The Legislative and Governance Forum on Gene Technology

2017 Review of the National Gene Technology Regulatory Scheme

Background Paper

July 2017

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Purpose of this Background Paper

This paper is being released to promote discussion about the National Gene Technology Regulatory Scheme (the Scheme), as part of the 2017 Review of the Scheme (the Review). The paper provides background and contextual information. It does not provide analysis or put forward policy options. Its purpose is to provide a starting point for an important consultation process that will inform the development of draft policy positions and next stages of consultation.

Introduction

The Legislative and Governance Forum on Gene Technology (the Forum) has announced its commitment to review the Scheme. The Forum, also known as the LGFGT, is responsible for overseeing and governing the operation of the Scheme. The Forum is established by an intergovernmental Gene Technology Agreement (GTA) and includes Ministers from the Commonwealth and all States and Territories across a range of portfolios including health, agriculture and primary industries. Reviews of the Scheme are conducted at approximately five yearly intervals, in accordance with the GTA.

The Review will be forward-looking and will consider appropriate policy settings in an environment of rapidly developing technology. The intention is to undertake a forward-looking strategic review to strengthen and improve Australia's gene technology scheme with settings that will be suitable into the future.

The Forum invites public submissions within the scope of the Review's Terms of Reference. The Review will be conducted in consultation with scientific, consumer, health, environmental and industry groups.

This is the first stage of a phased consultation process to better understand ideas, key issues and views of the Scheme in Australia.

The Review of the Scheme will also take into account any submissions which are provided into any other reviews which may have relevance during the review period.

The Forum encourages you to participate in the consultation process and is inviting you to contribute to this important review. This is the first stage of engagement where we are looking to identify all issues and opportunities for improvement. There will be further opportunities for engagement on specific issues throughout the Review, with a final report expected to be presented to the Forum for consideration in the first quarter of 2018.

Further information about how you can get involved can be found on the Department of Health website[1].

Relationship to Other Reviews

The Review of the Scheme by the Forum is independent of the Gene Technology Regulator (the Regulator) and the Office of the Gene Technology Regulator (OGTR), and is separate to the Review of the Gene Technology Regulations 2001[2] (GT Regulations) currently being undertaken by the Regulator.

[1] Available at: http://www.health.gov.au/
[2] Available at: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reviewregulations-1

The Regulator regularly reviews the GT Regulations to ensure they reflect current technology and scientific knowledge. This is important to provide clarity about whether organisms developed using a range of new technologies are subject to regulation as genetically modified organisms, and to ensure that new technologies are regulated in a manner commensurate with the risks they pose.

However, outcomes of the Technical Review cannot alter the policy settings of the Scheme. The Review of the Scheme will build, in part, on the Technical Review, but most importantly can address matters that are outside of the scope of the Technical Review. The Review of the Scheme provides the opportunity to consider any broader or contextual issues, with the intent of ensuring the Scheme is best placed to appropriately respond to emerging issues.

The Review of the scheme will take into account the publicly available submissions which have been provided into recent relevant reviews, including the Technical Review, the House of Representatives Standing Committee on Agriculture and Industry Smart farming – inquiry into agricultural innovation 2016 report[3], and the Productivity Commission 2016 report on the Regulation of Australian Agriculture[4].

[3]Available at: http://www.aph.gov.au/Parliamentary_Business/Committees/House/Agriculture_and_Industry/Agricultural_innovation/Report
[4]Available at: http://www.pc.gov.au/inquiries/completed/agriculture/report

Terms of Reference

The Review will investigate the National Gene Technology Scheme (the Scheme), including gene technology legislation, the Gene Technology Agreement and its interface with other regulatory schemes. The Review aims to improve and strengthen the Scheme's effectiveness whilst ensuring it is appropriately agile and supports innovation. The Review will include, but not be limited to, assessing and making recommendations in relation to:

1) current developments and techniques, as well as extensions and advancements in gene technology to ensure the Scheme can accommodate continued technological development.
2) existing and potential mechanisms to facilitate an agile and effective Scheme which ensures continued protection of health and safety of people and the environment.
3) the appropriate legislative arrangements to meet the needs of the Scheme now and into the future, including the Gene Technology Agreement.
4) funding arrangements to ensure sustainable funding levels and mechanisms are aligned with the level and depth of activity to support the Scheme.

What is Gene Technology and Genetically Modified Organisms?

Gene Technology
Gene technology provides a way of introducing precise changes to genetic material, which can include genes, parts of genes, groups of genes, etc. This allows researchers to transfer the properties 'instructed' by a single gene from one organism to another.

Using these techniques, researchers can modify organisms by directly inserting or removing one or more genes so that an organism gains, loses or changes a specific characteristic or set of characteristics. For example, a variety of cotton has been genetically modified to resist pest damage by producing toxins that target certain insects.

Under the *Gene Technology Act 2000 (Cwealth)* (GT Act), Gene Technology is currently defined 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 for the purposes of this paragraph.*

The Gene Technology Regulations 2001 (Cwlth) further defines techniques that are <u>not</u> gene technology:

Description of technique that is not gene technology
Somatic cell nuclear transfer, if the transfer does not involve genetically modified material.
Electromagnetic radiation-induced mutagenesis.
Particle radiation-induced mutagenesis.
Chemical-induced mutagenesis.
Fusion of animal cells, or human cells, if the fused cells are unable to form a viable whole animal or human.
Protoplast fusion, including fusion of plant protoplasts.
Embryo rescue.
In vitro fertilisation.
Zygote implantation.
A natural process, if the process does not involve genetically modified material. *Examples of natural processes include conjugation, transduction, transformation and transposon mutagenesis.*

Genetically Modified Organisms
The organisms changed or created using gene technology techniques are usually called genetically modified organisms (GMOs).

Under the GT Act, a GMO is currently defined as:

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.

The Gene Technology Regulations 2001 (Cwlth) further defines organisms that are <u>not</u> GMOs:

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

In recent times several technologies have developed rapidly, in particular site-directed nuclease techniques and oligonucleotide-directed mutagenesis. The current Technical Review of the *Gene Technology Regulations 2001* intends to clarify the regulatory status of these technological developments.

Submissions to the Technical Review of the Regulations raised broader definitional issues beyond the scope of that review. The Review of the Scheme gives the opportunity to evaluate how "Gene Technology" and "Genetically Modified Organisms" are defined and regulated in the Australian context.

Gene Technology Regulation in Australia

Australia's National Gene Technology Regulatory Scheme which regulates gene technology, arose from the need to provide regulatory coverage for genetically modified organisms (GMOs) and genetically modified (GM) products not regulated under existing regulatory schemes—for example, growing GM crops.

The design construct of the Scheme complements other regulators' powers and operates in conjunction with other Australian Government and state/territory regulatory schemes relevant to GMOs and GM products which regulate:

- food;
- human therapeutic goods;
- agricultural and veterinary chemicals;
- industrial chemicals; and
- biosecurity and protection of the environment.

It balances the appropriate constitutional reach of governments in the structure of legislative arrangements.

The current arrangements recognise that product based regulatory schemes already regulate most GM products. As such, the Scheme does not currently cover the use of a GMO, unless the use occurs for the purposes of a dealing[5].

The Scheme does not regulate those aspects of genetic modification which were already regulated under pre-existing regulatory regimes. Some genetic modifications of humans (for example, inheritable human gene therapy applications or embryo modification) are already regulated by the Therapeutic Goods Administration (TGA) and the National Health and Medical Research Council (NHMRC). Non-living food products produced from GMOs (for example, canola oil from GM canola plants) are regulated under the Australian and New Zealand Food Code.

History of the Scheme

The Scheme came into effect on 21 June 2001, replacing the previous voluntary system of oversight. The Scheme is designed 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.

Two previous reviews (the statutory review in 2006, and 2011) focussed on the operation of the Scheme and whether the policy objectives were being achieved. While there was some consideration given to the technical aspects, these Reviews were predominately retrospective in nature. Both Reviews confirmed that the policy objectives of the Scheme were still appropriate at the time. Resulting from each of the reviews, legislative amendments were made to improve the operation of the Scheme.

The 2006 statutory review was comprehensive in scope covering issues that had emerged or changed significantly since the *Gene Technology Act 2000* (Cwlth) (GT Act) was passed, and examined whether the policy objectives of the GT Act remained valid. The recommendations from the review encompassed changes to improve the operation

[5] As defined in the *Gene Technology Act 2000 (Cwlth)*

of the GT Act including increasing the powers of the Gene Technology Regulator in cases of non-compliance and reducing reporting requirements.

The 2011 review focussed on the efficiency and effectiveness of the operation of the GT Act across the national scheme, and the interface between the GT Act and other regulation. The 2011 review produced minor and technical amendments to the GT Act to make gene technology regulation more efficient, effective and clearer.

Legislative Arrangements

The Scheme comprises Commonwealth, State and Territory legislation to allow for the constitutional reach of each level of government in regulating GMOs. This approach helps avoid possible inconsistencies in regulation, enforcement and compliance of GMOs across jurisdictions, as the gene technology legislation is administered by a single independent regulator.

Governance Arrangements

The governance arrangements for the national scheme are expressed in the Gene Technology Agreement[6], an inter-governmental agreement which sets out the understanding between State and Territory governments and the Commonwealth regarding the operation of a nationally consistent regulatory system for gene technology. The governance, advisory and consultation structures for the national scheme are depicted in Figure 1 below.

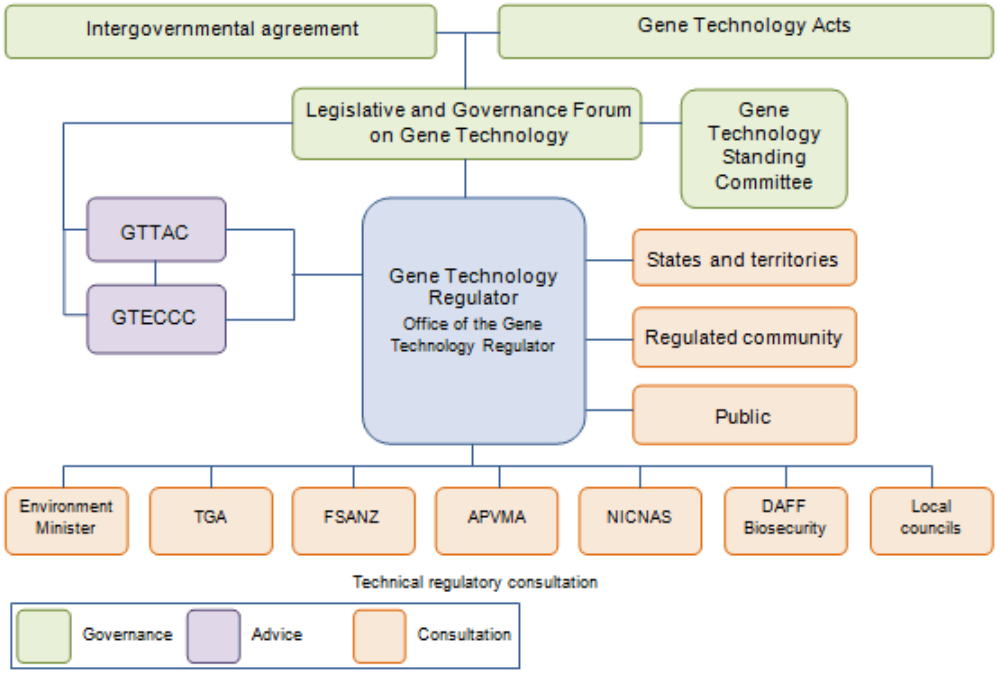

Figure 1: The national gene technology regulatory scheme (source: OGTR)[7]

Gene Technology Regulator: A statutory office holder appointed under the *Gene Technology Act 2000*, to administer the regulatory scheme.

Legislative Governance Forum on Gene Technology: The Ministerial Council established under the Gene Technology Agreement, with responsibility of overseeing the regulatory scheme.

[6] Available at: http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-tech-agreement

[7] **TGA**: Therapeutic Goods Administration, **FSANZ**: Food Standards Australia New Zealand, **APVMA**: Australian Pesticides and Veterinary Medicines Authority, **NICNAS**: National Industrial Chemicals Notification and Assessment Scheme, **DAFF**: Department of Agriculture and Water Resources.

Gene Technology Standing Committee: A committee of senior officials with responsibility to support and provide advice to the Ministerial Council.

Gene Technology Technical Advisory Committee: A committee established under the *Gene Technology Act 2000* to provide scientific and technical advice to the Regulator and Ministerial Council.

Gene Technology Ethics and Community Consultative Committee: A committee established under the *Gene Technology Act 2000* to provide advice on ethics and community consultation to the Regulator and Ministerial Council.

How can I be involved?

The Terms of Reference and this paper form the first stage of a phased consultation process for the 2017 Review of the National Gene Technology Regulatory Scheme and the future direction of gene technology regulation in Australia.

As outlined previously, the Forum invites you to participate in this process to help the policy development process by providing a submission on any issues within the scope of the Review's Terms of Reference.

While a number of issues have already been raised and noted under the Technical Review of the *Gene Technology Regulations 2001* currently being undertaken by the Gene Technology Regulator, the scope of this Review is much broader and this is an opportunity to emphasise any particular matters for consideration.

Further information about how you can get involved can be found on the Department of Health website.

All submissions received by the due date will be analysed and considered by the Review in formulating recommendations to government. The Review will not respond to individual submissions, but may seek further information or clarification of issues as necessary.

It is intended that submissions will be published on the Review's webpage.

Lodging your submission

Submissions should be lodged via the Citizen Space website[8]. Submissions over 10,000 words are required to have an Executive Summary covering all key points in the submission.

Please email the Review Secretariat should you have any questions on the process: Gene.Technology.Review@health.gov.au

If you wish to provide a hardcopy submission:
Please complete the Review Submission Cover Sheet and mail to:
Gene Technology Review
Department of Health
MDP 1060
GPO Box 9848
CANBERRA ACT 2601

[8] Consultation webpage accessible at: https://consultations.health.gov.au/health-systems-policy-division/genetechreview2017

Appendix 1: Submission Cover Sheet

COVER SHEET FOR SUBMISSIONS

2017 Review of the National Gene Technology Regulatory Scheme

This completed form must be included with your submission. If completing by hand, please ensure your writing is clear and legible.

DETAILS FOR PUBLICATION	
Individual name/group name/organisation name for publication on the website	

CONTACT DETAILS	
We need to collect your contact details should further information or clarification be required on your submission. Contents of your submission may be included in subsequent publications. Please provide at least one contact address. If you are making a submission for a group or organisation, please provide contact information for one member of your group or organisation.	
Title	
First Name	
Surname/Family Name	
Postal Address	
Email Address	
Telephone Number	

INTERNET PUBLICATION	
Please tick this box if you wish for your submission to remain confidential and **do not consent** to having your submission published on the internet.	
If you wish for only parts of your submission to remain **confidential** and not be published on the website, please outline the confidential sections clearly (with page numbers where possible). If you wish for only parts of your submission to be treated as confidential, it would be appreciated if you could provide the confidential parts of your submission as a separate document.	

ANONYMITY	
Please tick this box if you want your submission to be treated as anonymous and you **do not consent** to having your name, or the name of your organisation, published on the internet with your submission.	

THIRD PARTY PERSONAL INFORMATION	
Please tick this box if your submission contains **personal information of third party individuals.**	

EVIDENCE OF CONSENT	
You should not include personal information about a third party unless you are able to provide evidence of written consent. Please tick this box if you have **attached evidence of written consent**.	

N.B. Please provide your submission in .doc OR .docx (e.g. MS Word) format to comply with Government accessibility requirements.

Lodging your submission

Submissions should be lodged via the Citizen Space website[1]. Submissions over 10,000 words are required to have an Executive Summary covering all key points in the submission.

Please email the Review Secretariat should you have any questions on the process: Gene.Technology.Review@health.gov.au

If you wish to provide a hardcopy submission:
Please complete the Review Submission Cover Sheet and mail to:
Gene Technology Review
Department of Health
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GPO Box 9848
CANBERRA ACT 2601

Privacy

Unless otherwise requested, all submissions on the Review will be published on the Department of Health website.

The Department of Health will not publish submissions, or parts of submissions, which contain personal information, offensive language, potentially defamatory material or copyright infringing material.

Responsibility for copyright in submissions resides with the author(s), not with the Department of Health.

All submissions will be converted to Portable Document Format (PDF) for publication and may have a different appearance to the document that was submitted.

Your submission and contact details will be stored in accordance with the Australian Privacy Principles from Schedule 1 of the Privacy Amendment (Enhancing Privacy Principles) Act 2012 and the Archives Act 2012. Should you have any concerns about the storage of your submission, or if you wish to gain access to make a correction, please contact the Gene Technology Review via the following email address: Gene.Technology.Review@health.gov.au.

A copy of the Department's privacy policy is available on request. If you wish to make a complaint about the handling of your private information, you may contact the Department of Health Privacy Contact Officer on 02 6289 7156 and, if unsatisfied with the response, you may submit a complaint to the Office of the Australian Information Commissioner.

[1] Consultation webpage accessible at: https://consultations.health.gov.au/health-systems-policy-division/genetechreview2017