>Office of the Gene Technology Regulator.</td>
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<tr>
<td><strong>Part</strong></td>
<td>a Part of this report.</td>
</tr>
<tr>
<td><strong>Regulator</strong></td>
<td>the Gene Technology Regulator appointed under the <em>Gene Technology Act 2000</em> (Cwlth).</td>
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<tr>
<td><strong>a State or the States</strong></td>
<td>includes the Northern Territory and the Australian Capital Territory.</td>
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<td><strong>the State</strong></td>
<td>the State of Western Australia.</td>
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<tr>
<td><strong>the State’s GT laws</strong></td>
<td>Gene Technology Act 2006 (WA) and the subsidiary legislation in force under it.</td>
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<td><strong>submission</strong></td>
<td>a submission to the review.</td>
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<tr>
<td><strong>WA</strong></td>
<td>Western Australia.</td>
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